Life Science Investor Conf
Copenhagen

April 2023

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Biosergen

Biosergen

- Originally a Norwegian company from Trondheim
- Based on research from the Technical University in Trondheim
- Noted on First North in Stockholm in 2021 – Market Cap 52 M SEK
- Affiliate in Norway (all operational activities) and Australia (Phase I)
- Laboratory activities – mainly in Norway – but also in other countries
- Manufacture suppliers in Spain, Sweden and Scotland
- One active molecule (BSG005) in various formulation developments

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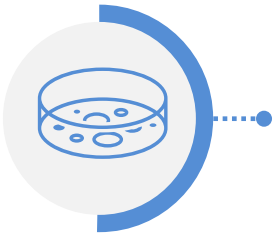
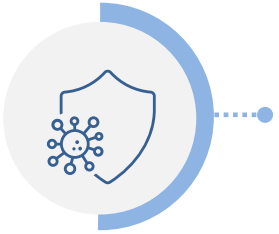
Biosergen's BSG005: a unique new gene-edited antifungal drug



BSG005 is fungicidal and therefore kills the fungus
BSG005 is a polyene, causing fungus death. Most other antifungal products only inhibit fungal growth



BSG005 is safe

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

BSG005 binds to ergosterol and leads to cell wall pores and ion leakage, which will cause cell death.

BSG005: A genetically improved polyene macrolide
A naturally occurring fungicidal chemical in the bacterial strain Streptomyces noursei

BSG005 will contribute to the reduction of resistance

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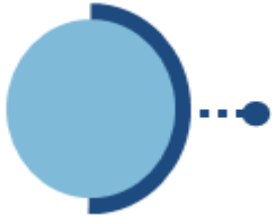
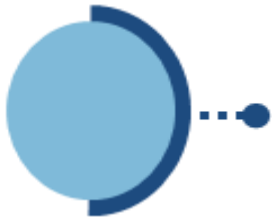
Biosergen Adresses One of the Worst Unmet Medical Needs: Invasive Fungal Infections



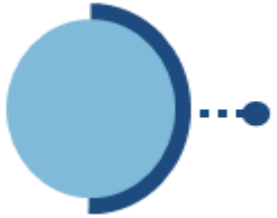
Opportunistic fungal infections
Are increasing because the number of people with weakened immune systems continues to increase

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



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

Emerging multidrug resistant (MDR) fungal pathogens (e.g Candida auris spreading)



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

A “silent” crisis

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BSG005 can potentially prevent and treat deadly Invasive fungal infections (IFI) in transplanted, cancer patients and other patients with compromised immune system and save patient lives.

Two causes: growing drug resistance and toxicity of existing treatments

1. An average healthy person
2. Anyone can get serious illness such as cancer
3. Transplanted and cancer patients with weakened immune system
4. Patients are exposed to fungal spores and may have IFI
5. Few effective treatments due to resistance and toxicity issues
6. Patients die from invasive fungal infection, not initial illness

- The drug resistance problem is growing

The Guardian — 2016

Millions at risk as deadly fungal infections acquire drug resistance

Researchers believe widespread use of fungicides on crops is reducing effectiveness of frontline medicines

CNN health — 2019

This drug-resistant fungus is spreading. Scientists warn of new superbugs to come

The New York Times — 2021

Outbreaks of Untreatable, Drug-Resistant Fungus Spread in 2 Cities

For the first time, the C.D.C. identified several cases of Candida auris that were resistant to all drugs, in two health facilities in Texas and a long-term care center in Washington, D.C.

