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6.5 mill people are affected each year by urgent life threatening fungal disease



Everyone with weakened immune systems is at high risk:

- Cancer patients, organ and hematological transplants, people with HIV, some with diabetes, these are examples





Resistant strains

- Routine use of antifungal drugs also in industry and agriculture creates basis for the emergence of resistant strains and number of resistant fungi increases



High mortality rates

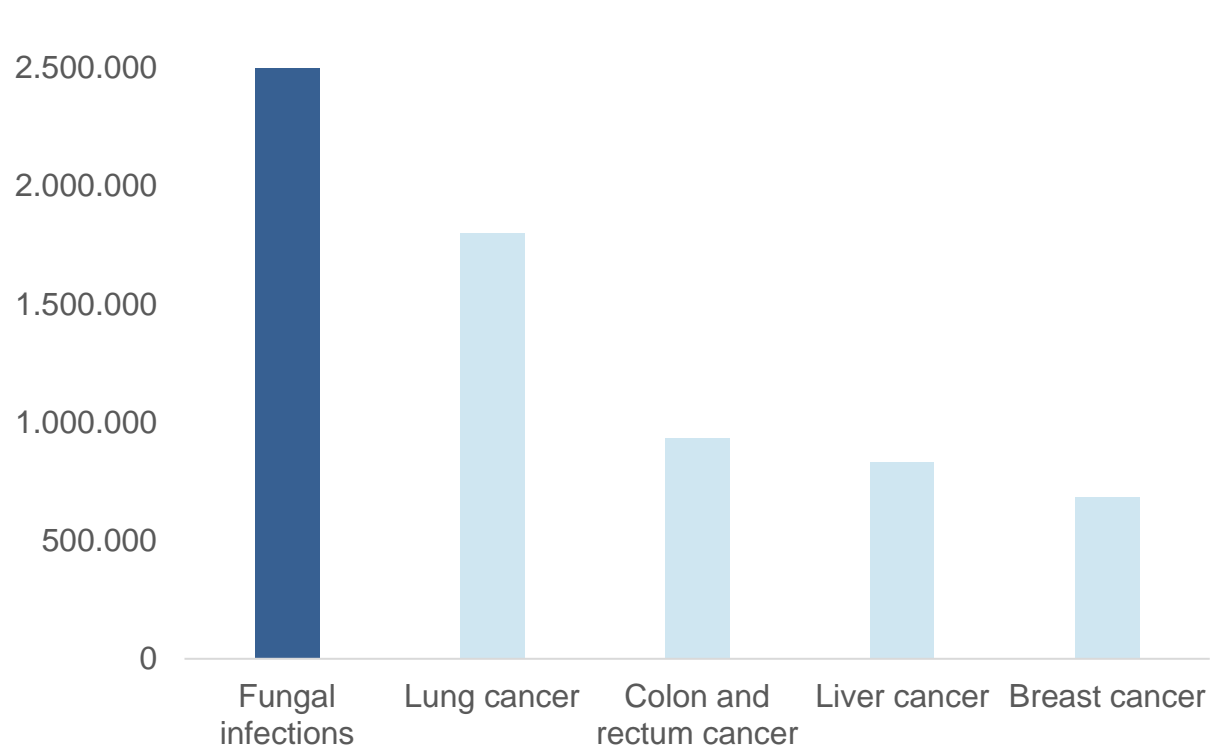
- Aspergillosis is underdiagnosed in particular in patients with COPD and lung cancer which leads to high mortality rates

 Disease	 Estimated prevalence/year	Mortality
<i>Aspergillosis</i>	■ 2,000,000	■ 75%
<i>Candidiasis</i>	■ 1,500,000	■ 40%
<i>Cryptococcosis</i>	■ 200,000	■ 60%
<i>Pneumocystis pneumonia/ Candida auris</i>	■ 500,000	■ 35%

More than 2.5 million deaths a year caused by invasive fungal infections

Invasive fungal infections (IFI) are life-threatening conditions that require rapid diagnosis and optimal management to alleviate high morbidity and mortality

Comparison to mortality of common cancers



Cause of death?

