ALL INDIA INSTITUTE OF MEDICAL SCIENCES

ANSARI NAGAR, NEW DELHI – 110029.

(R.P. CENTRE, AIIMS)

MEDICINE STORE

Dated: 19-November-2024

Subject: Procurement of Injection Faricimab 6mg/0.05ml (120mg/ml) (Vabysmo) on proprietary basis – Inviting comments thereon.

The request has been received from Sister In-Charge (VR Kit) and Forwarded by Dr. Namrata Sharma, OT In-Charge. For purchase of Subject item from M/s Medsurg Pharma (Mfg: M/s Roche Products India Private Limited) on proprietary basis. All the documents submitted by M/s Medsurg Pharma (Mfg: M/s Roche Products India Private Limited) including Quotation, Authorization, Fall Clause and Department PAC Certificate all copy attached.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the item within 15 days of issue of this letter with giving reference No. 48/PAC/RPC/MSK/2024-25. The comments should be received by office of Asstt. Stores Officer, R.P. Centre at AIIMS on or before 04-December-2024. Upto 12:00 p.m., failing which it will be presumed that any other Manufacture and vendor is having no comment to offer and case will be decided on merits.

19/11/2024

(Asstt. Stores Officer, RPC)

Encl: Related documents enclosed.

1. **Quotation**
2. **Departmental PAC Certificate**
3. **Authorization Letter**
4. **Fall Clause**

Eoffice–1679249/RPC/2024

To

The Store Officer

Dr. R.P.Centre ,

AIIMS New Delhi .

(Through proper channel)

Date:10/10/204

Sub: Six months demand of following item in V.R KIT store at Dr.R.P.C OT 5th floor (Medicine)

Respected Madam,

This is for your kind information that in OT 5th floor following item needed urgently for six months in VR Kit .

SL	Name of the Items	Quantity required In No.	Last Indent	Quantity In hand	Remarks
1.	Inj.Faricimab (Vabysmo)	100	Sept.2024	10	Total used 10

Sincerely

10/10/24

Sister In charge (VR Kit)

OT 5th Floor

ANS OT

Lakhpal Rawat 10-10-24

OT Incharge

Dr. NAMRATA SHARMA
Professor of Ophthalmology
Officer Incharge Unit- IV
Cataract, Cornea & Refractive Surgery Services
Dr. R.P. Centre for Ophthalmic Sciences
AIIMS, Ansari Nagar, New Delhi-110029

Rd/-
10/10/24

Sh. Manoj R

749
10/10/24

डॉ. विनोद कुमार / Dr. VINOD KUMAR
अपर आचार्य नेत्र विज्ञान
Additional Professor of Ophthalmology
डॉ. राजेन्द्र प्रसाद नेत्र विज्ञान केन्द्र
Dr. R.P. Centre for Ophthalmic Sciences
अ.भा.आ.सं., नई दिल्ली / A.I.I.M.S., New Delhi-29

Office – 1678998/RPC/2024

To

Date:10/10/2024

The Store Officer

Dr. R.P.Centre ,

AIIMS New Delhi .

Through proper channel

Sub: consumption of items in V.R.Kit OT5th floor (Medicine)

S.NO	Name of the Items	Used in the month of Sept and Oct.2024	Total
1.	**Inj.Faricimab**	**Sept .4 Oct.6**	**10**

Thanking you

Sincerely

10/10/24

Sister In charge (VR Kit)

OT 5th Floor

Vinod

डॉ. विनोद कुमार / Dr. VINOD KUMAR
अपर आचार्य नेत्र विज्ञान
Additional Professor of Ophthalmology
डॉ. राजेन्द्र प्रसाद नेत्र विज्ञान केन्द्र
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शरीरमाद्यं खलुधर्मसाधनम्
अ०भा०आ०सं०
A.I.I.M.S.

DR. RAJENDRA PRASAD CENTRE FOR OPHTHALMIC SCIENCES
ALL INDIA INSTITUTE OF MEDICAL SCIENCES
STORE SECTION

Date: 30-October-2024

Subject: Requirement of detailed specifications and information's for purchase of Inj. Faricimab (Anti-VEGF + Anti AnG2 Antibody) made by Roche – reg:

The demand letter dated 10-October-2024 has been received and duly forwarded by Prof. Namrata Sharma, Prof. of Ophthalmology for procurement of Inj. Faricimab (Anti-VEGF + Anti AnG2 Antibody) made by Roche under Patient Revolving Fund in Dr. R.P. Centre, AIIMS.

In view of above Prof. Namrata Sharma, Prof. of Ophtalmology is kindly request to provide the following details for procurement of said item,

I. **GeM Availability Report**
(If the product is available in GeM, kindly give the golden parameters/technical parameters of those items)
(or) store can go to GEM non availability report and get it verified.

II. **GeM Non-availability report**
(If the product is not available in GeM, kindly provide the detailed specifications of those items for purchasing through GeM bidding/GeM Custom catalogue based bidding/CPPP/ATE/LTE/PAC)

III. Source of the item (Manufacturers/Distributors, if any) 1) Faricimab - Roche

IV. Approx. Cost of each Injection/Vial/Ampoule/Number Rs 60000/- (Rs 58910.98/-)

V. Monthly consumption/Annual consumption (or one time demand)

for Vial 30/10/24

STORE KEEPER (DRUGS)

Submitted for consideration and further recommendations.

30/10/2024

STORES OFFICER (RPC)

Namrata Sharma

PROF. NAMRATA SHARMA
Prof. of Ophthalmology

Dr Rajpal Sir
Please

डॉ. राजपाल / Dr. RAJPAL
आचार्य नेत्र विज्ञान / Professor of Ophthalmology
डॉ. राजेन्द्र प्रसाद नेत्र विज्ञान केन्द्र
Dr. R.P. Centre for Ophthalmic Sciences
अ.भा.आ.सं. नई दिल्ली / AIIMS, New Delhi-110029

Report ID: GEM/GARPTS/28102024/UWV9S8N9BYQG
Report Name: Injection Faricimab 6mg/0.05ml
Generated By: Manoj Ramanujam

Generated On: 28/10/2024
Valid till: 27/11/2024

GeM Availability Report and Past Transaction Summary

GeM Availability Report and past transaction summary report is generated based on the search strings/specifications uploaded by the Buyer. The specification/strings may be modified appropriately for searching relevant categories on GeM. Buyer may navigate to the GeM category page to view category specifications and products/services available in the category.

Order Count and Order Value displayed is on a cumulative basis since GeM inception.

1. Search String: Injection Faricimab 6mg/0.05ml

Search type: Product

Search Result: The below categories are suggested as per specification/strings uploaded by the buyer.

Category Name	Catalog Count	Order Count			Order Value (in Lakhs)		
		Direct Purchase	Reverse Auction	Bid	Direct Purchase	Reverse Auction	Bid
Cat 6 Patch cord	3,399	7,425	139	477	940	105	195
books	1,01,730	1,51,639	136	1,708	14,103	58	1,323
Online UPS (V2)	34,485	24,571	826	2,228	39,267	7,206	12,218
Ondansetron Injection	7	0	0	5	0	0	1
Glass Tableware	2,603	66,574	78	550	4,697	22	161
Metoprolol Injection	1	0	0	2	0	0	0
Surgical Gloves as per IS 4148	21,798	28,523	268	1,437	17,042	6,709	7,562
FUROSEMIDE	2	1,050	0	0	186	0	0
nabulizer	5,007	4,536	17	132	1,635	15	83
Naloxone Injection	1	0	0	0	0	0	0

If the above suggested categories doesn't meet your requirement, try searching different string for more results.

2. Search String: Injection Faricimab 6mg

Search type: Product

Search Result: The below categories are suggested as per specification/strings uploaded by the buyer.

Category Name	Catalog Count	Order Count			Order Value (in Lakhs)		
		Direct Purchase	Reverse Auction	Bid	Direct Purchase	Reverse Auction	Bid

Category Name	Catalog Count	Order Count			Order Value (in Lakhs)		
		Direct Purchase	Reverse Auction	Bid	Direct Purchase	Reverse Auction	Bid
Metoprolol Injection	1	0	0	2	0	0	0
Electrical Box Extension (V2)	20,084	21,696	27	91	1,715	12	40
Labetalol Injection	1	0	0	0	0	0	0
CEFOPERAZONE + SULBACTAM	4	602	0	0	611	0	0
Esmolol Injection	0	0	0	0	0	0	0
Steel Bookcases as per IS 7761	45,404	18,537	117	987	8,440	808	1,995
Hydroxocobalamin Injection	0	0	0	0	0	0	0
AMOXICILLIN SODIUM + CLAVULANATE POTASSIUM	4	1,314	0	0	3,275	0	0
Dextrose Injection	0	0	0	0	0	0	0
modular electrical switches and accessories	7,271	52,600	171	1,569	3,882	57	409

If the above suggested categories doesn't meet your requirement, try searching different string for more results.

3. Search String: Injection Faricimab 0.05ml

Search type: Product

Search Result: The below categories are suggested as per specification/strings uploaded by the buyer.

Category Name	Catalog Count	Order Count			Order Value (in Lakhs)		
		Direct Purchase	Reverse Auction	Bid	Direct Purchase	Reverse Auction	Bid
nabulizer	5,007	4,536	17	132	1,635	15	83
books	1,01,730	1,51,639	136	1,708	14,103	58	1,323
galvanized steel chain link fence fabric as per IS 2721	2,582	3,487	109	332	9,257	2,246	5,808
PIPERACILLIN + TAZOBACTAM	3	1,418	0	0	5,184	0	0
Cat 6 Patch cord	3,399	7,425	139	477	940	105	195
Ondansetron Injection	7	0	0	5	0	0	1
DNA marker	290	1,525	0	14	277	0	6
Metoprolol Injection	1	0	0	2	0	0	0
Electric Kettles and Jugs for Household as per IS 367	1,469	38,123	24	240	3,345	23	103
Clindamycin Injection	3	0	0	0	0	0	0

If the above suggested categories doesn't meet your requirement, try searching different string for more results.

4. Search String: Injection Faricimab

Search type: Product

Search Result: The below categories are suggested as per specification/strings uploaded by the buyer.

Category Name	Catalog Count	Order Count			Order Value (in Lakhs)		
		Direct Purchase	Reverse Auction	Bid	Direct Purchase	Reverse Auction	Bid
Labetalol Injection	1	0	0	0	0	0	0
Intravenous Cannulas as per IS 10555 - 5	5,013	18,608	224	493	13,106	1,078	501
Metoprolol Injection	1	0	0	2	0	0	0
HDPE / PE Plastic Pallets (Injection Moulded)	605	938	24	129	1,341	145	1,295
Esmolol Injection	0	0	0	0	0	0	0
Foot Operated Pedal Bin or Bucket for Bio - Medical Waste Collection	22,627	9,359	26	117	3,526	101	115
Hydroxocobalamin Injection	0	0	0	0	0	0	0
Dextrose Injection	0	0	0	0	0	0	0
measured volume set	638	1,862	26	55	1,413	216	164
Docetaxel Injection	2	0	0	0	0	0	0

If the above suggested categories doesn't meet your requirement, try searching different string for more results.

Dt- 21/10/2024

To,

THE AIIMS
RP centre
New Delhi

Subject: Rate Quotation and authority letter.

Dear Sir,

Please find below the price of our following products.

S.No.	Generic Name	Brand Name	Strength	Unit/Pack	Rates offered to CGHS (Exclusive GST)	GST %	Net Rate offered to CGHS (Inclusive of GST)
1.	Vabysmo	Faricimab	6mg/0.05 ml	1 vial	52599.00	12%	58910.88

Medsurg Pharma. Shop no 116, Ground floor Shahid Bhagat Singh Market , New Delhi-110001 is authorized to collect the order, make the supply and raise their own bills & collect payments thereof against such supplies. The above quoted rates are valid till 31.03.2025 . The rates quoted are inclusive of all applicable taxes as per the present rules, in case of any revision takes place in MRP & other duties at the time of supply or any change in the price structure, we will intimate you.

