Biosergen

Biosergen AB targets the global need for new drugs against life-threatening fungal infection. The aspiration is to provide doctors with better treatment options, potentially saving thousands of lives every year

Biosergen addresses one of the worst unmet medical needs

With more than 1.5 million deaths per year fungal infection is the overlooked health crisis

Opportunistic fungal infections

Are increasing because the number of people with weakened immune systems continues to increase

Hospital acquired infections

Has multiple causes, including inadequate sanitation protocols and the routine use of antifungal drugs in hospital settings that creates a selection pressure for the emergence of resistant strains

Community acquired infections

These outbreaks are almost certainly linked to demographic changes and climate change

Majority of systemic fungal infection-related deaths are caused by four fungal pathogens: Candida, Aspergillus, Cryptococcus and Pneumocystis

Emerging multidrug resistant (MDR) fungal pathogens

Big-pharma has been pulling out of infectious diseases

This situation is now recognized by the WHO, CDC and others as a global health threat

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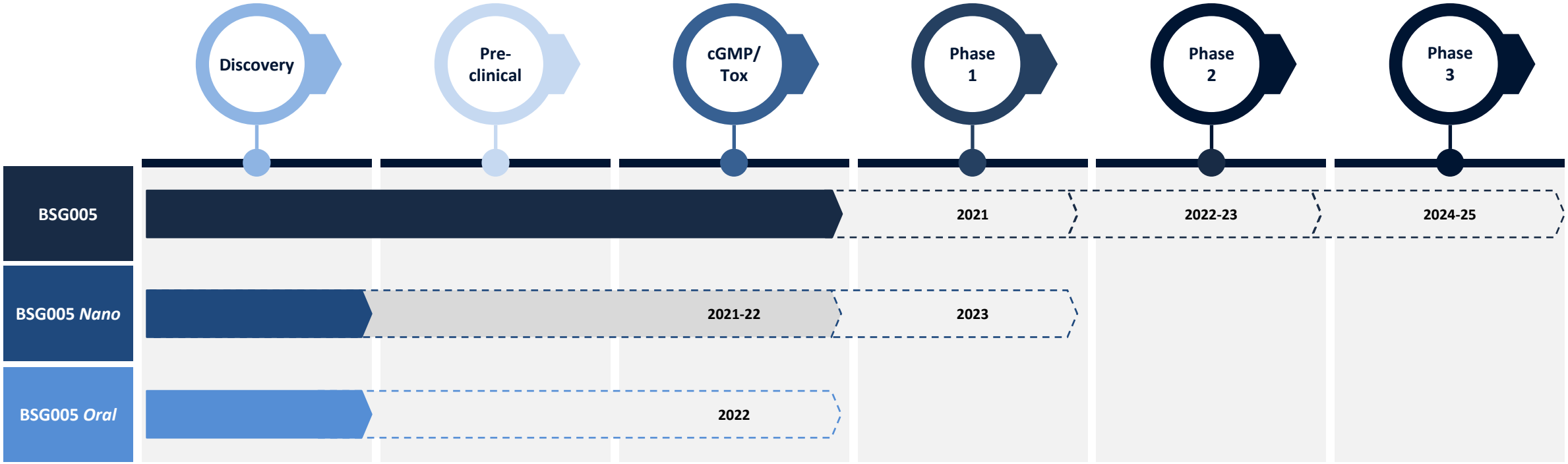
Pipeline leading to first product approval by 2026

Biosergen's lead compound BSG005 is about to enter clinical phase trials. Additional formulations to further increase the utility of the drug are close behind



- Phase I in Australia followed by ambitious multi-trial Phase II program leading to broad labeling against invasive fungal infection
- Applied for Orphan drug status with the FDA and EMA to obtain expedited clinical development and post approval market exclusivity
- New formulations in the pipeline
  - BSG005 **Nano** to specifically target the lung
  - BSG005 **Nano Oral** which allows for oral delivery

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BSG005 is a unique new antifungal

BSG005 belongs to the Polyene macrolide class of drugs but has been genetically improved

Based on two decades of scientific work at Norwegian University of Science and Technology (NTNU) in Trondheim in collaboration with the Department of Biotechnology and Nanomedicine at SINTEF, originally funded by the Research Council of Norway

Using state-of-art gene editing techniques to develop an improved version of Nystatin, a naturally occurring fungicidal chemical in the bacterial strain Streptomyces noursei

The researchers modified several gene clusters in an attempt to retain or even improve the efficacy of Amphotericin B while removing well-known dose limiting toxicity

They eventually expressed and evaluated in various in vitro and in vivo models more than 20 drug candidates

Original discovery from the Norwegian University of Science and Technology

Technology platform developed in partnership with Karolinska Development and SINTEF Research.

