The first subjects dosed successfully with no adverse events in the phase I trial of BSG005

April 19, 2022: Biosergen AB ("Biosergen" or the "Company") today announced that there were no adverse events at all reported after the first volunteers have been dosed with the Company's proprietary antifungal drug candidate BSG005.

The Company has received the first safety review group outcome of the safety and laboratory data following this first administration of BSG005 in the phase I study in Australia. The review of the data revealed that there were no adverse events reported at all and all laboratory data were OK. This is very positive news and also promising for the next dose administrations leading towards a clinical expected effective dose of BSG005 later on in this dose escalation study in healthy male volunteers. The company will report as doses are administered and full cohort data reviews are reported from the Safety Review Committee with recommendations to escalate to the next dose.

BSG005 is Biosergens lead development compound. It is an anti-fungal molecule from the group of polyene macrolides known for its 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 comparative products such as Amphotericine B/Ambisome. And the toxicology data has been free of any kidney toxicity which so far has been a strong draw back on the use of AmB which has mainly been as the last resort.

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 over 7 days with once daily infusions to investigate the safety and tolerability 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.

Biosergen's CEO Peder M. Andersen comments:

"This is very positive news and promising for the coming administrations of BSG005. First administration in Man is always the most exiting moment in any drug development program. That we with these first administrations have had no adverse event reports at all and nothing in the laboratory data is a

promising result and is the best possible start of this phase I study. The study dose escalations are done very carefully and only after full review of each cohort data by the Safety Review Committee. The committee recommends the escalation to the next dose level and if the data we have seen now after the first dosings continue to come out like this, then BSG005 has come a long way on the travel to phase II and phase III and ultimately a Marketing Approval.

We know this is early and few data however very positive.It is well known, that there is a high need for new drugs with a broad anti-fungal action and a high efficacy also against the fungus strains that are resistant to an increasing number of the drugs on the market. Recent reports on high resistance development in Asia are disturbing and important for the development of our anti-fungal drug."

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 biotechnology company that employs the majority of 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.