Thanking You
Yours Faithfully,
For Roche products India Private Limited

Name - Deepak Singh
Designation- Chapter lead Public accounts , Squad lead Delhi and Haryana
Contact no 9873310808

Roche Products (India) Pvt. Ltd. Regd. Office : 166, R. 166A, Unit No. 7,8,9, 8th Floor, R City Office
CIN - U74999MH19 Mall, Lal Bahadur Shastri Marg, Ghatkopar (W), Mumbai Suburban - 400 086, India.
www.rocheindia.com

Tel. +91-22-5045 7300
Fax +91-22-5045 7301

डॉ. विनोद कुमार / Dr. VINOD KUMAR
अपर आचार्य नेत्र विज्ञान
Additional Professor of Ophthalmology
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Dr. R.P Centre for Ophthalmic Sciences
अ.भा.आ.सं. नई दिल्ली / A.I.I.M.S., New Delhi-

डॉ. रोहन चावला / Dr. ROHAN CHAWLA
अपर आचार्य नेत्र विज्ञान
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Roche

Dt- 21.10.2-24

To,
The AIIMS ,
RP centre
Delhi

Subject: Fall Clause & Acceptance Letter

Dear Sir,

We the Roche Products India Private Limuted which also includes all authorization Distributor/Agent) hereby undertake that if at any subsequent date after submission of the quotations or placing of supply orders, the manufacturer (the term manufacturer will also include his authorised distributor/agent) reduces the sales price of such stocks or sell such stocks to any party at a price lower than price charged/chargeable against the supply order placed by Medical Store Depot, the manufacturer (including authorised distributor/ agent s as aforesaid in case quotation is submitted by them and supply is also effected by them) will forthwith notify such reduction in sales price to the AIIMS and price payable for the stores to be supplied against the supply order after the date of such reduction in sales price coming in force shall stand reduced accordingly.

All terms & conditions are accepted.

Thanking You
Yours Faithfully,
For Roche Products Private Limited

Deepak Singh
Designation- Chapter Lead -Public account
Contact no - 9873310808

डॉ. रोहन चावला/Dr. ROHAN CHAWLA
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अ.भा.आ.सं. नई दिल्ली / A.I.I.M.S., New Delhi-29

Roche

TO WHOM IT MAY CONCERN

Basel, 01 June 2023

Ref.: Proprietary Article Certificate for Vabysmo® (faricimab) 6 mg/0.05 mL (120mg/mL) solution for intravitreal injection in a single dose vial with filter transfer needle

This to certify and confirm that F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, CH- 4070, Basel, Switzerland is the product owner of Vabysmo® (faricimab) 6 mg/0.05 mL (120mg/mL) solution for intravitreal injection in a single dose vial with filter transfer needle at their manufacturing facility - M/s F. Hoffmann -La Roche AG Wurmisweg, CH-4303 Kaiseraugst, Switzerland.

Vabysmo® (faricimab) 6 mg/0.05 mL (120mg/mL) solution for intravitreal injection in a single dose vial with filter transfer needle is the proprietary product of F. Hoffmann-La Roche Ltd. This product is imported and marketed in India by Roche Products (India) Pvt. Ltd.

Yours sincerely,

F. Hoffmann-La Roche Ltd

F. Hoffmann-La Roche Ltd
International Regulatory
Basel, Switzerland
Catalina Rojas

F. Hoffmann-La Roche Ltd
International Regulatory
Basel, Switzerland
Julie Hofer

डॉ. रोहन चावला/Dr. ROHAN CHAWLA
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F. Hoffmann-La Roche Ltd Pharmaceuticals ... Grenzacherstrasse ... 4070 Basel ... Switzerland

डॉ. शौर्य वर्धन आजाद
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DR. RAJENDRA PRASAD CENTRE FOR OPHTHALMIC SCIENCES
ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI – 110029

PROPRIETARY /SPECIFIC BRAND GOODS CERTIFICATE

1.	Item/Type/Model No. required along with specification	Vabysmo 6mg/0.05ml
2.	Is the item a spare part attachment or accessory for an existing equipment	No
3.	Name of the manufacturers/supplier of the item proposed by the inventor	Roche
4.	Are the sole manufacturers/sole distributors of the item	Yes
5.	It there any other item with similar/equipment specification available in the market to meet the job requirement envisaged. Of the answer is yes, why the same can't be procured. Demanding	No other molecule with similar action
6.	What were the efforts made to locate alternative source of supply or use other substitutes	only one company manufactures worldwide
7.	Why open/limited tender can't be resorted to, for locating alternative source.	No other manufacturer
8.	Are the proprietary items certifying that the rates are reasonable or not	Reasonable
9.	Any other justification for procuring item for single source.	

Vinod
डॉ. विनोद कुमार / Dr. VINOD KUMAR
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अ.भा.आ.सं., नई दिल्ली/A.I.I.M.S., New Delhi-110029

Signature of Indenter
(Demanding Officer)

COUNTERSIGN
(Head of the Department)

I certified that the item at Sr. No. 1 above is required to be procured on single tender basis as the source of supply is definitely known/the specified brand proposed was advantages in meeting our functional requirement and limited tender system could be dispensed with as they would serve no useful purpose in this particular case.

डॉ. शौर्य वर्धन आजाद
Dr. SHORYA VARDHAN AZAD
अतिरिक्त आचार्य / Additional Professor
डॉ. राजेन्द्र प्रसाद नेत्र विज्ञान केन्द्र
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DR. RAJENDRA PRASAD CENTRE FOR OPHTHALMIC SCIENCES
ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI- 110 029

PROPRIETARY ARTICLE CERTIFICATE

Reference File Number and Date: _____

01.	Description of article	Vabycmo 6mg/0.05ml
02.	Manufacturer's name and address	Roche
03.	Name(s) of authorized dealers/stockiest	Med Surg pharma
04.	I approve the above purchase on PAC basis and certify that: **Note:** Tick to retain only one out of (B), (C) or (D) whichever is applicable and cross out others. Please do confirm (a) by ticking it – without which PAC certificate will be invalid	
04-A	This is the only firm who is manufacturing/ stocking this item. **AND**	☑
04-B	A similar article is not manufactured/sold by any other firm, which could be used in lieu OR	☑
04-C	No other make/brand will be suitable for following tangible reasons (like OEM/ warranty spares): OR	☐
04-D	No other make/brand will be suitable for following intangible reasons (if PAC was also given in the last procurement cycle, please also bring out efforts made since then to locate more sources):	☐
05.	Reference of concurrence of Finance wing to the proposal:	

History of PAC purchases of this item for past three years may be given below

Name of the Supplier	~~N/A~~ Med Surg pharma		
Order/ Tender Reference & Date	Quantity Ordered	Basic Rate on Order (Rs.)	Adverse Performance Reported if Any
S.O. No:-306/RPC/MSK/24-25 Date:- 30-August-2024	20	₹ 52,599.00 + 12% GST = ₹ 58910.88 (inclusive GST @ 12%)	N;l

I/We certified that the item mentioned at Sr. No. 01 is required to be procured on Single Tender Basis (Proprietary Article Basis) as the source of supply is definitely known/the specified brand proposed was advantages in meeting our functional requirement.

Vinod

Signature of Approving Authority

डॉ. रोहन चावला/Dr. ROHAN CHAWLA
अपर आचार्य नेत्र विज्ञान
Additional Professor of Ophthalmology
डॉ. राजेन्द्र प्रसाद नेत्र विज्ञान केन्द्र
Dr. R. P. Centre for Ophthalmic Sciences
अ.भा.आ.सं., नई दिल्ली/A.I.I.M.S., New Delhi-110029

अपर आचार्य नेत्र विज्ञान
Additional Professor of Ophthalmology
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Designation of Officer

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अपर आचार्य / Additional Professor
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आचार्य नेत्र विज्ञान / Professor of Ophthalmology
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Dr. R.P. Centre for Ophthalmic Sciences
Delhi 110029

GMP Certificate

F. Hoffmann-La Roche Ltd
Wurmisweg
4303 Kaiseraugst
Switzerland

To Whom It May Concern

22 November 2022

F. Hoffmann-La Roche AG, site Kaiseraugst – Herstellung, Verpackung und Prüfung von Arzneimitteln: GMP Certificate

We, F. Hoffmann-La Roche Ltd, CH-4070 Basel, Switzerland, confirm herewith that the attached GMP Certificate for F. Hoffmann-La Roche AG, Grenzacherstrasse 124, 4058 Basel, site Kaiseraugst – Herstellung, Verpackung und Prüfung von Arzneimitteln, Wurmisweg, 4303 Kaiseraugst, Switzerland, is a copy of the original document.

Sincerely,

F. Hoffmann-La Roche Ltd

ppa.

Dr. Johnny Aguilar
Global Quality Manager

Francoise Hirth
Global Quality Manager

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Tel. +41 61 68 71449
Basel.gmpdocuments@roche.com
ID: 59139

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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **F. Hoffmann-La Roche AG, Grenzacherstrasse 124, 4058 Basel,** Authorisation No. 511265-102670479 with its site **F. Hoffmann-La Roche AG Kaiseraugst - Herstellung,, Verpackung und Prüfung von Arzneimitteln, Wurmisweg, 4303 Kaiseraugst, Switzerland,** Site No. 1000114 has been duly authorised to perform the manufacturing activities according to the table below;

that the company is keeping the required level for Good Manufacturing Practices for Medicinal Products (GMP) according to the Swiss regulations in force. These regulations are in accordance with the requirements for good practices in the manufacture and quality control of the Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) as well as with The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union/Canada and Switzerland;

that the manufacturing plant of the company is subject to official periodic inspections; the last regular inspection was conducted on **25.11.2021** (dd.mm.yyyy).

No.	*Operation*	*Scope**
1	**MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)**	
1.1	**Sterile Products**	
1.1.1	Aseptically prepared (processing operations for the following dosage forms)	
1.1.1.2	Lyophilisates	H/V, I
1.1.1.4	Small volume liquids	H/V, I
1.1.1.6	Other aseptically prepared products: Rocephin	H/V
1.1.2	Terminally sterilised (processing operations for the following dosage forms)	
1.1.2.3	Small volume liquids	H/V
1.1.3	Batch certification (technical release)	H/V
1.2	**Non-sterile products**	
1.2.1	Non-sterile products (processing operations for the following dosage forms)	
1.2.1.1	Capsules, hard shell	H/V, I
1.2.1.8	Other solid dosage forms	H/V, I
1.2.1.13	Tablets	H/V, I
1.2.2	Batch certification (technical release)	H/V
1.3	**Biological medicinal products**	
1.3.1	Biological Medicinal Products	
1.3.1.5	Biotechnology products	H/V, I
1.3.2	Batch certification (technical release)	
1.3.2.5	Biotechnology products	H/V
1.5	**Packaging**	
1.5.1	Primary packaging	
1.5.1.1	Capsules, hard shell	H/V
1.5.1.2	Capsules, soft shell	H/V
1.5.1.8	Other solid dosage forms	H/V, I

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No.	Operation	Scope*
1.5.1.13	Tablets	H/V
1.5.2	Secondary packaging	H/V
1.6	**Quality control testing**	
1.6.1	Microbiological: sterility	H/V, I
1.6.2	Microbiological: non-sterility	H/V, I
1.6.3	Chemical/Physical	H/V
1.6.4	Biological	H/V
3	**MANUFACTURE OF ACTIVE SUBSTANCES**	
3.6	**Quality control testing**	
3.6.1	Physical / Chemical testing	-
3.6.2	Microbiological: testing (excluding sterility testing)	-
3.6.3	Microbiological: testing (including sterility testing)	-
3.6.4	Biological Testing	-

* Scope of authorisation:
H/V Human and veterinary medicinal products, without investigational products
V Veterinary medicinal products only, without investigational products
I Human investigational medicinal products
– Not specified

Berne, **13.05.2022** (dd.mm.yyyy)
No. GMP-CH-1003202

Swissmedic, Swiss Agency for Therapeutic Products

Jacqueline Büchi

Swiss Agency for Therapeutic Products swissmedic

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Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products
Swissmedic | Hallerstrasse 7 | CH-3012 Bern | www.swissmedic.ch | Fax +41 58 462 02 12

Legalisation

I, Dr. Benedikt A. Suter, the undersigned, sworn notary public to Basel (Switzerland), do hereby certify that the signature on the first page is that of **F. Hoffmann-La Roche Ltd**, a limited company under Swiss law, having its registered office in Basel (Switzerland), affixed by Mr **Dr. Johnny Aguilar Diaz**, Spanish citizen, domiciled in Ettingen (Switzerland), and Ms **Françoise Hirth**, French citizen, domiciled in Koetzingue (France), both with joint agent signature at two [*Kollektivprokura zu zweien*], both identified by comparison with other samples of indubitably authentic signatures.