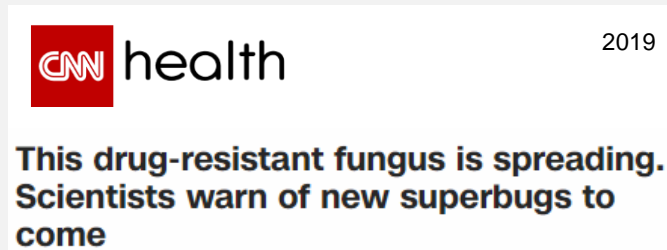
Patients often die from a severe invasive fungal infection/disease - not from the original disease



This situation is now recognized as a global health threat by the WHO, Centers for Disease Control and Prevention (CDC) and others

Growing Drug Resistance

- Drug resistance problem is growing. No safe antifungal treatment with broad efficacy available



Berlingske | 

6 January 2024

The hospital did not inform the family about a life-threatening infection in their cancer-stricken son. They feel deceived

The pediatric oncology department at Rigshospitalet has been the site of a serious outbreak of dangerous mold. Several children were affected by a particular fungus that can be fatal to weakened patients. Among them was Julius, who was fighting for his life. Rigshospitalet denies any wrongdoing.

Danish cancer patient left with damaged lungs because of fungal infection

- Diagnosed with leukemia in 2018, Julius was immediately hospitalized
- Alongside leukemia, **Julius got infected with a life-threatening fungal infection**, *Aspergillus flavus* in his lungs, critically impairing his breathing and oxygenation of blood.
- Most likely, **the infection was airborne mould growing inside DK's no. 1 hospital**, Rigshospitalet.
- In three days, **he was on a respirator**. He was weakened, emaciated, had a high fever.
- Evidence has shown **more children are** infected
- **Today, his lungs do not operate at normal capacity**, casting uncertainty over his future health and quality of life, for example, he can't go cycling.



- Using Ventoline (inhaler drug device) is an integrated part of his daily life.
- The problem with mould causing fungal infections appears to be widespread at the hospital, according to investigative reporting by Danish news paper Berlingske

BSG005: A Novel Polyene Macrolide for Severe Invasive Fungus Diseases



A genetically improved polyene macrolide (Known class of drugs)

- A naturally occurring fungicidal chemical synthesized in the bacterial strain *Streptomyces noursei*.
- BSG005 has a solid and long lasting patent portfolio



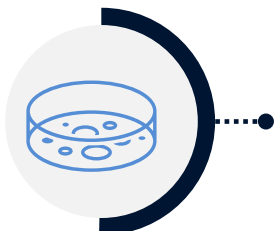
It is safe

- No kidney toxicity and no clinically relevant impact on liver and other blood parameters
- Free of cardiovascular, central nervous and respiratory adverse effects



MOA known from same class of drugs

- Ergosterol is present in every fungus cell wall and is not found in humans.
- Binds to ergosterol (fatty acid) and leads to cell wall pores and ion leakage, which causes cell death



It is fungicidal and therefore kills the fungus

- BSG005 is a polyene, causing fungus death. Most other antifungal products only inhibit fungal growth