Polyenes are fungicidal, causing fungus death. Most of the other antifungal products are fungistatic and therefore only inhibit fungal growth

Polyenes are known for their low resistance development

Polyenes have been the “last line of defense” for antifungal therapy for more than 50 years

Contrary to other Polyenes BSG005 has no nephrotoxicity

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Excellent scientific validation

The decades long research effort behind BSG005 has been published in 23 peer reviewed publications

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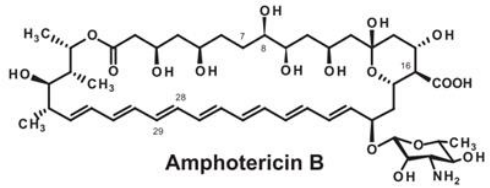

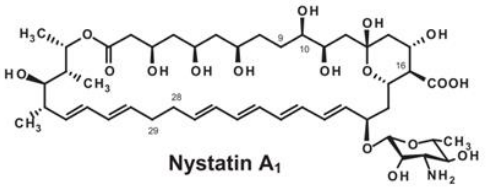

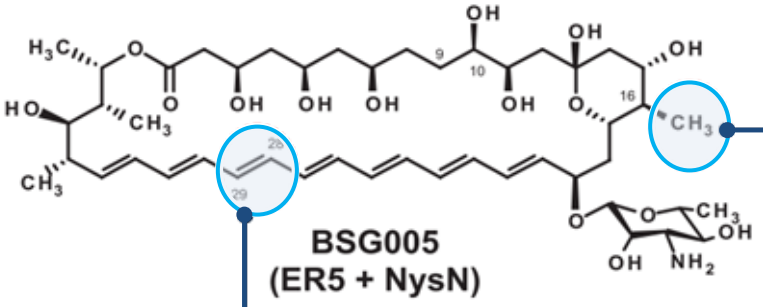

The genetic modification to the carboxyl group characteristic to both Amphotericin B and Nystatin has been shown to significantly reduce BSG005's toxicity

The re-formation of the covalent bond in the third position re-establishes AmB level of fungicidal efficacy

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BSG005 has strong patent protection

Additional market exclusivity may be afforded by orphan and GAIN status

Region	IP protection (incl. extensions)	Exclusivity protection after launch
USA	▪ Composition of matter patent: 2033 ▪ New formulation patent: 2041	▪ Orphan drug protection: 7 years ▪ GAIN protection: plus 5 years
EU	▪ Composition of matter patent: 2028 ▪ New formulation patent: 2041	▪ Orphan drug data exclusivity: 10 years ▪ Market exclusivity: plus 2 years
Japan	▪ Composition of matter patent: 2033 ▪ New Formulation patent: 2041	▪ Market exclusivity: 8 years
China	▪ Composition of matter patent: 2028 ▪ New Formulation patent: 2041	▪ Market exclusivity: 6 years

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Efficacy against resistant strains

BSG005 shows broad activity even against difficult-to-treat strains

Antifungals (MIC_{90}) (µG/ML)	Candida			
	C. Albicans (fluconazole-susceptible)	C. Albicans (fluconazole-resistant)	C. Glabrata (sensitive)	C. Glabrata (increased MIC capsofungin)
	n=13	n=7	n=14	n=6
Amphotericin B	0.5	0.5	0.5	0.5
Caspofungin	0.25	1	0.5	2
Fluconazole	0.25	>32	64	64
Voriconazole	0.06	0.5	4	4
BSG005	0.5	1	2	1

Antifungals (MFC_{90}) (µG/ML)	Aspergillus			
	A. flavus	A. fumigatus	A. niger	A. terreus
	n=20	n=20	n=20	n=10
Amphotericin B	>32	>8	>8	>32
Caspofungin	>32	>32	>32	>32
Fluconazole	>64	64	>64	>64
Voriconazole	>16	>8	>8	>4
BSG005	>4	>4	4	>4