B a s e l , this 23rd (twenty-third) day of November 2022 (two thousand and twenty two).

APOSTILLE

(Convention de la Haye du 5 octobre 1961)

1. Country / Land: Swiss Confederation, Canton of Basel-City / Schweizerische Eidgenossenschaft, Kanton Basel-Stadt

   This public document / Diese öffentliche Urkunde

2. has been signed by / ist unterschrieben von: Dr. iur. Benedikt A. Suter

3. acting in the capacity of / in seiner Eigenschaft als: Notary Public

4. bears the stamp/seal of / Sie ist versehen mit dem Stempel/Siegel des/der: Suter Benedikt A.

   Certified / Bestätigt

5. at / in: Basel

6. the / am: 24.11.2022

7. by the / durch das: Legalisation Office of the Canton of Basel-City / Beglaubigungsbüro des Kantons Basel-Stadt

8. No. / Nr.: 250305

   tax / Taxe: CHF 20.00

9. stamp/seal / Stempel/Siegel

10. Signature / Unterschrift: Stephan Schefer

CANTON BASEL-CITY * LEGALISATIONS *

Leg. Prot. 2022/3319

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U.S. FOOD & DRUG ADMINISTRATION

BLA 761235

BLA APPROVAL

Genentech, Inc.
Attention: Jay Bordoloi, Pharm.D.
Regulatory Program Management
1 DNA Way
South San Francisco, CA 94080-4990

Dear Dr. Bordoloi:

Please refer to your biologics license application (BLA) dated and received May 28, 2021, and your amendments, submitted under section 351(a) of the Public Health Service Act for Vabysmo (faricimab-svoa) injection, for intravitreal use.

We have approved your BLA for Vabysmo (faricimab-svoa) effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, Vabysmo under your existing Department of Health and Human Services U.S. License No. 1048. Vabysmo is indicated for the treatment of neovascular (wet) age-related macular degeneration and for the treatment of diabetic macular edema.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture faricimab-svoa drug substance at Roche Diagnostics GmbH in Penzberg, Germany. The final formulated drug product will be manufactured, filled, labeled, and packaged at F. Hoffmann-La Roche Ltd, Kaiseraugst, Switzerland. You may label your product with the proprietary name, Vabysmo, and market it in 6 mg/0.05 mL (120 mg/mL) single-dose vials.

DATING PERIOD

The dating period for Vabysmo shall be 30 months from the date of manufacture when stored at 2°C - 8°C, and protected from light. The date of manufacture shall be defined as the date of final sterile filtration of the formulated drug product. The dating period for your drug substance shall be 36 months from the date of manufacture when stored at -40°C (-30°C to -50°C).

The expiration date for the packaged product, faricimab-svoa plus transfer filter needle (BD Model 305211) shall be dependent on the shortest expiration date of any component.

FDA LOT RELEASE

You are not currently required to submit samples of future lots of Vabysmo with transfer filter needle (BD Model 305211) to the Center for Drug Evaluation and Research (CDER) for release by the Director, CDER, under 21 CFR 610.2. We will continue to monitor

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compliance with 21 CFR 610.1, requiring completion of tests for conformity with standards applicable to each product prior to release of each lot.

Any changes in the manufacturing, testing, packaging, or labeling of Vabysmo, or in the manufacturing facilities, will require the submission of information to your BLA for our review and written approval, consistent with 21 CFR 601.12.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

We note that your January 27, 2022, submission includes final printed labeling (FPL) for your Prescribing Information. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As (October 2009)*.[2] The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved BLA 761235.**" Approval of this submission by FDA is not required before the labeling is used.

ADVISORY COMMITTEE

Your application for Vabysmo was not referred to an FDA advisory committee because the safety profile is similar to that of other drugs or biological products approved for these indications.

[1] See http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm for FDA Guidance

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

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REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable. We are waiving the pediatric study requirement for this application because necessary studies are impossible or highly impracticable to conduct as the diseases do not occur in pediatric patients.

POSTMARKETING REQUIREMENTS UNDER 505(o)

Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (FDCA) authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute.

We have determined that an analysis of spontaneous postmarketing adverse events reported under subsection 505(k)(1) of the FDCA will not be sufficient to identify an unexpected serious risk of corneal endothelial cell loss. Furthermore, the active postmarket risk identification and analysis system as available under section 505(k)(3) of the FDCA will not be sufficient to assess this serious risk. We have determined that only a clinical trial (rather than a nonclinical or observational study) will be sufficient to identify an unexpected serious risk of corneal endothelial cell loss. Therefore, based on appropriate scientific data, FDA has determined that you are required to conduct the following trials:

4214-1 Conduct a controlled trial to evaluate the corneal endothelial health of eyes treated with faricimab by monitoring the number/density of corneal endothelial cells using specular microscopy at baseline and over a period of at least one year in at least 100 patients receiving faricimab.

The timetable you submitted on January 25, 2022, states that you will conduct this trial according to the following schedule:

Final Protocol Submission:	04/2022
Trial Completion:	12/2024
Final Report Submission:	04/2025

FDA considers the term *final* to mean that the applicant has submitted a protocol the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial.[3]

Submit clinical protocol(s) to your IND 119225 with a cross-reference letter to this BLA. Prominently identify the submission with the following wording in bold capital letters at the

[3] See the guidance for Industry *Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (October 2019).* https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

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top of the first page of the submission, as appropriate: **Required Postmarketing Protocol Under 505(o), Required Postmarketing Final Report Under 505(o), Required Postmarketing Correspondence Under 505(o).**

Section 505(o)(3)(E)(ii) of the FDCA requires you to report periodically on the status of any study or clinical trial required under this section. This section also requires you to periodically report to FDA on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Section 506B of the FDCA, as well as 21 CFR 601.70 requires you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

FDA will consider the submission of your annual report under section 506B and 21 CFR 601.70 to satisfy the periodic reporting requirement under section 505(o)(3)(E)(ii) provided that you include the elements listed in 505(o) and 21 CFR 601.70. We remind you that to comply with 505(o), your annual report must also include a report on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Failure to submit an annual report for studies or clinical trials required under 505(o) on the date required will be considered a violation of FDCA section 505(o)(3)(E)(ii) and could result in enforcement action.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[4]

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[5] Information and Instructions for completing the form can be found at FDA.gov.[6]

REPORTING REQUIREMENTS

You must submit adverse experience reports under the adverse experience reporting requirements for licensed biological products (21 CFR 600.80). Prominently identify all adverse experience reports as described in 21 CFR 600.80.

You must submit distribution reports under the distribution reporting requirements for licensed biological products (21 CFR 600.81).

You must submit reports of biological product deviations under 21 CFR 600.14. You should promptly identify and investigate all manufacturing deviations, including those

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[4] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.

[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf

[6] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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associated with processing, testing, packing, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
5901-B Ammendale Road
Beltsville, MD 20705-1266

Biological product deviations, sent by courier or overnight mail, should be addressed to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
10903 New Hampshire Avenue, Bldg. 51, Room 4207
Silver Spring, MD 20903

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.[7]

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[7] https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products

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POST APPROVAL FEEDBACK MEETING

New biological products qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, call the Regulatory Project Manager for this application.

If you have any questions, please call Wendy Streight, PhD, Regulatory Health Project Manager, at 240-402-6498.

Sincerely,

{See appended electronic signature page}

Charles Ganley, MD
Director
Office of Specialty Medicine
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
- Carton and Container Labeling

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HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use VABYSMO safely and effectively. See full prescribing information for VABYSMO.

VABYSMO™ (faricimab-svoa) injection, for intravitreal use
Initial U.S. Approval: 2022

INDICATIONS AND USAGE

VABYSMO is a vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2) inhibitor indicated for the treatment of patients with:

- Neovascular (Wet) Age-Related Macular Degeneration (nAMD) (1.1)
- Diabetic Macular Edema (DME) (1.2)

DOSAGE AND ADMINISTRATION

For intravitreal injection. (2.1)

- Neovascular (Wet) Age-Related Macular Degeneration (nAMD)
  - The recommended dose for VABYSMO is 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days, monthly) for the first 4 doses, followed by optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to inform whether to give a 6 mg dose via intravitreal injection on one of the following three regimens: 1) Weeks 28 and 44; 2) Weeks 24, 36 and 48; or 3) Weeks 20, 28, 36 and 44. Although additional efficacy was not demonstrated in most patients when VABYSMO was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4 week (monthly) dosing after the first 4 doses. Patients should be assessed regularly. (2.2)

- Diabetic Macular Edema (DME)
  - VABYSMO is recommended to be dosed by following one of these two dose regimens: 1) 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days ± 7 days, monthly) for at least 4 doses. If after at least 4 doses, resolution of edema based on the central subfield thickness (CST) of the macula as measured by optical coherence tomography is achieved, then the interval of dosing may be modified by extensions of up to 4 week interval increments or reductions of up to 8 week interval increments based on CST and visual acuity evaluations through week 52; or 2) 6 mg dose of VABYSMO can be administered every 4 weeks for the first 6 doses, followed by 6 mg dose via intravitreal injection at intervals of every 8 weeks (2 months) over the next 28 weeks. Although additional efficacy was not demonstrated in most patients when VABYSMO was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4 week (monthly) dosing after the first 4 doses. Patients should be assessed regularly. (2.3)

DOSAGE FORMS AND STRENGTHS

Injection: 120 mg/mL solution in a single-dose vial (3)

CONTRAINDICATIONS

- Ocular or periocular infection (4.1)
- Active intraocular inflammation (4.2)
- Hypersensitivity (4.3)

WARNINGS AND PRECAUTIONS

- Endophthalmitis and retinal detachments may occur following intravitreal injections. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay, to permit prompt and appropriate management. (5.1)
- Increases in intraocular pressure have been seen within 60 minutes of an intravitreal injection. (5.2)
- There is a potential risk of arterial thromboembolic events (ATEs) associated with VEGF inhibition. (5.3)

ADVERSE REACTIONS

The most common adverse reaction (≥ 5%) reported in patients receiving VABYSMO was conjunctival hemorrhage (7%). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Genentech at 1-888-835-2555 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 1/2022

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

VABYSMO is a vascular endothelial growth factor (VEGF) and angiopoietin 2 (Ang-2) inhibitor indicated for the treatment of patients with:

1.1 Neovascular (wet) Age-Related Macular Degeneration (nAMD)

1.2 Diabetic Macular Edema (DME)

2 DOSAGE AND ADMINISTRATION

2.1 General Dosing Information

For intravitreal injection. VABYSMO must be administered by a qualified physician. Each vial should only be used for the treatment of a single eye.

2.2 Neovascular (wet) Age-Related Macular Degeneration (nAMD)

The recommended dose for VABYSMO is 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days, monthly) for the first 4 doses, followed by optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to inform whether to give a 6 mg dose via intravitreal injection on one of the following three regimens: 1) Weeks 28 and 44; 2) Weeks 24, 36 and 48; or 3) Weeks 20, 28, 36 and 44. Although additional efficacy was not demonstrated in most patients when VABYSMO was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4 week (monthly) dosing after the first 4 doses. Patients should be assessed regularly.

