Biosergen is preparing a Phase II study of BSG005 against *Mucormycosis*, the Black Fungus.

May 2, 2022: Biosergen today announced that it is preparing a Phase II clinical trial of BSG005 against *Mucormycosis*, otherwise known as the Black Fungus. Mucormycosis is a difficult to treat fungal infection with high mortality.

As novel fungicidal polyene antifungal product BSG005 is well positioned to provide a broad single product treatment alternative for life threatening, difficult to treat, resistant, invasive fungal infections. Different to other polyene products, such as Amphotericin B or Ambisome, BSG005 is without any signs of nephrotoxicity. To support this unique product profile, Biosergen is focusing its clinical development on fungus strains, which are difficult to treat with currently available antifungal drugs. Mucormycosis falls into this category, as this fungus disease has a high mortality rate and only the polyene Amphotericin B has shown strong efficacy against this fungus. Therefore, as a novel polyene without nephrotoxicity BSG005 could become the drug of choice for the treatment of Mucormycosis.

Biosergen is planning to run this Mucormycosis study in India, where an epidemic outbreak of opportunistic *mucormycosis* infections during the COVID-19 crisis last year lead to an exponential increase of Black Fungus cases and deaths. The continued presence of the omikron variant, and the potential emergence of new variants, is expected to keep the number of mucormycosis cases high in India for years. Although approximately 70% of all the world cases of mucormycosis are in India, the medical need for an efficacious and safe product is equally high outside of India.

Biosergen is in the final stage of preparing the phase II mucormycosis study protocol, have identified a CRO to manage the study as well as a local and international Principal Investigator.

Mucor fungal strains often establishes itself in the patient's nose or sinusis and even in the eyes which over a matter of days have to be surgically removed to avoid the infection spreading to the brain, which leads to the high mortality or life-long disabilities. The only effective treatment is the antifungal drug Amphotericin B. However, the use of Amphotericin B is challenging, because the drugs' well-known kidney toxicity may lead to kidney damage or kidney failure. Many of the patients developing Mucormycosis also suffer from diabetes, which often damages the kidneys and thereby further limits the use of Amphotericin B.

Biosergens lead molecule – BSG005 – belongs to the polyene macrolide group of anti-fungal drugs known to be fungicidal and not fungistatic as many other anti-fungal drugs in the Azole and Echinocandin drug classes. Furthermore, BSG005 was in the GLP 28 day tox studies found to have no adverse effect on the kidneys, which makes it a strong alternative to Amphotericin B.

Biosergen's CEO Peder M. Andersen comments:

"Opportunistic *mucor-strain"* infections are a prime example of the kind of medical need BSG005 was invented to address. As recently announced, we expect to report the first data from the Australian safety and tolerability trial before the end of the year. Since we are confident BSG005 will perform well it makes good sense that we prepare to employ it against one of the worst opportunistic fungal infections there is. We will provide further updates when we know more about the exact design and timing of the program."

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ABOUT BIOSERGEN

Biosergen is a 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.