Biosergen receives regulatory approval to test lead candidate BSG005 in patients with invasive fungal infection.

Stockholm, Sweden – February 12, 2024 – Biosergen AB ("Biosergen" or the "Company is pleased to announce that it has received permission to test BSG005 as rescue therapy in patients with invasive fungal infections.

The Company's partner, Alkem Laboratories Limited ("Alkem"), has received an approval of the Clinical Trial Application from the Central Drugs Standard Control Organization (CDSCO) in India. The approval allows for the initiation of the first patient study for BSG005 in a clinical trial designed to address unmet medical needs in invasive fungal infections. Biosergen and Alkem will enrol patients suffering from severe fungal infections, including mucormycosis (Black Fungus), aspergillosis, and candidiasis.

The trial focuses on patient populations intolerant or resistant to Amphotericin B, the current last-resort treatment for severe invasive fungal diseases, as well as those who have experienced treatment failure with first-line therapy. Finally, also patients with mild to moderate kidney impairment can be enrolled. These populations urgently require an alternative treatment option, as currently, no effective alternatives are available. The primary objective of this patient trial is to evaluate the potential of BSG005 as a rescue treatment based on the promising safety and efficacy profile demonstrated in preclinical studies of BSG005 and the results of the Phase 1 trial, which showed the absence of severe side effects. Tine Olesen, CEO of Biosergen commented on the affirmative news stating: "A new study was recently published in the Lancet, concluding that 2.5 mill patients die of invasive fungal infections regardless of any other underlying disease. This is far more than previously estimated, invasive fungal infections are underreported and undertreated. It is the silent crisis. New and better drugs are needed within the therapeutic area. I am confident that BSG005 will be a strong candidate in this therapeutic field and offer patients both a safe and efficacious alternative treatment option." The next step is to receive Ethics Committee approval and first patient first visit is expected in March 2024.

For more information
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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.