2.3 Diabetic Macular Edema (DME)

VABYSMO is recommended to be dosed by following one of these two dose regimens: 1) 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days ± 7 days, monthly) for at least 4 doses. If after at least 4 doses, resolution of edema based on the central subfield thickness (CST) of the macula as measured by optical coherence tomography is achieved, then the interval of dosing may be modified by extensions of up to 4 week interval increments or reductions of up to 8 week interval increments based on CST and visual acuity evaluations through week 52; or 2) 6 mg dose of VABYSMO can be administered every 4 weeks for the first 6 doses, followed by 6 mg dose via intravitreal injection at intervals of every 8 weeks (2 months) over the next 28 weeks. Although additional efficacy was not demonstrated in most patients when VABYSMO was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4 week (monthly) dosing after the first 4 doses. Patients should be assessed regularly.

2.5 Preparation for Administration

1. Before you start:

- Read all the instructions carefully before using VABYSMO.
- The VABYSMO kit includes a glass vial and transfer filter needle. The glass vial is for a single dose only. The filter needle is for single use only.
- VABYSMO should be stored refrigerated at temperatures between 2°C to 8°C (36°F to 46°F). **Do not** freeze. **Do not** shake.

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Reference ID: 4929047

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- Allow VABYSMO to reach room temperature, 20°C to 25°C (68°F to 77°F) before proceeding with the administration. The VABYSMO vial may be kept at room temperature for up to 24 hours. Keep the vial in the original carton to protect from light.

- VABYSMO should be inspected visually for particulate matter and discoloration prior to administration. VABYSMO is a clear to opalescent and colorless to brownish-yellow liquid solution.
  Do not use if particulates, cloudiness, or discoloration are visible.
  Do not use if the packaging, vial and/or transfer filter needle are expired, damaged, or have been tampered with (see **Figure A**).

- Use aseptic technique to carry out the preparation of the intravitreal injection.

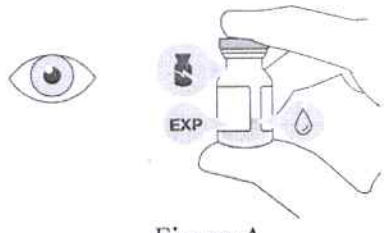

Figure A

2. Gather the following supplies:
   - One VABYSMO vial (included)
   - One sterile 5-micron blunt transfer filter needle 18-gauge x 1½ inch (included)
   - One sterile 1 mL Luer lock syringe with a 0.05 mL dose mark (**not included**)
   - One sterile injection needle 30-gauge x ½ inch (**not included**)
     Note that a 30-gauge injection needle is recommended to avoid increased injection forces that could be experienced with smaller diameter needles.
   - Alcohol swab (**not included**).

3. To ensure all liquid settles at the bottom of the vial, place the vial upright on a flat surface (for about 1 minute) after removal from packaging (see Figure B). Gently tap the vial with your finger (see Figure C), as liquid may stick to the top of the vial.

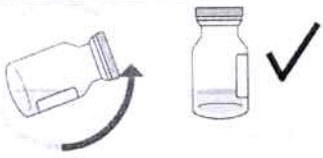

Figure B

Figure C

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4. Remove the flip-off cap from the vial (see **Figure D**) and wipe the vial septum with an alcohol swab (see **Figure E**).

Figure D

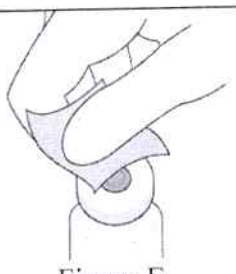

Figure E

5. Aseptically and firmly attach the included 18-gauge x 1½ inch transfer filter needle onto a 1 mL Luer lock syringe (see **Figure F**).

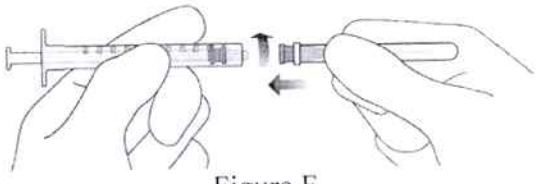

Figure F

6. Using aseptic technique, push the transfer filter needle into the center of the vial septum (see **Figure G**), push it all the way in, then tilt the vial slightly so that the needle touches the bottom edge of the vial (see **Figure H**).

Figure G

Figure H

7. Hold the vial slightly inclined and **slowly** withdraw all the liquid from the vial (see **Figure I**). Keep the bevel of the transfer filter needle submerged in the liquid, to avoid introduction of air.

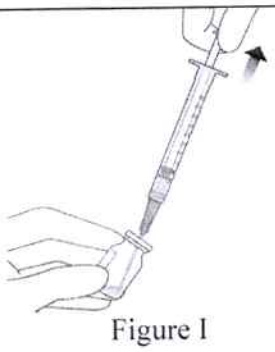

Figure I

8. Ensure that the plunger rod is drawn sufficiently back when emptying the vial, in order to completely empty the transfer filter needle (see **Figure I**).

9. Disconnect the transfer filter needle from the syringe and dispose of it in accordance with local regulations.

Do not use the transfer filter needle for the intravitreal injection.

10. Aseptically and firmly attach a 30-gauge x ½ inch injection needle onto the Luer lock syringe (see **Figure J**).

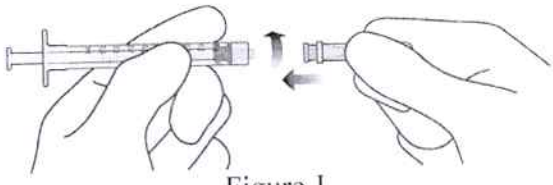

Figure J

11. Carefully remove the plastic needle shield from the needle by pulling it straight off.

12. To check for air bubbles, hold the syringe with the needle pointing up. If there are any air bubbles, gently tap the syringe with your finger until the bubbles rise to the top (see **Figure K**).

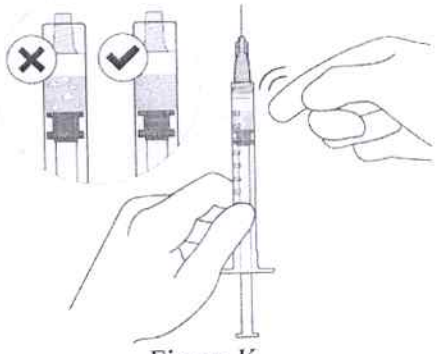

Figure K

13. Carefully expel the air from the syringe and needle, and **slowly** depress the plunger to align the rubber stopper tip to the 0.05 mL dose mark. The syringe is ready for the injection (see **Figure L**). Ensure that the injection is given **immediately** after preparation of the dose.

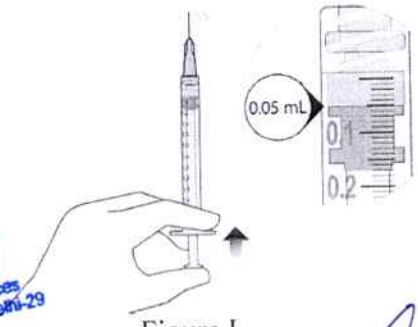

Figure L

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2.6 Injection Procedure

The intravitreal injection procedure must be carried out under aseptic conditions, which includes the use of surgical hand disinfection, sterile gloves, a sterile drape and a sterile eyelid speculum (or equivalent), and the availability of sterile paracentesis equipment (if required). Adequate anesthesia and a broad-spectrum microbicide should be administered prior to the injection. Inject slowly until the rubber stopper reaches the end of the syringe to deliver the volume of 0.05 mL. Confirm delivery of the full dose by checking that the rubber stopper has reached the end of the syringe barrel.

Any unused medicinal product or waste material should be disposed of in accordance with local regulations.

Immediately following the intravitreal injection, patients should be monitored for elevation in intraocular pressure. Appropriate monitoring may consist of a check for perfusion of the optic nerve head or tonometry. If required, a sterile paracentesis needle should be available. Following intravitreal injection, patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment (e.g., vision loss, eye pain, redness of the eye, photophobia, blurring of vision) without delay *[see Patient Counseling Information (17)]*. Each syringe should only be used for the treatment of a single eye. If the contralateral eye requires treatment, a new syringe should be used and the sterile field, syringe, gloves, drapes, eyelid speculum, filter, and injection needles should be changed before VABYSMO is administered to the other eye.

3 DOSAGE FORMS AND STRENGTHS

Injection: 120 mg/mL clear to opalescent, colorless to brownish-yellow solution in a single-dose vial.

4 CONTRAINDICATIONS

4.1 Ocular or Periocular Infections

VABYSMO is contraindicated in patients with ocular or periocular infections.

4.2 Active Intraocular Inflammation

VABYSMO is contraindicated in patients with active intraocular inflammation.

4.3 Hypersensitivity

VABYSMO is contraindicated in patients with known hypersensitivity to faricimab or any of the excipients in VABYSMO. Hypersensitivity reactions may manifest as rash, pruritus, urticaria, erythema, or severe intraocular inflammation.

5 WARNINGS AND PRECAUTIONS

5.1 Endophthalmitis and Retinal Detachments

Intravitreal injections have been associated with endophthalmitis and retinal detachments *[see Adverse Reactions (6.1)]*. Proper aseptic injection techniques must always be used when administering VABYSMO. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay, to permit prompt and appropriate management *[see Dosage and Administration (2.6) and Patient Counseling Information (17)]*.

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5.2 Increase in Intraocular Pressure

Transient increases in intraocular pressure (IOP) have been seen within 60 minutes of intravitreal injection, including with VABYSMO *[see Adverse Reactions (6.1)]*. IOP and the perfusion of the optic nerve head should be monitored and managed appropriately *[see Dosage and Administration (2.6)]*.

5.3 Thromboembolic Events

Although there was a low rate of arterial thromboembolic events (ATEs) observed in the VABYSMO clinical trials, there is a potential risk of ATEs following intravitreal use of VEGF inhibitors. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause).

The incidence of reported ATEs in the nAMD studies during the first year was 1% (7 out of 664) in patients treated with VABYSMO compared with 1% (6 out of 662) in patients treated with aflibercept *[see Clinical Studies (14.1)]*.

The incidence of reported ATEs in the DME studies during the first year was 2% (25 out of 1,262) in patients treated with VABYSMO compared with 2% (14 out of 625) in patients treated with aflibercept *[see Clinical Studies (14.2)]*.

6 ADVERSE REACTIONS

The following potentially serious adverse reactions are described elsewhere in the labeling:

- Hypersensitivity *[see Contraindications (4)]*
- Endophthalmitis and retinal detachments *[see Warnings and Precautions (5.1)]*
- Increase in intraocular pressure *[see Warnings and Precautions (5.2)]*
- Thromboembolic events *[see Warnings and Precautions (5.3)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in other clinical trials of the same or another drug and may not reflect the rates observed in practice.

The data described below reflect exposure to VABYSMO in 1,926 patients, which constituted the safety population in four Phase 3 studies *[see Clinical Studies (14.1, 14.2)]*.

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Table 1: Common Adverse Reactions (≥ 1%)

Adverse Reactions	VABYSMO		Active Control (aflibercept)	
	AMD N=664	DME N=1262	AMD N=622	DME N=625
Conjunctival hemorrhage	7%	7%	8%	6%
Vitreous floaters	3%	3%	2%	2%
Retinal pigment epithelial tear[a]	3%		1%	
Intraocular pressure increased	3%	3%	2%	2%
Eye pain	3%	2%	3%	3%
Intraocular inflammation[b]	2%	1%	1%	1%
Eye irritation	1%	1%	< 1%	1%
Ocular discomfort	1%	1%	< 1%	< 1%
Vitreous hemorrhage	< 1%	1%	1%	< 1%
[a] AMD only [b] Including iridocyclitis, iritis, uveitis, vitritis				

Less common adverse reactions reported in < 1% of the patients treated with VABYSMO were corneal abrasion, eye pruritus, lacrimation increased, ocular hyperemia, blurred vision, eye irritation, sensation of foreign body, endophthalmitis, visual acuity reduced transiently, retinal tear and rhegmatogenous retinal detachment.

