Positive topline data from phase 1 study of BSG005 shows it is safe and well tolerated. It gives hope for a change in the treatment paradigm of patients with invasive fungal infections.

March 13, 2023: Biosergen today announced completion of the phase 1 study with BSG005. The study included both a single ascending dose (SAD) and a multiple ascending dose (MAD) part. Topline data showed a satisfactory safety profile with no serious adverse events reported and no impact on kidney and liver function after BSG005 administration both as single infusions as well as after 7-days repeated IV infusions at multiple dose levels. The repeated IV infusion treatment regimen and the satisfactory safety profile supports advancement of testing BSG005 in a phase 2 clinical study in patients with invasive fungal infection. Our goal is with the very broad antifungal effect and the well-known fungicidal effect to position BSG005 as a first line product in Invasive Fungal Infection patients with or without a diagnose.

Biosergen has received the outcome of the final Safety Review Committee following the multiple – 7-days iv infusions – administration of BSG005 in the double-blinded placebo-controlled phase I study in Australia. The review of the data revealed that there were no major safety concerns. In particular there was no negative safety signal on kidney and liver parameters, which is a major advantage compared to other polyenes. The plasma levels after 7 days of dosing of BSG005 were approaching the No Observable Adverse Effect Level (NOAEL) plasma levels from the toxicology studies, which is the upper limit for testing in healthy subjects.

BSG005 is the lead development compound of Biosergen. It is an anti-fungal molecule from the group of polyene macrolides known for its broad anti-fungal and fungicidal (fungal killing) effect on a broad range of fungal strains – including resistant and difficult to treat fungal strains. Furthermore in vivo animal data with immunocompromised mouse model have shown that BSG005 has a higher potency than comparative products such as Amphotericine B/Ambisome. Animal toxicology data of BSG005 have also demonstrated an absence of any kidney toxicity which restricts the use of AmB as a treatment of last resort.

The clinical phase 1 trial was a double-blinded, placebo-controlled study (randomised 4:2) where 24 subjects received a single dose in the SAD part and another 12 subjects received a dose every day for 7 days in the MAD part in a dose escalation fashion. In both parts of the trial the plasma BSG005 level either reached or approached the approvable NOAEL level from the toxicology study, which is why further increase in doses would not be allowed.

Study objectives

The phase I study was conducted at the Nucleus Network phase I Unit in Melbourne, Australia. It had three defined objectives:

- To test the safety of BSG005 in general and specifically in reference to the kidney function. 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 products on the market.
- To investigate the tolerability of intravenous infusions of BSG005 and whether BSG005 would have any adverse effects on body functions.
- To investigate the pharmacokinetics of BSG005 in order to determine which concentrations of drug is present in the blood stream after different dose levels, and for how long it is present.

Biosergen's CEO Peder M. Andersen comments:
"This is amazing news for BSG005. First administration in Man is always the most critical moment in any drug development program. Although we do not have final data yet, the topline data shows BSG005 to be safe and well tolerated. It is a strong signal that BSG005 is a promising antifungal drug that is safe and well tolerated when infused in patients.The data also shows no impact on kidney or liver function which is a key point and confirms what we observed in the animal data. It leads us to the next exciting step -- testing BSG005 in patients, who have limited options for an efficient and safe treatment.
Passing the safety and tolerability hurdle in phase 1 is a major accomplishment for Biosergen. It is a critically important milestone for the development of BSG005 and the upcoming phase 2 program."

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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.