Biosergen's groundbreaking antifugal drug BSG005 is granted Orphan Drug status in the United States

Monday, June 28, 2021: Biosergen AB ("Biosergen" or the "Company") today announced that the United States Food and Drug Administration (the "FDA") has granted BSG005, the Company's groundbreaking antifungal drug of the polyne macrolide class, Orphan Drug status in the United States with the indication "Invasive Aspergillus Infections". Orphan Drug status confers a number of important advantages including an expedited regulatory path and prolonged market exclusivity.

Biosergen's CEO Peder M. Andersen comments:

"This is an important milestone for BSG005 and Biosergen. In addition to increasing the commercial value of the project the orphan drug designation will make a number of things easier for us in the United States in the future. Hopefully, the approval in Europe is not far behind. Aspergillus fungus is resistant to several existing drugs on the market and is general a "difficult to treat fungus". This approval is a major step forward for BSG005 and Biosergen.

About Orphan Drug Status

The FDA created the Orphan Drug Act in 1983 to create additional financial incentives for Companies developing new drugs against rare diseases. Among the incentives are 7 years guaranteed market exclusivity, protocol assistance from the FDA and a 50% tax credit of the clinical costs in the United States once the drug is approved. The designation also reduces waiting times and the NDA application fee once Biosergen is ready to submit the New Drug Application for BSG005 in the United States, expectedly by the end of 2025.

The European Medicines Agency (the "EMA") has created a largely similar program and Biosergen has likewise applied for Orphan Drug status in Europe.

About Aspergillosis

While invasive fungal infections is a large and growing problem in the United States, Biosergen applied for Orphan Drug status for BSG005 on the basis that less than 200,000 patients per year would be expected to be treated with the drug against invasive Aspergillosis in this country. Aspergillosis is caused by the *Aspergillus* pathogen and primarily affects people with weakened immune systems or lung diseases and is one of the difficult to treat fungus strains. Types of aspergillosis include allergic bronchopulmonary aspergillosis, invasive aspergillosis and chronic Aspergillosis, all of which are potentially lethal. It is estimated that more than 300,000 people worldwide develop Aspergillosis every year and that approximately one fifth of all sales of antifungal drugs are directed against the *Aspergillus* pathogen.

For further information about Biosergen, please contact:

Dr. Peder M. Andersen, CEO

Telephone: +45 2080 2470
E-mail: peder.andersen@biosergen.net

ABOUT BIOSERGEN

Biosergen is a *No-Research-Development-Only* biotechnology company that employs all its organisational and financials resources on the clinical development of BSG005. BSG005 is a potentially disruptive antifungal drug with blockbuster potential based on significant safety and potency advantages over competing antifungals, including Amphotericin B, in more than a decade of preclinical studies. The research behind BSG005 and its unique properties has been documented in over 20 peer reviewed scientific papers. Biosergen initially aims BSG005 towards invasive fungal infections that claim the lives of hundreds of thousands of immune-compromised AIDS-, cancer- and transplant patients every year. At equal dose levels BSG005 shows a three-to-fourfold potency advantage against relevant fungal strains compared to current standards of care, while being completely free of the kidney toxicity hampering other drugs in its class. The Company is also developing BSG005 *Nano* where the drug is packed in special nano particles to specifically target the lung, often the first affected organ in an invasive fungal infection. BSG005 *Nano Oral* is an extension of BSG005 *Nano*. An oral formulation would greatly increase the usefulness, particularly as a prophylactic and as home treatment after transplants or cancer treatment to prevent invasive fungal infection. Biosergen has received orphan drug status for BSG005 in the United States and expects to file the NDA by the end of 2025.