6.2 Immunogenicity

The immunogenicity of VABYSMO was evaluated in plasma samples. The immunogenicity data reflect the percentage of patients whose test results were considered positive for antibodies to VABYSMO in immunoassays. The detection of an immune response is highly dependent on the sensitivity and specificity of the assays used, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to VABYSMO with the incidence of antibodies to other products may be misleading.

There is a potential for an immune response in patients treated with VABYSMO. In the nAMD and DME studies, the pre-treatment incidence of anti-faricimab antibodies was approximately 1.8% and 0.8%, respectively. After initiation of dosing, anti-faricimab antibodies were detected in approximately 10.4% and 8.4% of patients with nAMD and DME respectively, treated with VABYSMO across studies and across treatment groups. As with all therapeutic proteins, there is a potential for immunogenicity with VABYSMO.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate and well-controlled studies of VABYSMO administration in pregnant women.

Administration of VABYSMO to pregnant monkeys throughout the period of organogenesis resulted in an increased incidence of abortions at intravenous (IV) doses 158 times the human exposure (based on C_{max}) of the maximum recommended human dose *[see Animal Data]*. Based on the mechanism of action of VEGF and Ang-2 inhibitors, there is a potential risk to female

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reproductive capacity, and to embryo-fetal development. VABYSMO should not be used during pregnancy unless the potential benefit to the patient outweighs the potential risk to the fetus.

All pregnancies have a background risk of birth defect, loss, and other adverse outcomes. The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects is 2%-4% and of miscarriage is 15%-20% of clinically recognized pregnancies.

Data

Animal Data

An embryo fetal developmental toxicity study was performed on pregnant cynomolgus monkeys. Pregnant animals received 5 weekly IV injections of VABYSMO starting on day 20 of gestation at 1 or 3 mg/kg. A non-dose dependent increase in pregnancy loss (abortions) was observed at both doses evaluated. Serum exposure (C_{max}) in pregnant monkeys at the low dose of 1 mg/kg was 158 times the human exposure at the maximum recommended intravitreal dose of 6 mg once every 4 weeks. A no observed adverse effect level (NOAEL) was not identified in this study.

8.2 Lactation

Risk Summary

There is no information regarding the presence of faricimab in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production. Many drugs are transferred in human milk with the potential for absorption and adverse reactions in the breastfed child.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VABYSMO and any potential adverse effects on the breastfed child from VABYSMO.

8.3 Females and Males of Reproductive Potential

Contraception

Females of reproductive potential are advised to use effective contraception prior to the initial dose, during treatment and for at least 3 months following the last dose of VABYSMO.

Infertility

No studies on the effects of faricimab on human fertility have been conducted and it is not known whether faricimab can affect reproduction capacity. Based on the mechanism of action, treatment with VABYSMO may pose a risk to reproductive capacity.

8.4 Pediatric Use

The safety and efficacy of VABYSMO in pediatric patients have not been established.

8.5 Geriatric Use

In the four clinical studies, approximately 60% (1,149/1,929) of patients randomized to treatment with VABYSMO were ≥ 65 years of age. No significant differences in efficacy or safety of faricimab were seen with increasing age in these studies. No dose adjustment is required in patients 65 years and above.

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11 DESCRIPTION

Faricimab-svoa is a humanized bispecific immunoglobulin G1 (IgG1) antibody that binds both vascular endothelial growth factor A (VEGF-A) and angiopoietin-2 (Ang-2). The fragment crystallizable (Fc) region of faricimab was engineered by selected point mutations to abolish binding interactions with Fcγ and FcRn receptors. Faricimab-svoa has a total molecular weight of approximately 149 kDa and is produced by recombinant DNA technology using mammalian Chinese Hamster Ovary (CHO) cell culture.

VABYSMO (faricimab-svoa) injection is a sterile, clear to opalescent, colorless to brownish-yellow solution in a single-dose glass vial for intravitreal administration. Each single-dose vial is designed to deliver 0.05 mL (50 microliters) of solution containing 6 mg faricimab-svoa, L-histidine (155 mcg), L-methionine (52.2 mcg), polysorbate 20 (20 mcg), sodium chloride (73.1 mcg), D-sucrose (2.74 mg) and Water for Injection, adjusted to pH 5.5 with acetic acid. The product does not contain an anti-microbial preservative.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Faricimab is a humanized bispecific antibody that acts through inhibition of two pathways by binding to VEGF-A and Ang-2. By inhibiting VEGF-A, faricimab suppresses endothelial cell proliferation, neovascularization and vascular permeability. By inhibiting Ang-2, faricimab is thought to promote vascular stability and desensitize blood vessels to the effects of VEGF-A. Ang-2 levels are increased in some patients with nAMD and DME. The contribution of Ang-2 inhibition to the treatment effect and clinical response for nAMD and DME has yet to be established.

12.2 Pharmacodynamics

Increased retinal thickness, assessed by optical coherence tomography (OCT), is associated with nAMD and DME. Leakage of blood and fluid from choroidal neovascularization, assessed by fluorescein angiography, is associated with nAMD. Reductions in central subfield thickness (CST) were observed from baseline through the first year of treatment across all treatment arms in the four Phase 3 studies in nAMD and DME.

12.3 Pharmacokinetics

Absorption/Distribution

Maximum faricimab plasma concentrations (Cmax) are estimated to occur approximately 2 days post-dose. Mean (±SD) free faricimab (unbound to VEGF-A and Ang-2) plasma Cmax are estimated to be 0.23 (0.07) mcg/mL and 0.22 (0.07) mcg/mL in nAMD and in DME patients, respectively. After repeated intravitreal administrations, mean plasma free faricimab trough concentrations are predicted to be 0.002-0.003 mcg/mL for Q8W dosing. Although not directly measured in the vitreous, no accumulation of faricimab is expected in the vitreous and no accumulation has been observed in plasma when faricimab has been administered as repeat doses in the vitreous.

Metabolism/Elimination

Metabolism and elimination of faricimab has not been fully characterized. Faricimab is expected to be catabolized in lysosomes to small peptides and amino acids, which may be excreted

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renally, in a similar manner to the elimination of endogenous IgG. The estimated mean apparent systemic half-life of faricimab is 7.5 days.

Specific Populations
The systemic pharmacokinetics of faricimab were not influenced by gender, race, or mild to severe renal impairment (i.e., estimated normalized creatinine clearance by Cockroft-Gault equation: 15 to 89 mL/min/1.73 m^2). The effect of severe renal impairment or any degree of hepatic impairment on the pharmacokinetics of VABYSMO is unknown. No special dosage modification is required for any of the populations that have been studied (e.g., elderly, gender, race).

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No carcinogenicity or mutagenicity data are available for VABYSMO injection in animals or humans.

Based on the anti-VEGF and Ang-2 mechanisms of action, treatment with VABYSMO may pose a risk to reproductive capacity *[see Females and Males of Reproductive Potential (8.3)]*.

14 CLINICAL STUDIES

14.1 Neovascular (wet) Age-Related Macular Degeneration (nAMD)

The safety and efficacy of VABYSMO were assessed in two randomized, multi-center, double-masked, active comparator-controlled, 2-year studies (TENAYA – NCT03823287 and LUCERNE – NCT03823300) in patients with nAMD.

A total of 1,329 newly diagnosed, treatment-naive patients were enrolled in these studies, and 664 patients received at least one dose of VABYSMO. Patient ages ranged from 50 to 99 with a mean of 75.9 years. The studies were identically designed two year studies. Patients were randomized in a 1:1 ratio to one of two treatment arms: 1) aflibercept 2 mg administered fixed every 8 weeks (Q8W) after three initial monthly doses; and VABYSMO 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days, monthly) for the first 4 doses, followed by optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to determine whether to give a 6 mg (0.05 mL of 120 mg/mL solution) dose via intravitreal injection on one of the following three regimens: 1) Weeks 28 and 44; (also referred to as Q16W dosing); 2) Weeks 24, 36 and 48 (also referred to as Q12W dosing); or 3) Weeks 20, 28, 36 and 44 (also referred to as Q8W dosing). However, the utility of these criteria to guide dosing intervals has not been established.

At week 48, after 4 initial monthly doses in the VABYSMO arm, 45% of patients received the Weeks 28 and 44 dosing, 33% of patients received the Weeks 24, 36 and 48 dosing, and the remaining 22% of patients received dosing every 8 weeks. These percentages are reflective of what happened within the conduct of these trials and indicate that some patients did well on two (2) doses spaced 16 weeks apart, or three (3) doses spaced 12 weeks apart, but the percentages may not be generalizable to a broader nAMD population for a variety of reasons. The inclusion/exclusion criteria limited enrollment to a select subset of treatment naive, newly diagnosed nAMD patients and there is no empirical data that a similar magnitude would be observed if eligibility criteria allowed for broader enrollment. The disease activity criteria, which

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was instrumental in determining dose frequency, is unvalidated. Stricter criteria would have changed how patients were treated resulting in different percentages of subjects in each dose interval cohort. There was not a similarly dosed aflibercept arm for comparison, which makes the percentages difficult to interpret.

Both studies demonstrated non-inferiority to the comparator control (aflibercept) at the primary endpoint, defined as the mean change from baseline in Best Corrected Visual Acuity (BCVA) when averaged over the week 40, 44, and 48 visits and measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) letter chart. The primary endpoint analysis was a non-inferiority comparison for the mean change in BCVA between the aflibercept and the VABYSMO arm. The lower bound of the 95% confidence interval for the mean change in BCVA could not be lower than minus 4 letters to declare non-inferiority. In both studies, VABYSMO treated patients had a non-inferior mean change from baseline in BCVA compared to patients treated with aflibercept. Detailed results of both studies are shown in Table 2, Figure 1, and Figure 2 below. The clinical efficacy for the second year of the study has not been reviewed.

Table 2: Primary Endpoint Results[a] in the TENAYA and LUCERNE Studies

	TENAYA		LUCERNE	
	VABYSMO N = 334	Aflibercept N = 337	VABYSMO N = 331	Aflibercept N = 327
Mean change in BCVA as measured by ETDRS letter score from baseline (95% CI)	5.8 (4.6, 7.1)	5.1 (3.9, 6.4)	6.6 (5.3, 7.8)	6.6 (5.3, 7.8)
Difference in LS mean (95% CI)	0.7 (-1.1, 2.5)		0.0 (-1.7, 1.8)	

[a] Average of weeks 40, 44 and 48
BCVA: Best Corrected Visual Acuity
ETDRS: Early Treatment Diabetic Retinopathy Study
CI: Confidence Interval
LS: Least Square

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Figure 1: Mean Change in Visual Acuity from Baseline to Week 48 in TENAYA

