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.

Our biosimilar Insulin Aspart has undergone full Global Clinical Trials and is approved by global regulatory agencies like EMA and Health Canada.

The rationale for seeking a waiver of Phase 3 clinical trials for Insulin Aspart in India, 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.

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