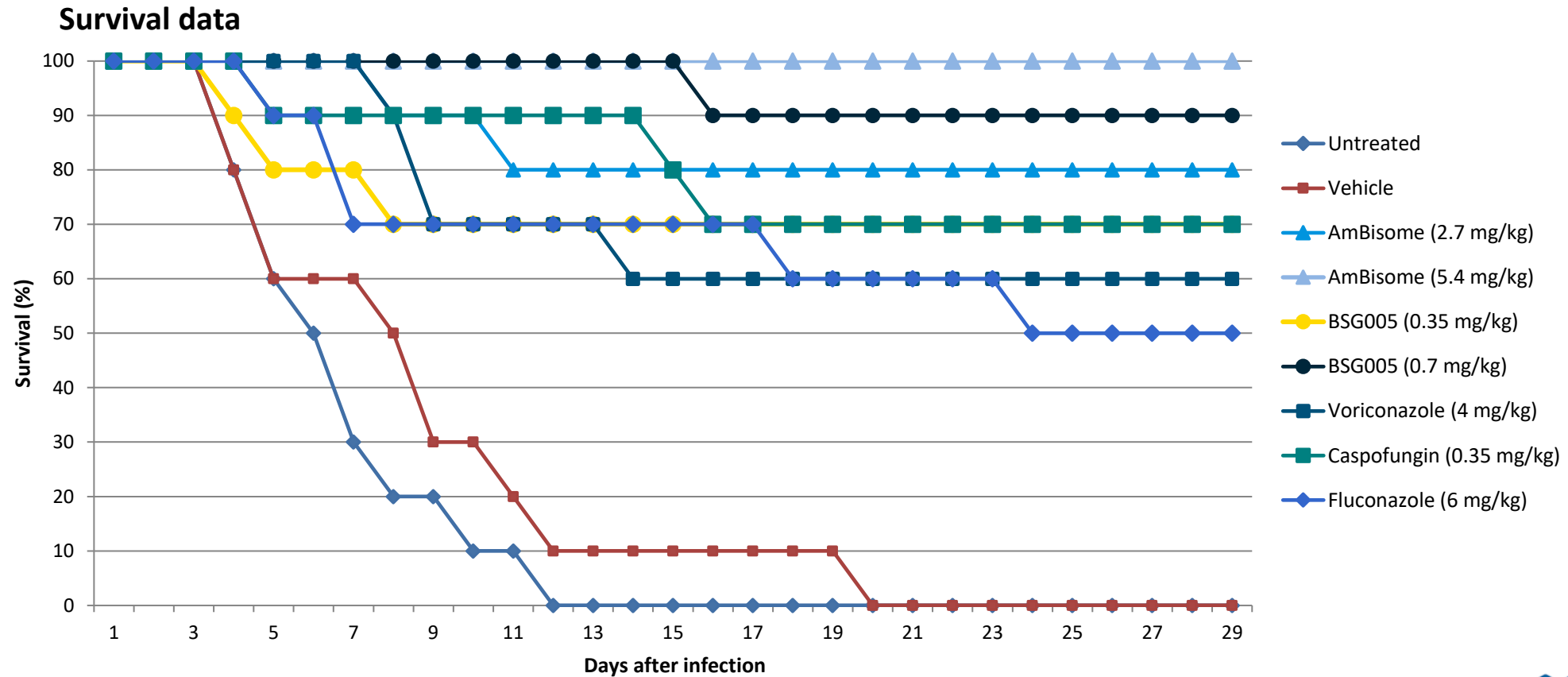
Competition: BSG005 has a unique Product Profile

Class	Agent	Fungus Genus				
		Candida	Aspergillus	Fusarium	Mucor	Cryptococcus
Polyene macrolide (fungicidal - kills)	BSG005	Yes	Yes	Yes	Yes	Yes
	Amphotericin B (Side effect limits the use)	Yes	Yes	Yes	Yes	Yes
Azole (fungistatic – inhibits growth)	Fluconazole	Variable	No	No	No	Yes
	Posaconazole	Variable	Yes	No	No	Yes
	Voriconazole	Yes	Yes	Variable	No	Yes
	Isavuconazole	Yes	Yes	Variable	Variable	Yes
Echinocandin (fungistatic – inhibits growth)	Caspofungin	Yes	Yes	No	No	No