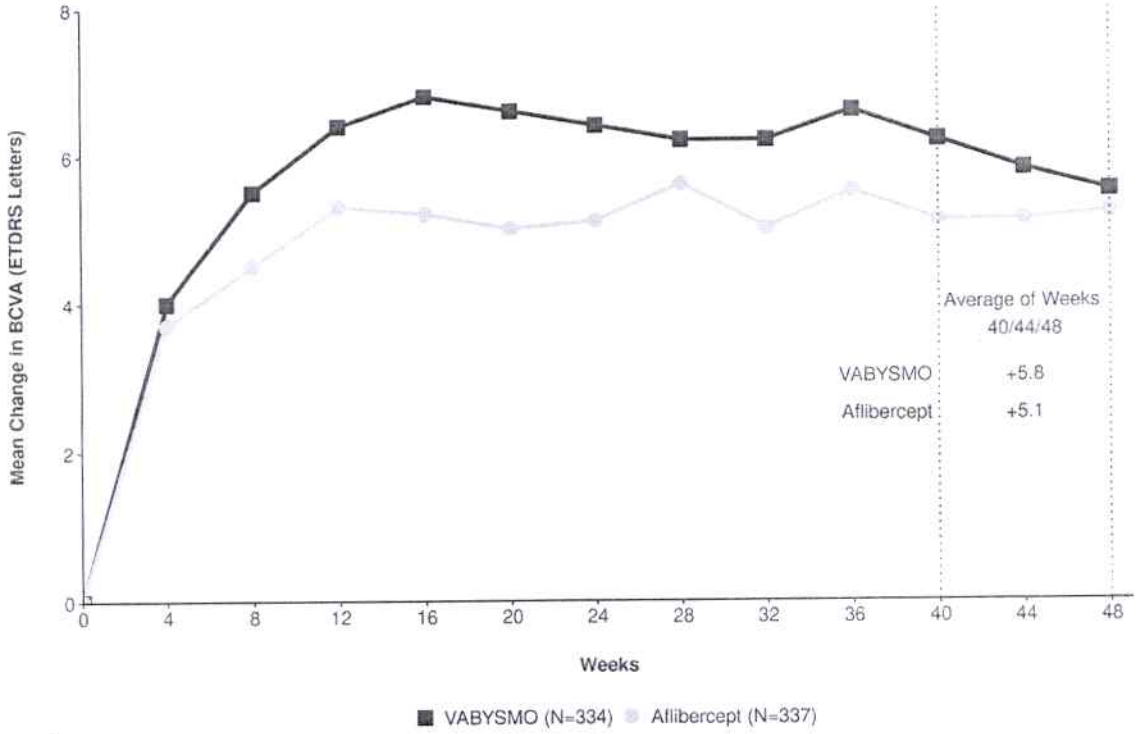
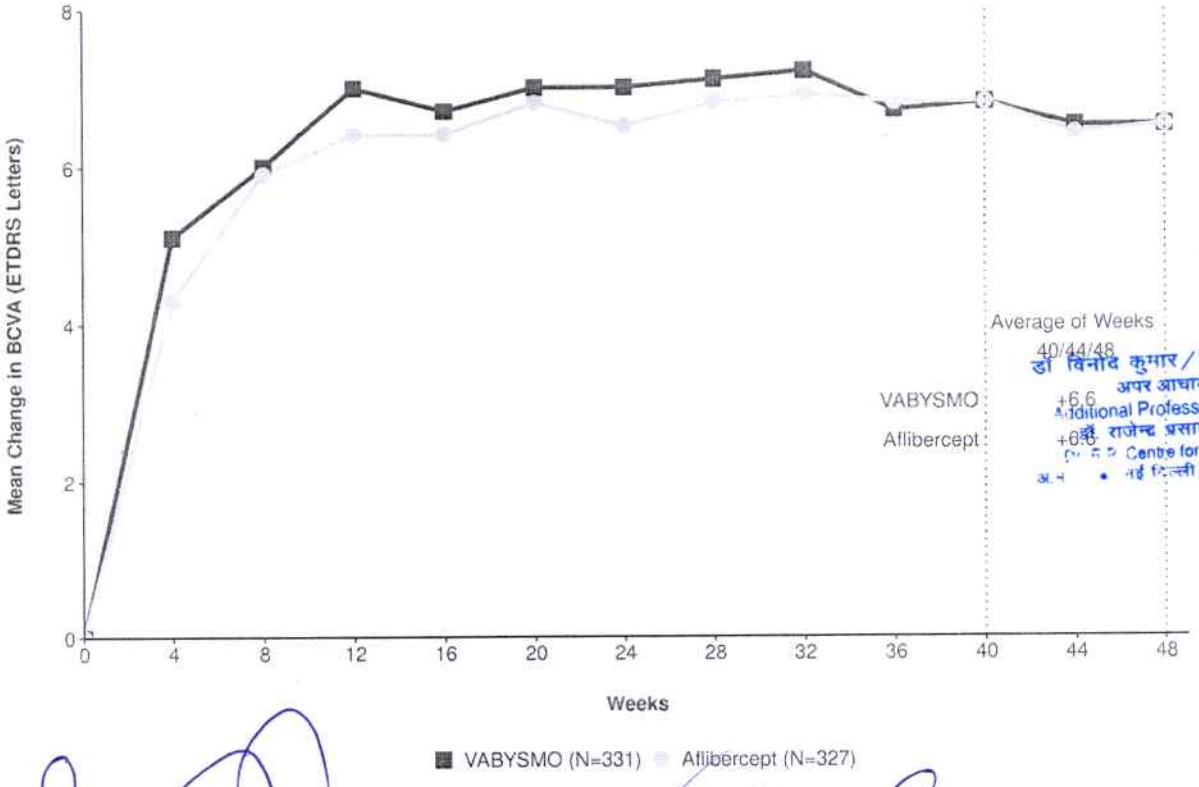


Figure 2: Mean Change in Visual Acuity from Baseline to Week 48 in LUCERNE



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Treatment effects in evaluable subgroups (e.g., age, gender, race, baseline visual acuity) in each study were consistent with the results in the overall population.

14.2 Diabetic Macular Edema (DME)

The safety and efficacy of VABYSMO were assessed in two randomized, multi-center, double-masked, active comparator-controlled 2-year studies (YOSEMITE – NCT03622580 and RHINE – NCT03622593) in patients with DME.

A total of 1,891 diabetic patients were enrolled in the two studies with a total of 1,262 patients treated with at least one dose of VABYSMO. Patient ages ranged from 24 to 91 with a mean of 62.2 years. The overall population included both anti-VEGF naive patients (78%) and patients who had been previously treated with a VEGF inhibitor prior to study participation (22%).

The studies were identically designed 2 year studies. Patients were randomized in a 1:1:1 ratio to one of three treatment regimens: 1) aflibercept Q8W, patients received fixed aflibercept 2 mg administered every 8 weeks (Q8W) after the first five monthly doses; 2) VABYSMO Q8W, patients received fixed VABYSMO 6 mg administered Q8W after the first six monthly doses; and 3) VABYSMO Variable, patients received VABYSMO 6 mg administered every 4 weeks for at least 4 doses and until the central subfield thickness (CST) of the macula measured by optical coherence tomography was less than approximately 325 microns, then the interval of dosing was modified by up to 4 week interval extensions or reductions in up to 8 week interval increments based on CST and visual acuity disease activity criteria at study drug dosing visits. However, the utility of these disease activity criteria to guide dosing intervals has not been established.

After 4 initial monthly doses, the patients in the VABYSMO Variable arm could have received between the minimum of three and the maximum of eleven total injections through Week 56 inclusive. At Week 56, 32% of patients had completed at least one Q12W interval followed by one full Q16W interval. Seventeen percent (17%) of patients were treated on Q8W and/or Q4W dosing intervals through Week 56 (7% only on Q4W). Sustainability of the Q16W dosing interval cannot be determined based on year one data alone. These percentages are reflective of what happened within the conduct of these trials, but the percentages are not generalizable to a broader DME population for a variety of reasons. The inclusion/exclusion criteria limited enrollment to a select subset of DME patients and there is no empirical data that a similar magnitude would be observed if eligibility criteria allowed for broader enrollment. The disease activity criteria, which was instrumental in determining dose frequency, is unvalidated. Stricter criteria would have changed how patients were treated resulting in different percentages of subjects in each dose interval cohort. There was not a similarly dosed aflibercept arm for comparison which makes the percentages difficult to interpret.

Both studies demonstrated non-inferiority to the comparator control (aflibercept) at the primary endpoint, defined as the primary endpoint, defined as the mean change from baseline in BCVA at year 1 (average of the week 48, 52, and 56 visits), measured by the ETDRS Letter Score. The primary endpoint analysis was a non-inferiority comparison for the mean change in BCVA between the aflibercept and VABYSMO groups. The lower bound of the 97.5% confidence interval for the mean change in BCVA could not be lower than minus 4 letters to declare non-inferiority. In both studies, VABYSMO Q8W and VABYSMO Variable treated patients had a

mean change from baseline in BCVA that was non-inferior to the patients treated with aflibercept Q8W. Detailed results of both studies are shown in Table 3, Figure 3, and Figure 4 below. The clinical efficacy for the second year of the study has not been reviewed.

Table 3: Primary Endpoint Results[a] in the YOSEMITE and RHINE Studies

	YOSEMITE			RHINE		
	VABYSMO Q8W N = 315	VABYSMO Variable N = 313	Aflibercept Q8W N = 312	VABYSMO Q8W N = 317	VABYSMO Variable N = 319	Aflibercept Q8W N = 315
Mean change in BCVA as measured by ETDRS letter score from baseline (97.5% CI)	10.7 (9.4, 12.0)	11.6 (10.3, 12.9)	10.9 (9.6, 12.2)	11.8 (10.6, 13.0)	10.8 (9.6, 11.9)	10.3 (9.1, 11.4)
Difference in LS mean (97.5% CI)	-0.2 (-2.0, 1.6)	0.7 (-1.1, 2.5)		1.5 (-0.1, 3.2)	0.5 (-1.1, 2.1)	

[a]Average of weeks 48, 52, 56
BCVA: Best Corrected Visual Acuity
ETDRS: Early Treatment Diabetic Retinopathy Study
CI: Confidence Interval
LS: Least Square

Figure 3: Mean Change in Visual Acuity from Baseline to Year 1 (Week 56) in YOSEMITE

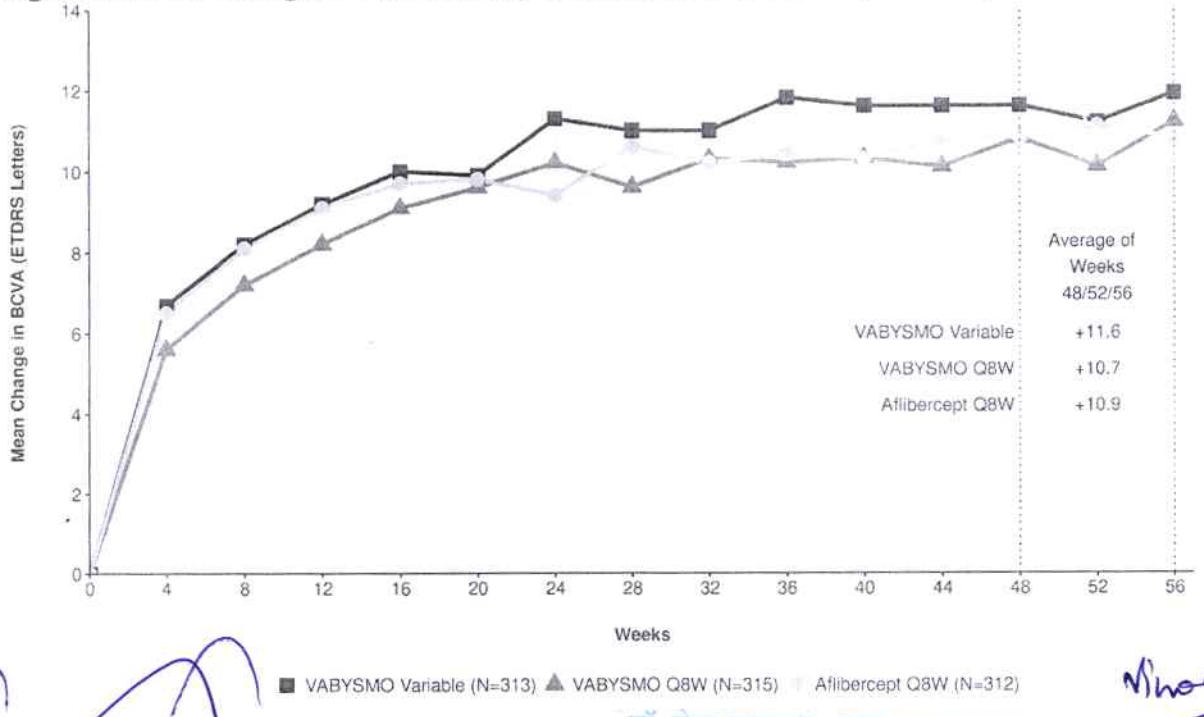
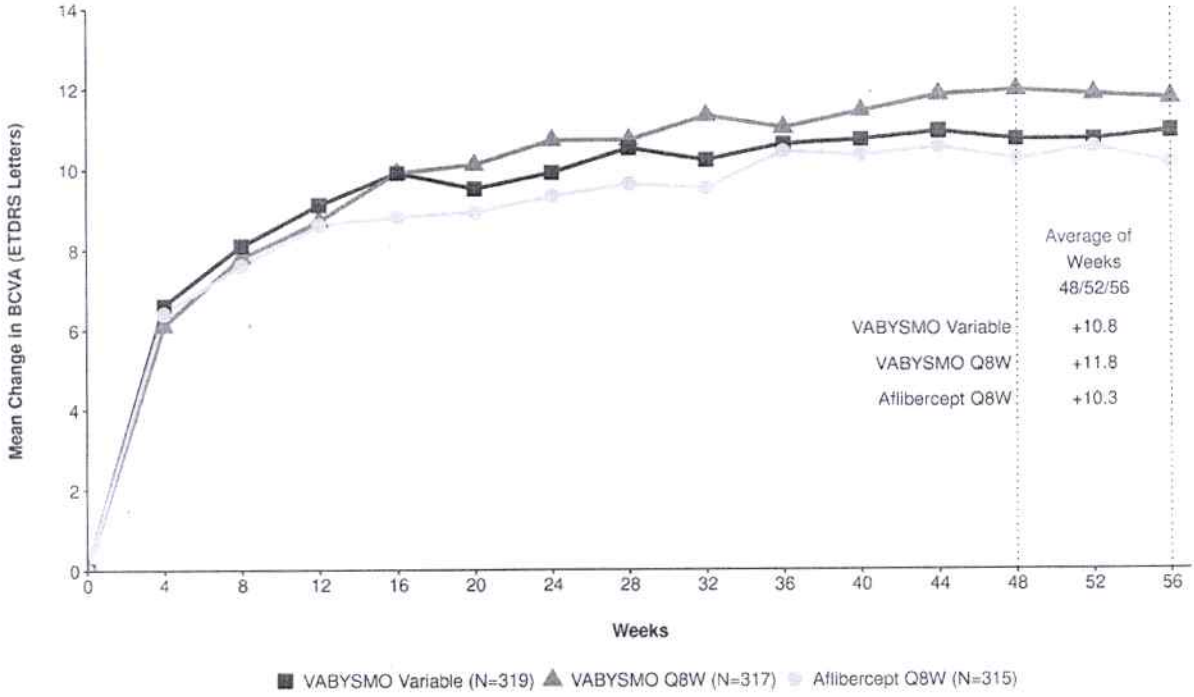


