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Biocon out-licenses two biosimilar assets for commercialization in Japan

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bUstekinumab and bDenosumab to address market opportunity of ~ $700 million



Indian firm Biocon Biologics has entered into a strategic out-licensing agreement with Japanese pharmaceuticals company Yoshindo Inc. for commercializing two of its pipeline biosimilar assets, bUstekinumab and bDenosumab, in the Japanese market.

Under the terms of this deal, Yoshindo gets exclusive commercialization rights in Japan for bUstekinumab and bDenosumab developed and manufactured by Biocon Biologics, for an addressable market opportunity of ~$700 million. Biocon Biologics will receive an upfront license fee as well as additional payments on the achievement of certain development milestones over the next few years. The financial terms of the agreement are confidential.

Ustekinumab, a biosimilar referencing Stelara, is a monoclonal antibody used to treat several autoimmune conditions, including psoriasis, Crohn's disease, ulcerative colitis, plaque psoriasis and psoriatic arthritis. Denosumab, a biosimilar referencing Prolia, is a monoclonal antibody for the treatment of osteoporosis.

The strategic partnership with Yoshindo will build upon Biocon Biologics' successful progress in its global development programmes for these two biosimilar assets. Clinical trials for these two assets commenced in FY22 and include both Phase 1 and Phase 3 clinical trials backed by robust pre-clinical chemistry, manufacturing and control (CMC) packages.