

Biosergen and Alkem Labs collaborate to develop anti-infective for severe fungal infections

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Sweden-based Biosergen AB and Indian firm Alkem Laboratories have announced the signing of a co-development and license agreement for BSG005, an innovative polyene macrolide, through phase II and phase III trials for sale in the Indian market.

Biosergen is developing BSG005 for the treatment of severe and difficult-to-treat invasive fungal diseases. After the successful completion of two phase I studies, the first patient trial will be conducted in India on patients with severe fungus disease, who are intolerant or resistant to treatment with Amphotericin B. India is one of the countries with the highest incidence of difficult-to-treat life-threatening fungal infections.

Mumbai-based pharma company Alkem, with its established clinical development engine and access to a broad clinical network, will prove to be a strong corporate partner for Biosergen.

Alkem will manage the first clinical patient trial, which is expected to start immediately after the regulatory approval. The trial will enroll patients suffering from severe fungal infections such as mucormycosis (Black Fungus), aspergillosis, and candidiasis, who are intolerant or resistant to Amphotericin B. Based on the safety and efficacy profile demonstrated in the preclinical studies and the phase I trials, BSG005 may provide a suitable treatment option for these patients. Once the clinical

trials are successfully completed in India, Biosergen and Alkem aim to expand its use for similar patient groups in the US and EU via pivotal trials.

Alkem will invest in the clinical development of BSG005 and will be granted an exclusive license to market it in India.