Figure 4: Mean Change in Visual Acuity from Baseline to Year 1 (Week 56) in RHINE



Treatment effects in the subgroup of patients who were anti-VEGF naive prior to study participation were similar to those observed in the overall population. Treatment effects in evaluable subgroups (e.g., by age, gender, race, baseline HbA1c, baseline visual acuity) in each study were generally consistent with the results in the overall population.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

VABYSMO (faricimab-svoa) injection is supplied as a clear to opalescent, colorless to brownish-yellow 120 mg/mL solution in a single-dose glass vial. Each glass vial contains an overfill amount to allow for administration of a single 0.05 mL dose of solution containing 6 mg of VABYSMO. Each VABYSMO carton (NDC 50242-096-01) contains one glass vial and one sterile 5-micron blunt transfer filter needle (18-gauge x 1½ inch, 1.2 mm x 40 mm).

16.2 Storage and Handling

Store VABYSMO in the refrigerator between 2°C to 8°C (36°F to 46°F). Do not freeze. Do not shake. Keep the vial in the original carton to protect from light.

Prior to use, the unopened glass vial of VABYSMO may be kept at room temperature, 20°C to 25°C (68°F to 77°F), for up to 24 hours. Ensure that the injection is given immediately after preparation of the dose.

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17 PATIENT COUNSELING INFORMATION

Advise patients that in the days following VABYSMO administration, patients are at risk of developing endophthalmitis. If the eye becomes red, sensitive to light, painful, or develops a change in vision, advise the patient to seek immediate care from an ophthalmologist *[see Warnings and Precautions (5)]*.

Patients may experience temporary visual disturbances after an intravitreal injection with VABYSMO and the associated eye examinations *[see Adverse Reactions (6)]*. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

VABYSMO™ [faricimab-svoa]
Manufactured by:
Genentech, Inc.
A Member of the Roche Group
1 DNA Way
South San Francisco, CA 94080-4990
U.S. License No.: 1048

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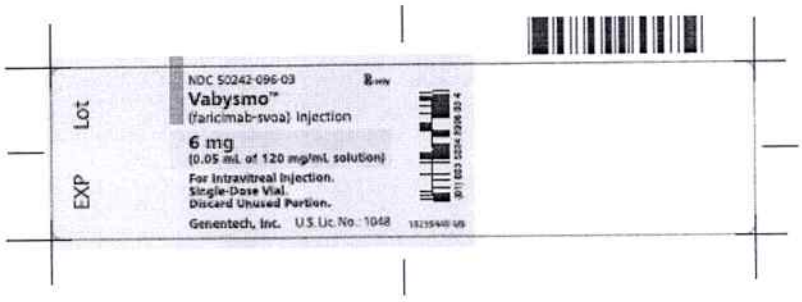

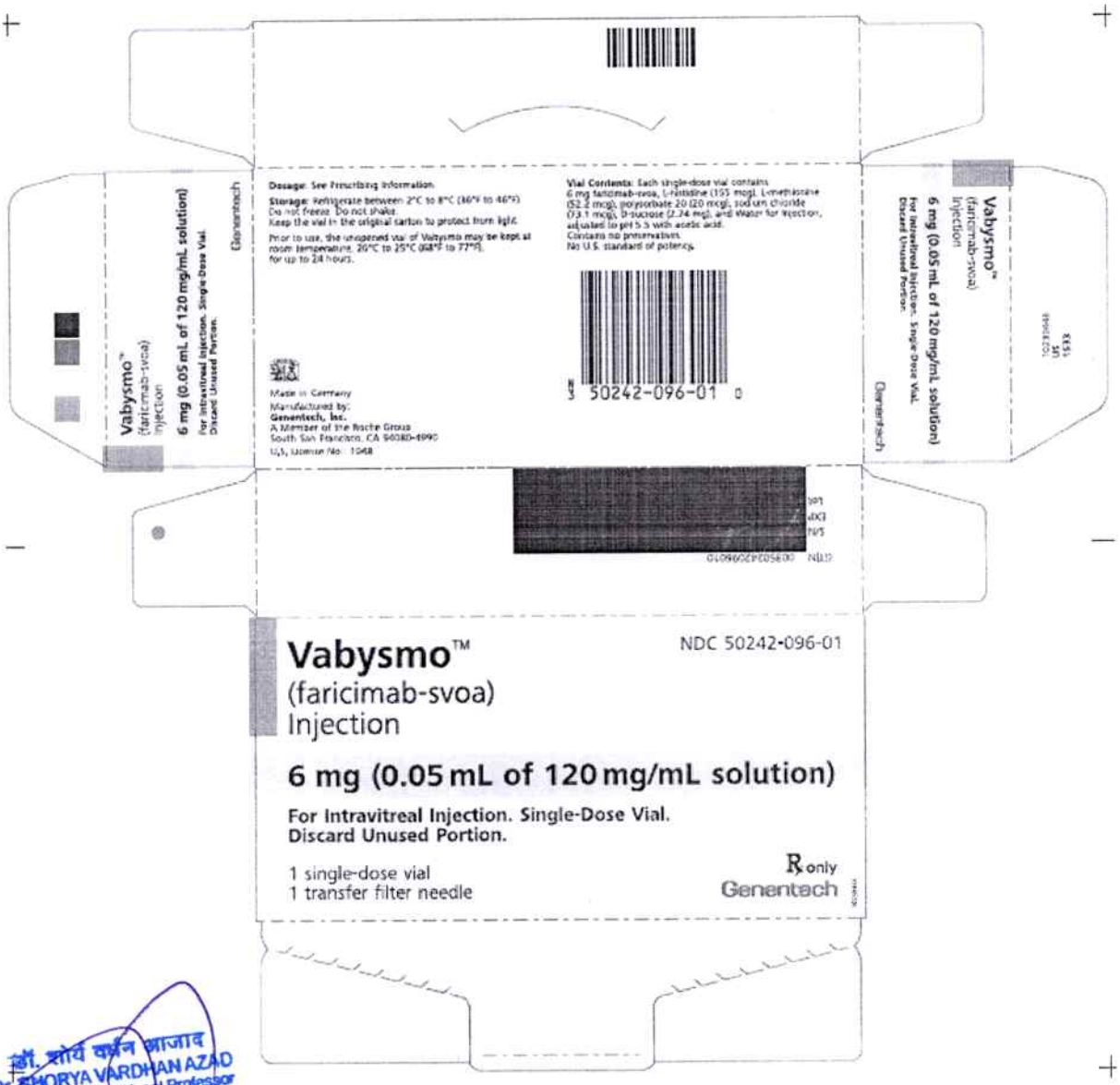

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

CHARLES J GANLEY
01/28/2022 03:35:50 PM

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Reference ID: 4929047

No.F.4/1/2023-PPD(pt.)
Government of India
Ministry of Finance
Department of Expenditure
Procurement Policy Division
*****

502, Lok Nayak Bhavan,
Khan Market, New Delhi,
07.06.2024

OFFICE MEMORANDUM

Subject: - Relaxation under Rule 161(iv) of General Financial Rules 2017 for issuance of Global Tender Enquiry (GTE) for procurement of Drugs -reg.

Attention is invited to this Department's OM No. F.12/17/2019-PPD dated 15.05.2020 regarding amendment in Rule 161(iv) of General Financial Rules (GFRs) 2017 stipulating that *no Global Tender Enquiry (GTE) shall be invited for tenders upto Rs.200 crore.* However, in exceptional cases, where the Ministry or the Department feels that there are special reasons for issuance of GTE, it may record its detailed justification and seek prior approval for relaxation to the above Rule from the competent authority i.e. Secretary (Coordination), Cabinet Secretariat.

2. In this context, Ministry of Health & Family Welfare (MoH&FW) has requested to exempt procurement of 120 drugs from the above instructions.

3. In view of request of MoH&FW, a general exemption has been granted herewith under Rule 161 (iv) of GFRs 2017, from the instructions issued by this department vide OMs No. F.12/17/2019-PPD dated 15.05.2020 & 28.05.2020, for issuance of GTE for procurement of 120 drugs listed at Annexure-A till 31.03.2027 or further orders.

4. This issues with the approval of Finance Secretary.

Encls: As above.

(Anil Kumar)
Deputy Secretary (Procurement Policy)
Tel. No. 24627920
Email: anil.kumar14@nic.in

To,

All the Secretaries and Financial Advisors to Government of India.

Copy to:

Secretary (Coordination), Cabinet Secretariat, Rashtrapati Bhawan, New Delhi.

