



ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI-110029
(HOSPITAL STORES)
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E-mail : storesofficer.aiims@gmail.com

Dt. 24.12.2018

Ref:- 60/H/Proprietary/18-19

Sub.: Procurement of Tab. Caprelsa 100mg. for emergency cases, EHS & BPL patient on proprietary basis- Inviting comments thereon.

Hospital Stores is in receipt of quotation/ proforma invoice with Proprietary Article Certificate from M/s Sandor Medicaids Pvt. Ltd. wherein firm certify and conform that **Tab. Caprelsa 100mg** is the proprietary product of M/s AstraZeneca UK Limited.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of **Tab. Caprelsa 100mg** within 15 days after issue of this letter to Hospital Stores, 1st Floor at AIIMS, New Delhi on before **08.01.2019** upto 12.30 P.M, failing which it will be presumed that any other vender is having no comments to offer and case will decided on merits.

[Signature]
24/12/18

ASST. STORES OFFICER
(Hosp)

Encl: Related documents enclosed.

1. Proprietary Certificate

(3) *rem...
of 201.12*

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	Tab. Caprelsa 100mg (Pack of 30 tabs)
2.	Is the item a spare part attachment or accessory for an existing equipment	No
3.	Name of the manufacturers/suppliers of the item proposed by the indenter	M/s AstraZeneca UK Limited.
4.	Are they sole manufacturers / sole distributors of the item	Yes
5.	Is there any other item with similar/ equivalent specification available in the market to meet the job requirement envisaged. If the answer is yes, why the same can't be procured. Demanding officer should bring out comparative advantages/ cost effectiveness of the recommended item from those offered from others.	No
6.	What were the efforts made to locate alternative source of supply or use other substitutes	Proprietary item
7.	Why open/ limited tender can't be resorted to for locating alternative source	Being Proprietary in nature.
8.	Are the proprietary items rates are reasonable or not.	Yes, Reasonable.
9.	Any other justification for procuring item from single source.	Being Proprietary in nature.

CSE
**Signature of Indenter
(Demanding Officer)**

CSE
(Head of the Department)

I certify 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 specific brand proposed was advantageous in meeting our functional requirements and limited tender system could be dispensed with as they would serve no useful purpose in this particular case.
(Strike out whichever is not applicable)



6th December 2018

TO WHOM SO EVER IT MAY CONCERN

Pursuant to the Asset Purchase Agreement signed on 24 July 2015 between AstraZeneca UK Limited and Genzyme Corporation (Genzyme, A Sanofi Company), AstraZeneca has transferred ownership of all rights and responsibilities for the finished product Caprelsa® containing Vandetanib as its active ingredient to Genzyme Corporation, A Sanofi Company.

Sanofi-Synthelabo (India) Private Limited having its registered office at Sanofi House, CTS No 117-B, L and T Business Park, Saki Vihar Road, Powai, Mumbai – 400072, India is the authorised representative of Genzyme Corporation, a Sanofi affiliated Company for the conduct of clinical trials and to obtain marketing authorization of Caprelsa (Vandetanib Tablets) in India.

Currently, Sanofi has not registered Caprelsa (Vandetanib Tablets) for the import and marketing in India. However, Sanofi can provide assistance in obtaining this drug for the needy patients in India for personal use as per regulations.

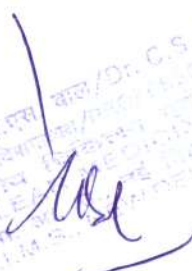
Caprelsa is approved in the European Union for the treatment of aggressive and symptomatic medullary thyroid cancer (MTC) in patients with unresectable locally advanced or metastatic disease. Caprelsa is indicated in adults, children and adolescents aged 5 years and older. For patients in whom Rearranged during Transfection (RET) mutation is not known or is negative, a possible lower benefit should be taken into account before individual treatment decision

In US, Caprelsa is indicated for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease. It is advised to use Caprelsa in patients with indolent, asymptomatic or slowly progressing disease only after careful consideration of the treatment related risks of the product.

For Sanofi-Synthelabo (India) Private Limited


Yasmin Shenoy
Sr. Director-Regulatory Affairs




Dr. C.S. BAL
Head, Regulatory Affairs
Nucleon Pharmaceuticals Pvt. Ltd.
Sanofi-Synthelabo (India) Private Limited
New Delhi-110029