Biosergen's Partner Alkem Laboratories Submits Clinical Trial Application for First Patient Study with BSG005 in Invasive Fungal Infections in India as a Rescue Therapy

Stockholm, Sweden – December 12, 2023 – Biosergen AB ("Biosergen" or the "Company"), a clinical-stage biotech company specializing in the development of innovative antifungal therapies, is pleased to announce that the Company's partner, Alkem Laboratories Limited ("Alkem"), has submitted a Clinical Trial Application to the Central Drugs Standard Control Organization (CDSCO) in India. The application pertains to the initiation of the first patient study for BSG005, Biosergen's leading antifungal drug candidate, a clinical trial designed to address unmet medical needs in invasive fungal infections.

This application follows the licensing and co-development agreement between Biosergen and Alkem, which was announced on September 25, 2023. Under this agreement, Alkem and the CRO will enroll 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. Additionally, patients with mild to moderate kidney impairment, for whom Amphotericin B treatment is not feasible, will be included. These populations urgently require an alternative treatment option, as currently, no effective alternatives are available.

Building 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, the primary objective of this patient study trial is to evaluate the potential of BSG005 as a rescue treatment for these patients.

Peder M. Andersen, CEO of Biosergen, commented on this significant development, stating: "The submission of this Clinical Trial Application to the CDSCO by Alkem marks a major milestone for Biosergen. Our shared goal is to challenge the role of Amphotericin B as the last resort antifungal treatment, offering hope to patients who currently have no viable treatment options. This is especially crucial as up to 30 percent of patients must discontinue Amphotericin B treatment due to its serious kidney side effects or cannot get started as they have existing kidney impairment. At the same time, the study may also provide data on BSG005 as a means of tackling the growing resistance formation of other antifungals."

The submission of the Clinical Trial Application in India, known as a Clinical Trial-1 application, is equivalent to what is referred to as an Investigational New Drug (IND) application in other countries. The Alkem medical and regulatory team, together with the Biosergen team, has

made an effort and included two more sites and a new local CRO to make this study run smoothly. This is a major successful effort in this cooperation.

India has one of the world's highest incidences of difficult-to-treat, life-threatening invasive fungal infections.

For more information

For further information please contact:
Dr. Peder M. Andersen, CEO
Telephone: +45 2080 2470
E-mail: peder.andersen@biosergen.net

Niels Lauren, CFO
Telephone: +45 4014 5059
E-mail: niels.laursen@biosergen.net

The Company's Certified Adviser is Carnegie Investment Bank AB (publ).

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.