



The outbreak of mucormycosis (the so-called “Black Fungus”) in India is a prime example of the great need for a safer antifungal drug with true fungicidal activity

Monday, May 31, 2021: India is seeing an outbreak of an opportunistic fungal infection called mucormycosis. The outbreak, which is rapidly approaching epidemic proportions, is caused by the *Mucormyces* fungus, otherwise known as the Black Fungus because it makes the infected tissue go black, and kills approximately half of those affected. The only effective treatment is a drug called Amphotericin B. Unfortunately the use of Amphotericin B in India is particularly challenging because of the drugs’ well known kidney toxicity. BGS005 is active against this fungus and would be a safe alternative without kidney toxicity. This unfolding health tragedy once again underlines the need for a safer antifungal drug with true fungicidal activity.

India has been hit hard by the COVID-19 pandemic. The official estimate is that around 27 million infections have led to some 320.000 deaths in the country. However, a more likely, but still conservative, estimate is that more than 500 million people have in fact been infected in India so far, and that the death toll is above 1 million people.

It is now increasingly clear that an epidemic of a normally rare invasive fungal infection called mucormycosis is emerging inside the COVID-19 pandemic. The number of patients dying of this infection has been exploding in recent weeks inside a perfect storm caused by the combination of COVID-19 which affects the patient’s respiratory system and is often treated with corticosteroids, combined with the extremely high prevalence of poorly treated diabetes in India. While corticosteroids may save the patient from the worst symptoms of COVID-19, the down-regulation of the immune response renders the patient vulnerable to opportunistic infections. And this pattern is greatly exacerbated in diabetes patients. India is home to the second largest diabetic population in the world. It is estimated that more than 75 million Indians live with the disease. More than 75% of these patients have poorly controlled glycemic levels leading over time to massive vascular and organ damage. The combination of a compromised immune system and already established organ damage makes diabetes patients especially susceptible to the mucormycosis infection.

By May 17th, just a few weeks after the first reports, the Global Action Fund for Fungal Infections (GAFFI) estimated there were over 4,000 cases (India would normally have around 20 cases per year), and that as a result of this explosion, even though Amphotericin B is toxic when given to these patients, there was no longer any Amphotericin B left in India. BSG005 would be a safer treatment alternative and when approved could save thousands of lives. This is one acute example of the urgent need for a safe and efficacious treatment against resistant, severe fungal diseases.

Biosergen’s CEO Peder M. Andersen comments:

“These are heart-breaking reports. Patients come in with a stuffy nose or swollen eyes. Very often and in a matter of a few days, one or both eyes have to be removed to stop the infection from reaching the brain. And it should be emphasised that these opportunistic outbreaks will not be limited to India. *Mucormyces* is not as prevalent in our part of the world, but we are already seeing increased incidences of *Candida Aureus* and *Aspergillus* infections in the United States and Western Europe as one of the complications from COVID-19. To me, this once again underlines how vitally important it is that we bring BSG005 forward as quickly as we can. Once our IPO is behind us, I will be discussing with our new board what we can do to help. It may be that we can add a mucormycosis trial to the Phase II program we are currently planning for next year, but this remains to be seen”.

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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 applied for orphan drug status for BSG005 and expects to file the NDA by the end of 2025.