Biocon Limited
20th KM, Hosur Road
Electronic City
Bangalore 560 100, India
T 91 80 2808 2808
F 91 80 2852 3423
CIN: L24234KA1978PLC003417
www.biocon.com

June 22, 2022

To
The Manager,
National Stock Exchange of India Limited
Corporate Communication Department
Exchange Plaza, Bandra Kurla Complex
Mumbai – 400 050
Scrip Symbol- Biocon

Dear Sir/Madam,

Subject: Clarification on news item appearing in media/publication.
Ref: NSE/CM/Surveillance/12022 dated June 21, 2022

This is with reference to the news item titled "*Biocon subsidiary caught offering bribe to waive off trial of new drug*" which was published by The Hindu on June 21, 2022.

In this regard, please note that the Company vide its letter dated June 21, 2022 has submitted the Company Statement issued by Biocon Biologics, to the stock exchanges. The aforesaid letter is attached herewith for reference.

The Company has always ensured that all material information is disclosed under Regulation 30 of the SEBI (Listing Obligation and Disclosure Requirements) Regulations, 2015 ('SEBI Listing Regulations').

We confirm that there is no unpublished price sensitive information available with the Company and there is no information that is material and not disclosed to the stock exchanges. We are cautious of the regulatory provisions and will be informing the stock exchanges of any such event as per the materiality policy of our company.

Accordingly, the specific responses to your queries are provided below:

Response to point (a): Please refer the Company Statement attached herewith.

Response to point (b): We confirm that there is no such material information available with the Company, which has not been disclosed to the stock exchanges.

Response to point (c): We are not in a position to assess the impact of the media report on the Company.

We trust the information and explanation provided herein is in order.

Thanking you,

Yours faithfully,

For Biocon Limited

BIOCON LIMITED ★ BANGALORE ★

_____

Mayank Verma
Company Secretary and Compliance Officer

Biocon Limited
20th KM, Hosur Road
Electronic City
Bangalore 560 100, India
T 91 80 2808 2808
F 91 80 2852 3423

CIN : L24234KA1978PLC003417

www.biocon.com

June 21, 2022

To The Manager, **BSE Limited** Department of Corporate Services Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai – 400 001	To The Manager, **National Stock Exchange of India Limited** Corporate Communication Department Exchange Plaza, Bandra Kurla Complex Mumbai – 400 050
Scrip Code - 532523	**Scrip Symbol - Biocon**

Subject: Notification to Stock Exchanges

Dear Sir/Madam,

Please find attached a statement from Biocon Biologics, in response to the media reports related to bribery allegations.

The above information will also be available on the website of the Company at www.biocon.com.

Kindly take the same on record and acknowledge.

Thanking You,

Yours faithfully,

For **Biocon Limited**

BIOCON LIMITED ★ BANGALORE ★

_____

Mayank Verma
Company Secretary and Compliance Officer

COMPANY STATEMENT

June 21, 2022

Bengaluru, India

Biocon Biologics issues a statement in response to the media reports related to bribery allegations.

We strongly deny the allegations of bribery against the Company and its officials associated with the approval process of one of our products in India.

Biocon Biologics is Governed by a Strong Code of Conduct

We strongly condemn any acts of corruption and violation of rules by way of offering or paying bribes or undue favours, either directly or indirectly. We adopt global best practices in corporate governance and business responsibility.

Besides our employees, all our consultants, suppliers and partners are also bound by a strong code of conduct that has a detailed clause on anti-bribery and anti-corruption.

Seeking Waiver of Phase 3 Clinical Trials for Insulin Aspart in India

All our product approvals are backed by science and clinical data.

The rationale for waiver of Phase 3 clinical trials was based on the following Indian regulatory guidance {*Similar* Biologics Guidelines 2016 & New Drugs and Clinical Trials 2019 (GSR 227 E)}.

The guidelines provide a framework for waiver of Phase 3 clinical trials to be conducted in India based on a commitment to undertake a Phase 4 trial, the *design of which should be approved by the Central Licencing Authority.*

In line with the above regulations, Biocon Biologics presented a proposal for import and marketing of Insulin Aspart with a waiver of Phase 3 clinical trial in India. The Company presented a detailed proposal along with CMC, pre-clinical and clinical trial data.

The Subject Expert Committee (Endocrinology and Metabolism) in its meeting held on May 18, 2022 at CDSCO, New Delhi, noted that Biocon Biologics has conducted Phase 1 and Phase 3 trials with Aspart in Germany and USA, respectively, and based on the

results of this global trial, Biocon Biologics' product, Aspart, has been granted marketing authorization by EMA and Health Canada.

"After detailed deliberation, the committee recommended for grant of permission to import and market the drug with waiver of Phase 3 clinical trial in the country with the condition that firm should conduct Phase 4 clinical trial in India (which also includes a sub-set population to generate PK/PD and immunogenicity and submit the protocol to CDSCO before placing the drug in the market) as per existing guidelines in the country," the SEC concluded.

[Source: Recommendations of the SEC (Endocrinology & Metabolism) made in its 87th meeting held on 18.05.2022 at CDSCO (HQ), New Delhi.
Link:https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=MTY4OQ==]

Due Regulatory Process Followed for All our Product Approvals

Biocon Biologics follows due regulatory process for all our product approvals by the DCGI. The entire application process in India is online and all meeting minutes can be found on the website of the Central Drugs Standard Control Organization (CDSCO).

Biocon Biologics Condemns all Acts of Corruption and Bribery

It is unfortunate that Biocon Biologics has been named in this controversy.

We reiterate that we strongly condemn all acts of bribery and corruption and have been co-operating with the investigation agency.

Media Contact: seema.ahuja@biocon.com
+919972317792