Higher activity against azole resistant *Aspergillus* than liposomal Amphotericin B

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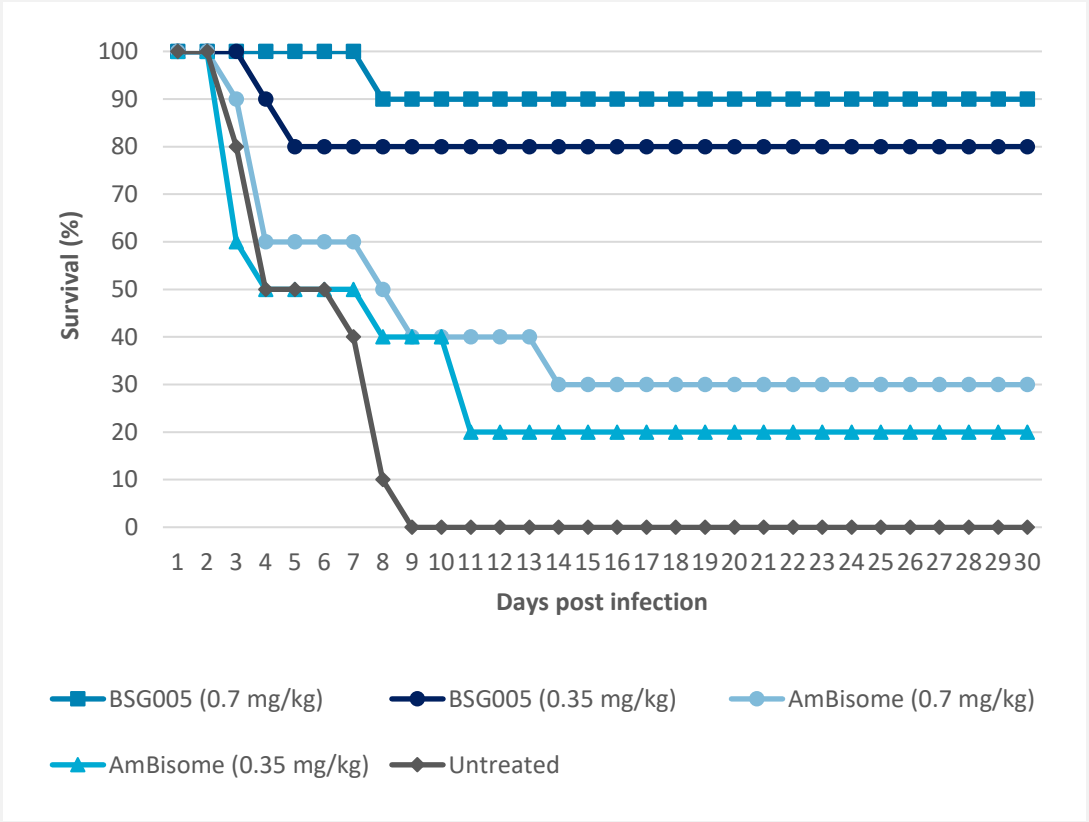
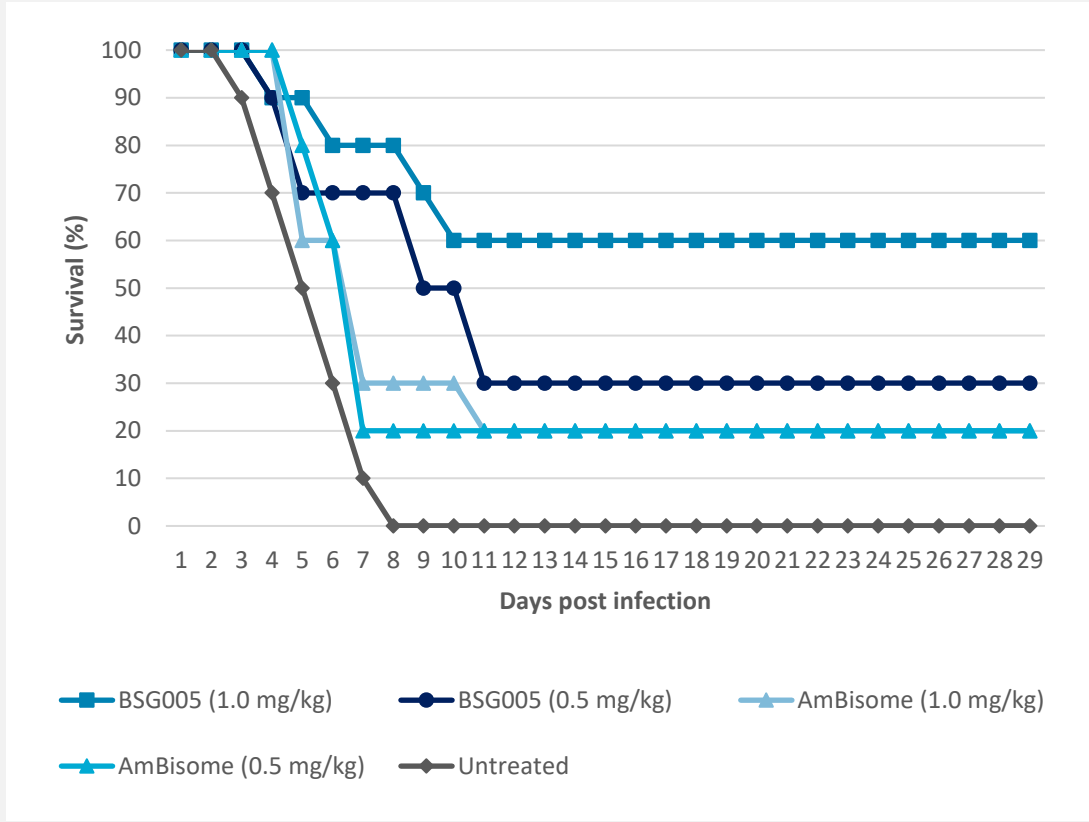
Superior performance at equal dose

