



Biosergen and Alkem Laboratories Ltd collaborates to develop anti-infective for severe fungal infections

Stockholm, September 25, 2023: Biosergen AB (Biosergen) and Alkem Laboratories Ltd. (Alkem) are pleased to announce 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.

Alkem is among the five largest pharmaceutical companies in India, and has more than 17,000 employees, with affiliates in the USA, Australia, UK, Germany and many other emerging countries. Alkem is a leader in the anti-infective market, with clinical development expertise and an established commercial infrastructure. Moreover, Alkem has 144 ANDAs, two manufacturing sites and two R&D sites in the US market. 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.

Mr Sandeep Singh, Alkem's Managing Director, said, *"This is a strategic fit for Alkem's portfolio given our presence in acute care segment, especially in hospital-based treatment."*

Dr. Peder M Andersen, CEO of Biosergen, said, *"Alkem has capabilities and a strong track record in drug development. They have been very responsive and fast in their evaluation and decision making."*

Dr. Akhilesh Sharma, president and chief medical officer at Alkem, said that *"BSG005 should strengthen treatment of challenging systemic fungal infections such as black fungus."*

We are very grateful to Dr. C.B.Sanjeevi at Karolinska Institute, who assisted Biosergen in establishing the partnership with Alkem.

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ABOUT BIOSERGEN

Biosergen is a leading clinical-stage biotechnology company at the forefront of antifungal drug development. Our mission is to develop BSG005, our lead drug candidate, into the new first-line treatment choice for invasive fungal diseases, while generating significant returns for our shareholders. Our Phase I trial showcased the exceptional safety and tolerability of BSG005, especially when compared to existing alternatives. Building on those results we are now advancing to test the drug in patients expected to clinically validate BSG005's potential as a new and strong antifungal treatment. Biosergen's development of BSG005 is based on two decades of scientific work at the Norwegian University of Science and Technology. For more information, visit www.biosergen.net.

ABOUT ALKEM LABORATORIES

Alkem Laboratories Ltd is an Indian pharmaceutical company engaged in the development, manufacture, and sale of pharmaceutical and nutraceutical products. The company produces branded generics, generic drugs, active pharmaceutical ingredients (APIs) and nutraceuticals in acute and chronic therapeutic areas, such as anti-infective, pain and analgesics, vitamins/minerals/nutrients, cardiac and Diabetology, Gynecology, Ophthalmology, neuro/central nervous system, dermatology, anti-diabetes, anti-osteoporosis, cardiovascular, and muscle relaxants, which are marketed in Indian and International markets. It operates through the pharmaceutical business segment. Read more at <http://www.alkemlabs.com/index.php>

This information is information that Biosergen AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, on 2023-09-25 07.30 CEST.