Biosergen's application to start human clinical trials with BSG005 is approved

Tuesday, August 24, 2021: Biosegen AB ("Biosergen" or the "Company") today announced that it has received positive feed back from the Australian regulatory authorities on the application to initiate a phase I study in Austrialia of the Company's proprietary antifungal drug candidate BSG005. With the approval, Biosergen is ready to conduct its First in Man clinical trial with BSG005.

Biosergen submitted the application for the clinical phase I safety and tolerability study in 72 healthy male volunteers in Australia in May. The trial is so-called a single ascending dose and a multiple ascending dose trial to investigate the safety and tolerability of BSG005, Biosergens proprietary antifungal candidate of the polyene macrolide class. The Company previously announced that it expects the first trial subjects to be enrolled in Q3 2021. Due to a delay in manufacturing the first trial subjects is assumed to be inrolled early Q4 and the Company still expects to be able to report top line results from the trial by Q1 2022.

Biosergen's CEO Peder M. Andersen comments:

"This approval is a major milestone for BSG005 and Biosergen. We expect the data from this trial to be particularly interesting because the fungicidal activity of polyenes on a range of fungal strains is undisputed, just as no fungal resistance development towards this class of drugs has previously been reported, in fact ever since our main competitor Amphotericin B was launched 50 years ago. All our preclinical tests have shown a broad spectrum activity for BSG005 against almost all fungal strains, including otherwise resistant *Aspergillosis* strains, and including *Mucormycosis* (the "Black Fungus") which is right now spreading rapidly in India. The breadth of BSG005's killing ability is one of its key advantages over the existing Azole and Echinocandin drugs on the market. The phase I trial will show if it is also safer than Amphotericin B."

About the Phase I trial

The phase I study will run in a phase I unit called Nucleus Network in Melbourne, Australia and has three defined objectives:

- To test the safety of BSG005 in general and specifically as relates to the kidneys. To date BSG005 has in animal toxicology studies not shown any adverse effects on the kidneys. Kidney toxicity is a key problem for Amphotericin B, the other polyene product on the market.
- The study will also investigate the tolerability of the intravenous infusions of BSG005 and how the body reacts to BSG005.
- Finally, the study will look at the pharmacokinetics of BSG005, meaning that it will investigate what concentrations of drug is achieved in the blood stream after different dose levels.

For further information about Biosergen, please contact:

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

Certified Adviser

Erik Penser Bank
Telefon: +46 8 463 8000
E-mail: certifiedadvisor@penser.se

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 applied for orphan drug status for BSG005 and expects to file the NDA by the end of 2025.