Outperforms liposomal Amphotericin B in Aspergillosis and Candidiasis

BSG005 vs ambisome against Candidiasis



BSG005 vs ambisome against Aspergillosis



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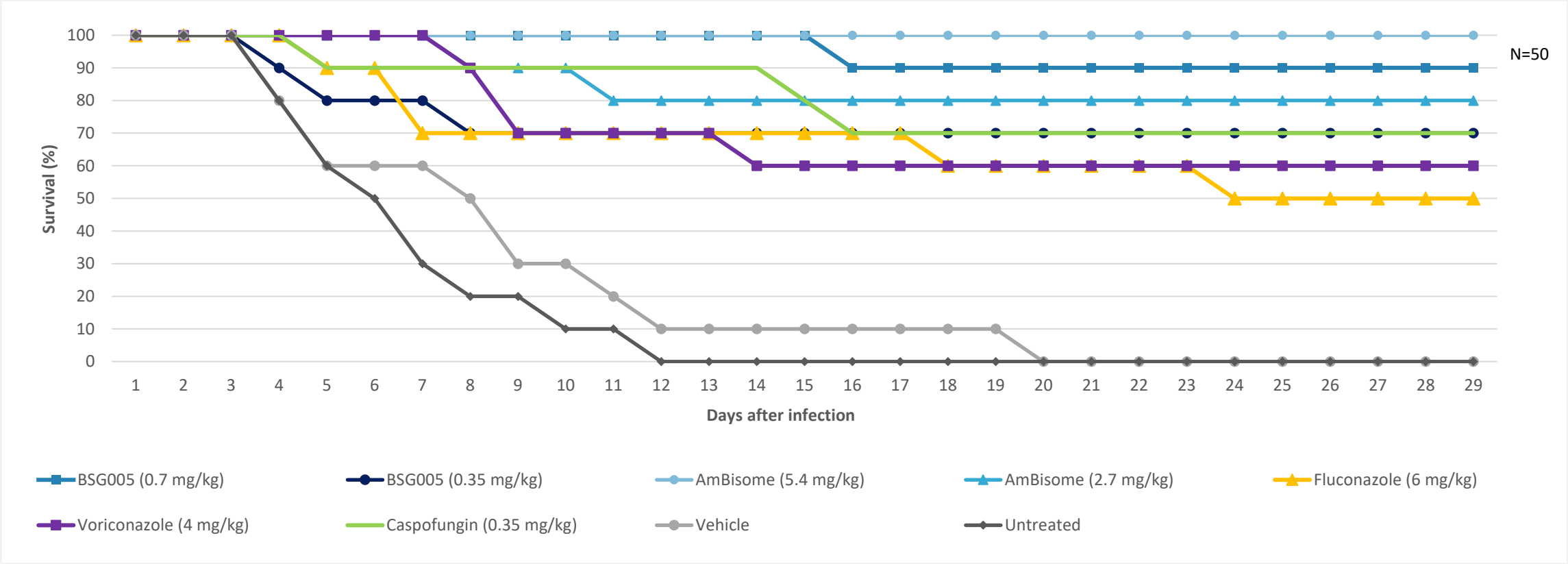
Higher Potency in candidiasis in Immunocompromised Mice (clinical dose)

