Biosergen completes the third cohort of BSG005 phase I trial

August 26, 2022: Biosergen AB ("Biosergen" or the "Company") today announced that the Safety Review Committee has decided to continue the trial with cohort 4 in the Single Ascending Dose part of BSG005's phase I trial.

BSG005 is Biosergen's lead development compound. It is a novel anti-fungal molecule from the group of polyene macrolides known for their broad anti-fungal and fungicidal effect, including on resistant and difficult-to-treat fungal strains, which make them unique within all antifungal drug classes. The successful completion of the phase I trials will demonstrate, that BSG005 is a safe polyene anti-fungal compound, which is the most important step in the clinical development of BSG005. The main short-coming of other polyenes are their side effects, such as the kidney toxicity.

In the completed cohort 3 there was no impact on any of the kidney parameters followed in blod and urine samples. There were two incidents of mild and transient infusion reactions which could be expected based on what is seen with other intravenous products including Amphotericin B.

Biosergen's CEO Peder M. Andersen comments:
"We are looking forward to continue the trial and start the dosing of the next cohort. We expected to see some infusion reactions and the reported reactions were mild and short. Infusion reactions can often be alleviated with prolonged infusion time and some pre-medications. We are happy to see, that there has been no impact on the kidney parameters so far and we do not expect this given our toxicology data, which were very clean on the kidneys."

Phase I study design

The phase I study is divided into two sequential parts:

- The Single Ascending Dose (SAD) part of the trial will enrol up to 42 subjects divided into 7 groups of 6 subjects each. In each cohort, 4 subjects receive a single dose of BSG005, whereas 2 receive placebo. Each subject participates in just one treatment cohort, and no subject receives more than one dose of BSG005 (or placebo as the case may be). The dose of BSG005 will be increased for each progressive group if previous dose levels are well tolerated and no safety issues observed. These safety reviews are performed by the study's Safety Review Committee after each dose level.
- The Multiple Ascending Dose (MAD) part of the trial will enroll up to 30 subjects divided into 5 cohorts of 6 subjects each. In this part of the trial, the subjects receive infusion daily over 7 days with increasing dose of BSG005 for each cohort. While the objectives of the Single Ascending Dose part of the trial above is to establish a basic understanding of BSG005's pharmacokinetics and maximum tolerated dose when given as a single dose, the Multiple Ascending Dose part of the trial aims to establish what dose level of BSG005 is required to obtain a steady, clinically relevant concentration of the drug in the subject's blood stream.

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This information is such information that Biosergen AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication on August 26, 2022.

ABOUT BIOSERGEN

Biosergen is a clinical stage 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 laboratory and 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.