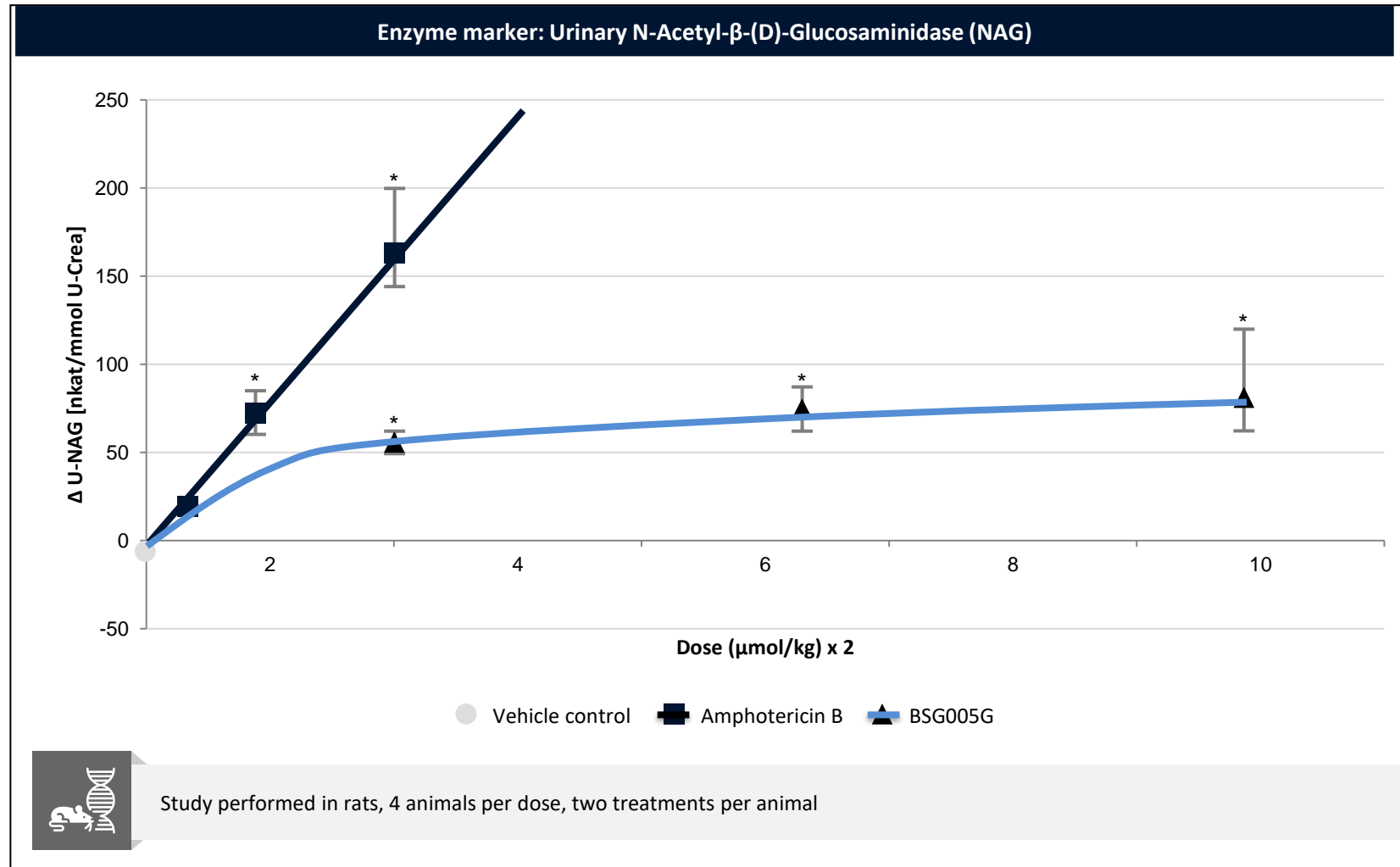
Candidiasis in Immunocompromised Mice

Summary

- Polyene macrolides are most effective
- BSG005 shows better survival rates than standard of care
- BSG005 shows higher potency than AmBisome



BSG005 does not show nephrotoxicity



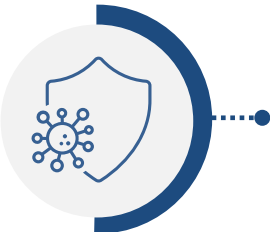
- NAG is a biomarker for kidney damage
- The higher release of NAG the more damage to the kidneys

Top line results from phase I trial in healthy subjects: No significant side effects!



Overall top line conclusion

- A classical designed phase 1 study, with 38 healthy males and females receiving a single dose or multiple doses.
- No serious adverse event occurred. Adverse events were mild to moderate in severity.
- No clinically relevant changes in post baseline laboratory parameters – including kidney, liver and potassium – and no clinically relevant electrocardiogram (ECG) changes.