BSG005 in Candidiasis vs. Ambisome, Fluconazole, Voriconazole and Caspofungin



AmBisome dose as amphotericin B

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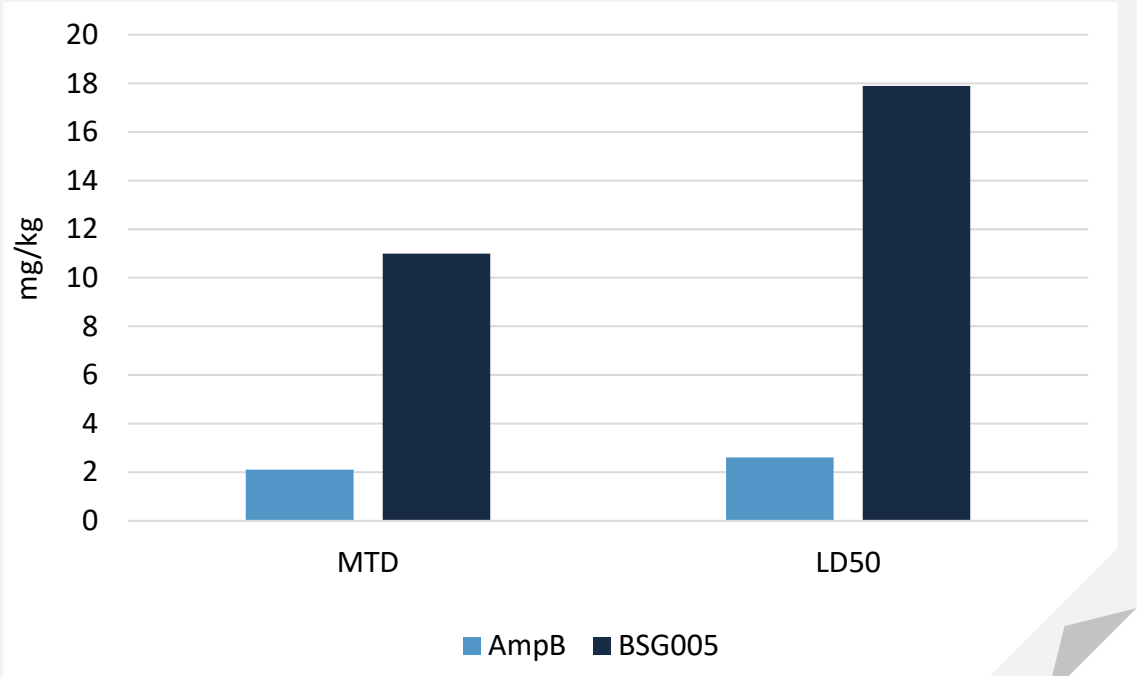
Comparison of Toxicology in Mice

