Biosergen moves into the MAD (Multiple Ascending Dose) part of its phase I study after 4 cohorts tested in the SAD (Single Ascending Dose) part of the study.

September 8, 2022: Biosegen AB ("Biosergen" or the "Company") today announced that the phase I study in Australia will now move into the MAD part of the study after testing 4 cohorts in the SAD part of the study. It was expected that infusion reactions would appear in the healthy volunteers and limit further dose escalations. There were no impact at all on the kidney and liver parameters which is a major achievement for the development of BSG005.

The Safety Review Committee for this study has reviewed all the available safety and PK data and concluded that the dose level achieved did not provoke any serious adverse event but mild to moderate events that made further dose increases in the healthy volunteers not an option. At the same time the Committee decided to move on with the MAD study part on the planned dose level that did not induce any adverse event in the SAD study. This is a major step forward for the development and the phase I study.

Biosergen's CEO Peder M. Andersen comments:
"We are very exited that we did not see any adverserse reaction on the kidneys and also no effect on the liver parameters, which was a key point for us in the development of BSG005. We are very happy that we can now move into the MAD part of the phase I study and see how a 7 day infusion will work. Biosergen is at an exciting stage. We are on a good track with our clinical phase 1 trial. We are planning new trials and in parallel optimizing manufacturing. With the current and ongoing capital raise, which has been successful so far with pre-subscription of 70% of our goal, Biosergen will be able to ccomplete the phase I and initiate the next trials to prove the efficacy of BSG005."

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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.