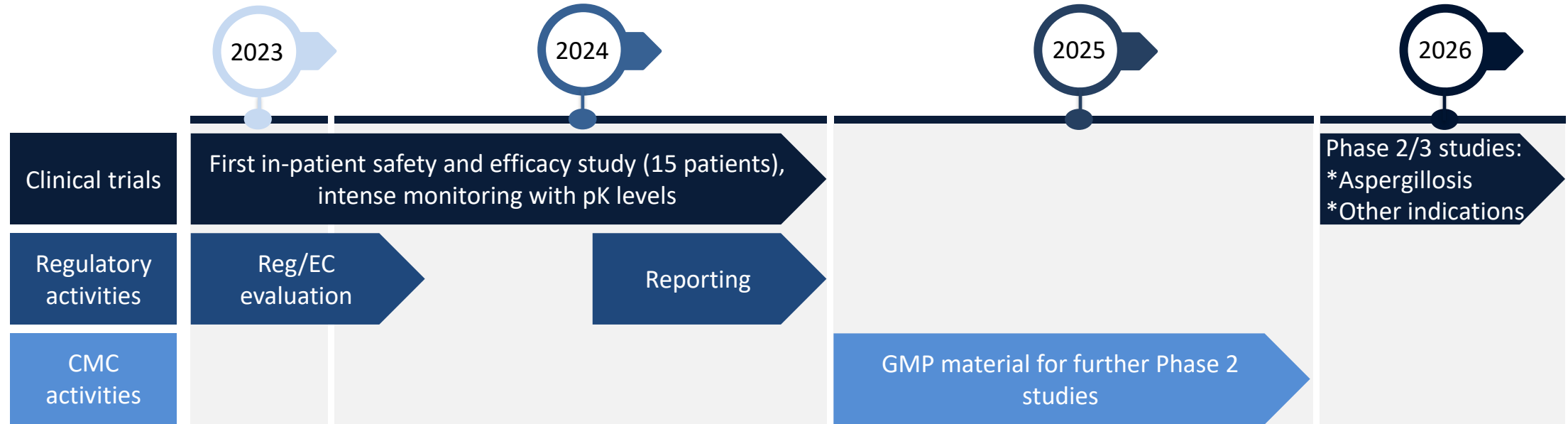


BSG005 were safe in the healthy subjects.



Next step: BSG005 to be tested in patients with Invasive Fungal Infections.

Planned Development Steps
















- 15 patients with proven invasive fungal infection, where patients:
 - do not tolerate standard of care or are resistant to first line therapy
- Trial application submitted 8 December 2023
- Topline data Q4 2024

Expected filing in EU and US 2029
Expected launch in EU and US 2030

The global antifungal drug market is approximately USD 16 billion

Biosergen aims to lead the Polyene market, become first line treatment for invasive fungal infections and thereby grow the total Polyene market share

 Antifungal class	 Drugs in this class include	 2019 sales (USD billion)	 Share of market	 Projected annual growth rate
Polyenes	Amphotericin B, Candidicin, Nystatin	1.6 	 10% 	6.6% 
Azoles	Fluconazole, Ketoconazole, Miconazole, Voriconazole, posaconazole, isavuconazole	6.6	 42%	6.3%
Echinocandins	Caspofungin, Micafungin, Anidulafungin	5.0	 32%	6.8%
Allylamines, pyrimidines and others	Naftifine, Terbinafine, Bacimethrin, Flucytosin	2.6	 16%	≈5%
Total		15.8	 100%	6.4%

Sources: Market Research Future. Global Antifungal Treatment Market forecast to 2027

Biosergen signed Co-development Agreement with Alkem Laboratories

- Alkem is the 5th largest pharmaceutical company in India with affiliates in several countries
- Alkem will fund the phase 2 and 3 clinical trial cost in India reducing the clinical development costs substantially.
- Biosergen can add centers and patients outside India to all clinical trials according to regulatory consultation (FDA and EMA) at its own cost.
- Access to the high number of patients with invasive fungus diseases will reduce the development time.
- Alkem receive exclusive commercial rights for India.
- Biosergen will receive a 1-digit royalty from the sales on the Indian market, which however is to be renegotiated depending on sales achieved by Alkem.
- Alkems investment in the development in India will be converted into shares in Biosergen at a premium price.



Further clinical development and clinical trial supply

Aspergillosis - Further clinical development

- Biosergen was granted orphan drug status for invasive aspergillosis by the FDA in June 2021,
- The patients to be included should have proven/probable invasive aspergillosis at any site.
- The endpoint is all cause mortality at 6 weeks and clinical progression.
- Approximately 150 patients are planned
- Alkem will sponsor the study and recruit patients in India.

Clinical trial supply

- Current available supply covers next 10-15 patients
- New clinical trial material is required to cover additional patients.
- Estimated timeframe for manufacturing is 9-12 months
- Additional development and manufacturing for phase 2/3 material to be initiated end 2024