BSG005 shows more than 5 times lower toxicity than Amphotericin B

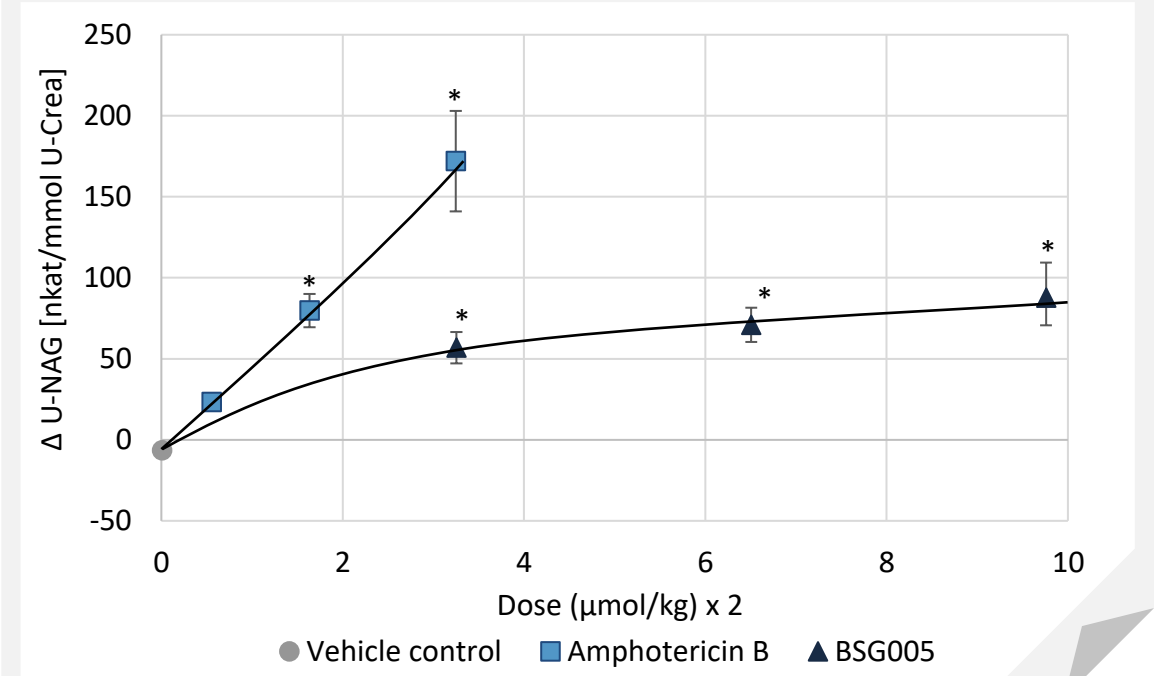
Acute toxicity in mice



MTD – Maximum Tolerated Dose
LD50 – Lethal Dose, 50%. It is the amount of the substance required to kill 50% of the test population.

BSG005 shows significantly less toxicity in mice kidneys

Enzyme marker: Urinary N-Acetyl-β-(D)-Glucosaminidase (NAG)



NAG is a sensitive indicator of early renal tubular injury.

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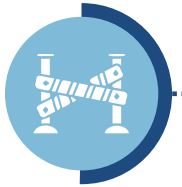
Clinical program designed to lead to NDA filing by end 2025

The company has filed for orphan status for BSG005 to achieve expedited regulatory revue and prolonged market exclusivity



Phase I underway

The phase I trial of BSG005 will take place in Australia as a dose escalation trial with 72 healthy male volunteers

Phase II programme consisting of three/four trials

The phase II clinical program is planned to include several trials to document the clinical efficacy and create full indication profile of BSG005

Phase III

The Company expects to be able to report the top line date from the first phase II trial by Q2 2023 and present the data and the phase III plans to achieve a first line treatment status at an End of Phase II meeting with the FDA in Q3 2023

The Company has applied for orphan drug status with the FDA and EMA

- Orphan drug status provides a number of benefits including expedited regulatory approval
- Another benefit is guaranteed market exclusivity for a period of time following market approval

BSG005 will likely also be awarded GAIN status

- The United States Congress created GAIN in 2012 (Generating Antibiotic Incentives Now) to provide incentives for the development of antibacterial and antifungal drugs for human use
- Under GAIN, a drug may be designated as a qualified infectious disease product (QIDP) if it meets the criteria outlined in the statute
- QIDP designated drugs are eligible for fast-track designation and priority review, as well as additional market exclusivity

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The market global antifungal drug market is approx. USD 16 billion

The three main classes of drugs – the Polyenes, the Azoles and the Echinocandins which together comprise more than 80% of the market - all focus on the fungal cell wall

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	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

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An investment in Biosergen is associated with risk. Any decision to participate in Biosergen's IPO should be based on the full prospectus which can be found on www.biosergen.net.