Annexure-A

S.No	Name of the Drug
1	Abemaciclib 50mg/100mg/150mg/200mg
2	Abrocitinib Tab 50 mg/100mg/ 200 mg
3	AFLIBERCEPT 40 MG
4	ALECENSA 150 MG [(Alectinib (150mg)]
5	Alglucosidase Alfa vial for Inj.
6	Amivantamab 350 mg
7	ATEZOLIZUMAB 840 MG/ 1.2MG
8	Avalglucosidase Alfa-ngpt vial for inj.
9	Avelumab injection: 200 mg/10 mL (20 mg/mL) solution in single-dose vial
10	BASILIXIMAB 20 MG
11	Brolucizumab solution for injection 120 mg/ml(vial + filter needle)
12	Capmatinib Film-coated Tablet 200 mg
13	Catridecacog (rDNA factor XIII 2500IU)
14	Crizanlizumab 100mg/ 10ml
15	Crizotinib Tab/Capsule (250 Mg)
16	Dabrafenib capsules 75 mg
17	DARATUMUMAB 100 MG 400mg & Daratumumab Subcutaneous(Faspro) 1800 mg
18	DEGLUDEC 100 I.U./ML INSULIN. PREFILLED PEN 3 ML.
19	Desfulrane Anesthetic Liquid (SUPRANE)
20	Detemir Insulin 100 IU/ml 3ml Pen
21	Dulaglutide 0.75 MG (BRAND TRULICITY 0.75MG pre filled pen) & Dulaglutide Inj- [Brand TRULICITY 1.5mg Pre Filled Pen
22	Dupilumab Injection 300mg/2ml and 200mg/1.14ml
23	DURVALUMAB 120 MG/ 500MG
24	EMPAGLIFLOZIN + METFORMIN TABS VARIOUS FIXED DOSE COMBINATION)
25	Evrysdi 0.75MG 1ML 80 POSO IN (Risdiplam)
26	Fabrazyme (Agalsidase beta)

27	FACTOR EIGHT INHIBITOR BYPASSING ACTIVITY - Containing : Factor Eight Bypassing activity. Anti-Inhibitor-Coagulant Complex. 500 IU.
28	FASENRA™ (Benralizumab, prefilled syringe) Benralizumab Each injection contains Benralizumab 30mg
29	FINERENONE 10 MG / 20 mg TAB
30	Genryzon (SomatogroPn)
31	Golimumab 50mg/0.5ml [Simponi 50mg Injection-J&J]
32	Herpes Zoster Vaccine recombinant adjuvanted Brand Name: Shingrix
33	HUMAN COAGULATION FACTOR VII INJ - Each vial to contain: Human Recombinant Coagulation Factor VII activated (r-DNA origin) 1 mg Each vial to contain: Human Recombinant Coagulation Factor VII activated (r-DNA origin) 2mg
34	Idursulfase injection : 6 mg/3 ml. (2 mg/mL) in single-use vial
35	Imiglucerase injection: 400 units of imiglucerase as a lyophilized powder in a single-dose vial.
36	Inj Natalizumab 300mg/15ml
37	INJ PANITUMUMAB 100 MG
38	INJ PEMBROLIZUMAB 100 MG
39	Inj Spesolimab IV infusion 450 mg/7.5ml
40	Inj Tissue type plasminogen activator (tPA)
41	Inj. Insulin Degludec 70% + Insulin Aspart 30% 100 IU/ml., 3 ml. Cartridge (RYZODEG PENFILL.)
42	Inj. Ixekizumab 80mg (Copellor)
43	INJ. MEPOLIZUMAB SOLUTION 100 MG
44	Inj. Thyrotropin alfa 1.1 mg (THYROGEN)
45	Inonza (Inotuzumab Ozogamicin)
46	Insulin Analogue of 50% Insulin Aspart + 50% longer acting analogue 100 IU/ml.
47	Insulin Aspart Inj- Each Vial to contain: Insulin Aspart (r-DNA Origin)
48	INSULIN GLULISINE INJECTION(MONOCOMPONENT INSULIN GLULISINE) 100 I.U./ML.3ML

49	Insulin Inj-Each Cartridge to contain: 25% Lispro And 75% Lispro Protamine Suspension (100 IU/ml) [Monocomponent Insulin, Recombinant DNA Origin] & 3ml Cartridge. Each Cartridge to contain: 50% Lispro And 50% Lispro Protamine Suspension (100 IU/ml) [Monocomponent Insulin, Recombinant DNA Origin] & 3ml Cartridge
50	Intravitreal Dexamethasone Implant- Each inj to contain: Intravitreal Dexamethasone 0.7mg
51	KADCYLA (Trastuzumab emtansine) (Sterile powder for concentrate for infusion solution 100mg and 160mg vial [20mg/ml]
52	Kyzific® (Asciminib film-coated tablets 40 mg)
53	Laronidase injection: 2.9 mg/5 mL (0.58 mg/mL) of Laronidase in a single-dose vial
54	Lemtrada (Alemtuzumab)
55	Lorbriqua® (Lorlatinib)
56	Luspatercept 25 mg and 75 mg [Brand Name: Rojuzda]
57	Lutropin Alfa-r-DNA (Recombinant Leutinising Hormone 75 IU) Powder with 1ml solvent for solution for injection
58	Miglustat (Zavesca) (Opfolda)
59	Obinutuzumab Inj- Each Vial to contain: Obinutuzumab 1000 mg
60	OCREVUS (Ocrelizumab)Concentrate for solution for infusion 300 mg/10 mL vial [30 mg/mL]
61	Olipudase alfa-rpcp vial for Inj.
62	Pertuzumab Inj- Each 14ml Vial to contain: Pertuzumab 420mg (30mg/ml)
63	PHESGO Solution for subcutaneous injection 600mg + 600 mg (10 ml/15cc vial) 1200mg + 600mg (15ml/20cc vial) Pertuzumab (600mg) + Trastuzumab (600mg) Pertuzumab (1200mg) + Trastuzumab (600mg)
64	Pneumovax 23(pneumococcal vaccine polyvalent for 25 serotypes) & Pneumococcal Vaccine- Each 0.5ml to contain: Pneumococcal Polysaccharide Conjugate Vaccine (13 Valent)

65	POLIVY (Polatuzumab vedotin) [20mg/mL] Powder for concentrate for solution for infusion 30mg/vial and 140 mg/vial
66	RAMUCIRUMAB 100 mg & 500 MG(BRAND-CYRAMZA)
67	RECOMBINANT ANTI HEMOPHILLIC FACTOR-VIII
68	RUXOLITINIB 5MG. 15 MG. 20MG TABLET
69	Secukinumab Inj- Each 1 ml to contain: Secukinumab 150mg. Sucrose 92.43mg. L-Histidine / L- Histidine Hcl Monohydrate 4.656 mg. Polysorbate 80 - 0.60mg.
70	Selumetinib (Koselugo)
71	SEMAGLUTIDE 3 mg/ 7 mg/14 mg TAB
72	Sybrava (Inclisiran solution for injection in pre-filled syringe 284 mg/1.5 mL)
73	Tab. Dacomitinib Monohydrate 30 mg.(Tab Dacoplice 30 Mg.)
74	Thymoglobulin (Anti human thymocyte immunoGlobulin (rabbit). 25 mg/ml)
75	Trametinib 0.5 mg and 2 mg tablets
76 -	Trelegy Ellipta ((Fluticasone Furoate (100mcg) + Umeclidinium (62.5mcg) + Vilanterol (25mcg))
77	Ustekinumab 90 mg and 130 mg
78	VABYSMO (Faricimab) [120mg/mL]
79	VERICIGUAT 2.5 mg/ 5 mg/ 10 mg
80	VERTEPORFIN 15 MG
81	YERVOI®(Ipilimumab)
82	Follitropin Alfa 450 IU (r-hFSH) + Lutropin Alfa 225 IU (r-FSH) in Pre-filled Pen (Pergoveris ™ 450IU Pre-Filled Pen) & Follitropin Alfa 900 IU (r-hFSH) + Lutropin Alfa 450 IU (r-FSH) (Pergoveris ™ 900IU Pre-Filled Pen)
83	TEPOTINIB HYDROCHLORIDE HYDRATE 250 MG EQUIVALENT TO TEPOTINIB 225 MG
84	GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant) Suspension for intramuscular injection & Human Papillomavirus- Each 0.5ml to contain: Human Papillomavirus Quadrivalent (6,11, 16, 18) Vaccine, Recombinant

85	Synvisc One (Hylan Polymer (A&B)G-F 20) (8mg/ml) & Hyaluronic Acid (20 mg) & Cross Linked Sodium Hyaluronic Acid, 1-2.9 mDa, 22 mg/ml 4ml PFS
86	CANAGLIFLOZIN 100/ 300 MG TABS
87	Canagliflozin 50mg + Metformin 1000 mg & Canagliflozin 50mg + Metformin 500 mg
88	EMPAGLIFLOZIN + LINAGLIPTIN TABS VARIOUS FIXED DOSE COMBINATION) & EMPAGLIFLOZIN 10 MG+LINAGLIPTIN 5 MG TAB/CAP
89	EMPAGLIFLOZIN 10 MG /25MG
90	OSIMERTINIB 80 MG
91	RIBOCICLIB TABLET(CAPSULE 200 MG
92	Tab. Baricitinib 2mg/ 4mg
93	CETUXIMAB 100 MG/ 500 MG
94	Inactivated Influenza Vaccine (Surface Antigen) (Quadrivalent)
95	TOUJEO SOLOSTAR 1.5ML PEN(INSULIN GLARGINE INJECTION 300 U/ML)
96	Injection Human Rabies Immunoglobulin (HRIG) 150 IU/ML in 2ML PFS
97	Emicizumab Inj- Each Vial Contains : Emicizumab 30mg For Sub Cut Injection (R-DNA Origin), Each Vial Contains . Emicizumab 60mg For Sub Cut Injection (R-DNA Origin)
98	Flavedon OD 80 mg (Trimetazidine (80mg)) (Prolonged Release)
99	Ibrutinib Tab/Cap- Each Cap/Tab to contain : Ibrutinib 140 mg.
100	NIVOLUMAB 100 MG INJ, Nivolumab 40mg
101	Nonacog Beta Pegol 500 IU/1000 IU/2000 IU
102	Trastuzumab deruxtecan (Enhertu)
103	ACTEMRA (Tocilizumab) Concentrate solution for infusion 80mg/4ml vial, 200 mg/10ml vial and 400 mg 20 ml vial [20mg/ml]

104	CAPD Bag- Each bag to contain: CAPD Bag 7.5% Of Icodextrin With Asymmetrical Y Connector
105	Goserelin Inj- Each PFS to contain: Goserelin 3.6mg or 10.8mg
106	Floseal 5ml (Haemostatic- Each 5ml to contain: Haemostatic Matrix With Prefilled Gelatin Granules In Syringes) & Floseal 10 ml (Hemostat- Each PFS to contain: Hemostatic Matrix With Thrombin In Prifilled Syringe 10ml)
107	Infliximab (Powder for Concentrate for Solution for Infusion. 100 mg)
108	Isavuconazole 100 mg caps.
109	LIRAGLUTIDE 6 MG/ML 3ml
110	Meningcoccal tetravalent Conjugated
111	Methoxy Polyethylene Glycol- Epoetin Beta Each PFS to contain: Methoxy Polyethylene Glycol-Epoetin Beta 100mcg. Methoxy Polyethylene Glycol- Epoetin Beta Each PFS to contain: Methoxy Polyethylene Glycol-Epoetin Beta 50mcg. Methoxy Polyethylene Glycol- Epoetin Beta Each PFS to contain: Methoxy Polyethylene Glycol-Epoetin Beta 75mcg
112	Omalizumab 150mg PFS
113	Paliperidone palmitate - Prolonged-Release Suspension for Inj. 75mg, 100mg & 150 mg
114	Ranibizumab 1.650mg/ 0.165ml PFS
115	Risperidone prolonged-release suspension Injection 25.0 mg/37.5 mg/50.0 mg
116	Tab./ Cap. (Netupitant 300 mg. + Palanosetron 0.5 mg.) (AKYNZEO CAPS.)

117	Triple Chamber Bag- Each Bag to contain: Triple Chamber Bag With Lipid Emulsion (80% Olive Oil & 20% Soya Oil), Amino Acids, Glucose And Electrolytes Separated By Peel Seals For Central Intravenous. & Triple Chamber Bag- Each Bag to contain: Triple Chamber Bag With Lipid Emulsion (80% Olive Oil & 20% Soya Oil), Amino Acids, Glucose And Electrolytes Separated By Peel Seals For Peripheral Intravenous
118	Triptorelin Pamoate Inj- Each Single Dose Vial Contains:(Sterile Lypholized) Triptorelin Pamoate Equivalent to Triptorelin 11.25mg
119	Peritoneal Dialysis Solution With 1.5% Dextrose & Peritoneal Dialysis Solution With 2.5% Dextrose
120	Human Growth Hormone- Each Cartridge to contain: Somatropin 16 IU (R-DNA Origin)/ Somatropin 5.3mg/ml (R-DNA Origin)