Large medical need for new treatments

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More than 1.7 million deaths a year caused by fungal infections

Everyone with weakened immune systems is at high risk:

- Cancer patients, organ and hematological transplants, people with HIV, some with diabetes, and many others

Resistant strains

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

High mortality rates

- Example: Invasive candida in-hospital all-cause mortality rate in the US is approx. 25%

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

a global health threat

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The challenge diagnosing and treating invasive fungal infections

- Increase in total fungi pathogenic for humans
- Increase in frequency and severity of fungal infections and increasing resistance against drugs
- Early diagnostic of fungal infections is critical – after day 4 mortality increases without correct treatment
- Current diagnostic methods lack sensitivity and specificity and are not widespread in developing countries
- Some of the current diagnostics take too long to be clinically useful
- Most anti fungal treatments only inhibit fungal growth – do not kill the fungus
- Toxicity of drugs

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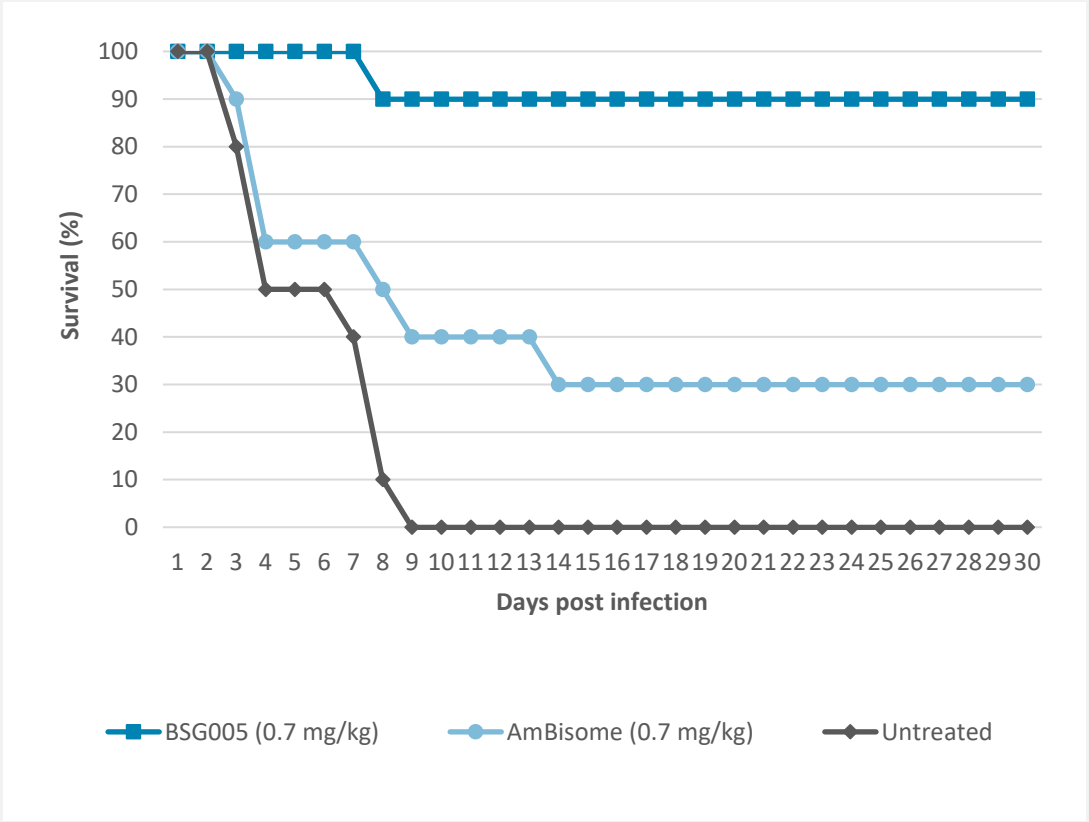
BSG005 with Broad Spectrum Activity of Polyenes

Class	Agent	Fungus Genus				
		Candida	Aspergillus	Fusarium	Mucor	Cryptococcus
Polyene macrolide	**BSG005**	Yes	Yes	Yes	Yes	Yes
	Amphotericin B	Yes	Yes	Yes	Yes	Yes
Azole	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	Caspofungin	Yes	Yes	No	No	No

