The first subject has been dosed in the phase I trial of BSG005

April 7, 2022: Biosergen AB ("Biosergen" or the "Company") today announced that the first volunteer has been dosed with the Company's proprietary antifungal drug candidate BSG005.

Biosergen has enrolled the first subject into the phase I trial of BSG005. This subject will be part of a first cohort of six healthy volunteers. The trial will have up to seven cohorts in the SAD and up to five cohorts in the MAD part of the study. We will report about the successful completion of these cohorts during the next coming months. The successful completion of this phase I trial will be a major milestone for Biosergen, as it will underline the safety of BSG005. We know already from our in-vitro and in-vivo studies, that BSG005 has a broad anti-fungal and fungicidal (killing fungals) effect on a broad range of fungal strains – including resistant and difficult to treat fungal strains. Furthermore in vivo animal data with immunocompromised mouse has shown BSG005 to have a higher potency than other comparative polyene macrolide products such as Amphotericine B/Ambisome. Polyene antifungals are the only class of product with a proven fungicidal efficacy. Kidney toxicity has been the limiting factor, which made Amphotericine B/Ambisome a highly needed, but nevertheless last resort in systemic antifungal therapy. BSG005 toxicology and safety data has been free of any kidney toxicity so far. Therefore, showing safety and no kidney toxicity in humans of the BSG005 is one of the key events in the successful development of BSG005, as it will allow for BSG005 as the first antifungal product to access the full commercial potential of the polyene antifungals.

The clinical phase I trial is a double-blinded, placebo-controlled study in up to 72 healthy male volunteers (subjects). The trial is designed as a Single Ascending Dose (SAD) study followed by a Multiple Ascending Dose (MAD) study to investigate the safety and tolerability of BSG005 as well as the pharmacokinetics of BSG005, Biosergens proprietary antifungal candidate of the polyene macrolide class.

Study objectives

The phase I study is conducted in the Nucleus Network phase I Unit in Melbourne, Australia. It has three defined objectives:

- To test the safety of BSG005 in general and specifically as relates to the kidneys. In previous animal toxicology studies BSG005 showed no 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, and for how long.

Study design

The two study parts are conducted sequentially:

- The Single Ascending Dose 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. Biosergen expects to publish data from this part of the trial in Q3 2022.

- The Multiple Ascending Dose part of the trial will enroll up to 30 subjects divided into 5 groups of 6 subjects each. In this part of the trial, the subjects in each cohort will receive 7 days of dosing and each cohort will have increasing doses of BSG005. While the objectives of the Single Ascending Dose 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 still being safe and tolerated. Biosergen expects to be able to publish data from this part of the trial in Q4 2022.

Biosergen's CEO Peder M. Andersen comments:

"The importance of this trial is difficult to overstate. If this study shows acceptable or very good safety and tolerability as we expect from the animal studies the road is open to test efficacy in the phase II program where we will look for special indications such as resistant or difficult to treat fungal strains. After more than a decade of research, we have good reasons to believe that BSG005 will be effective in humans. Biosergens in vitro and animal in vivo data supports the efficacy of BSG005. There is a high medical need for new effective anti-fungal treatments and BSG005 needs to get out there and explore the effect towards fungal strains where no other or very few products can handle such fungal strains and test the transmission from in vitro and vivo animal data into Humans.

Biosergen is looking forward to the next steps in the development of BSG005.

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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 April 7, 2022.

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 EU.