NOTIFICATION TO STOCK EXCHANGE

COMPANY STATEMENT

USFDA issues a CRL for the Biologics License Application for Bevacizumab

Bengaluru, Karnataka, India, Feb 12, 2023

"The U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) for the Biologics License Application (BLA) for Bevacizumab filed by our partner Viatris (Mylan). The CRL informs the need for a satisfactory resolution of the observations made during the facility inspection conducted in August, 2022. We have submitted a comprehensive Corrective and Preventive Action (CAPA) plan, to the agency and are confident of addressing the observations within the stipulated timeframe. The CRL did not identify any outstanding scientific issues with the dossier."

– Company Spokesperson

For queries: seema.ahuja@biocon.com