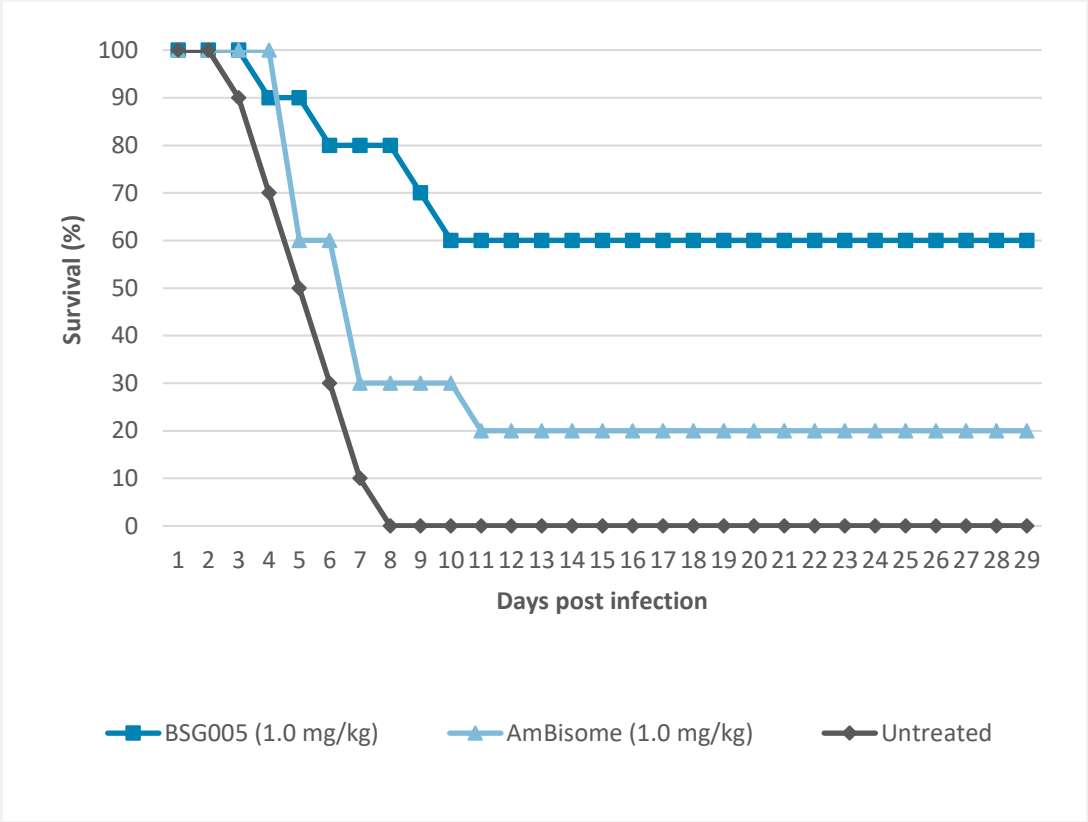
BSG005 is superior to Ambisome in performance at equal dose

Outperforms liposomal Amphotericin B in Aspergillosis and Candidiasis

BSG005 vs ambisome against Candidiasis



BSG005 vs ambisome against Aspergillosis



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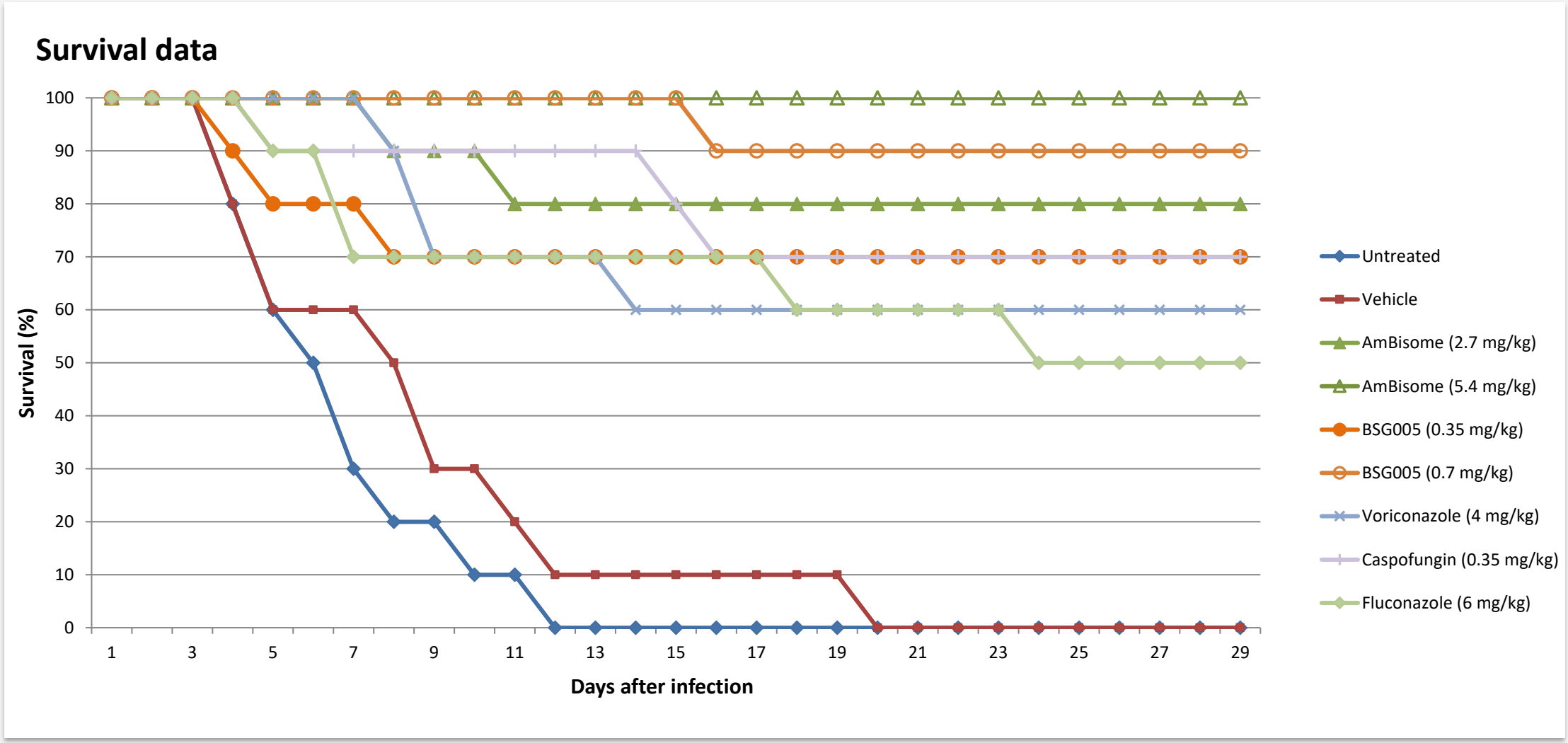
Higher Potency in candidiasis in Immunocompromised Mice (clinical dose)

BSG005 dosed 8 times lower with same result as Ambisome



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Phase I trial completed – Top line results

	Phase I trial in healthy volunteers
Study design	The study was as a placebo-controlled, double-blinded study. There was a single ascending dose part (SAD) followed by a multiple ascending dose part (MAD) with daily dosing over 7 days. Cohorts of 6 healthy volunteers (4 BSG and 2 placebo) on each dose level.
Objective	To evaluate safety, tolerability and pharmacokinetics of BSG005 in healthy adult subjects
SAD results	BSG005 was in 4 cohorts up to 0.1 mg/kg safe and well tolerated – No SAE's – AE's of mild to moderate severity including headache, dizziness, fever, increased hearth rate and infusion related reactions.
MAD results	In 2 cohorts up to 0.05 mg/kg was safe and well tolerated – No SAE's – No deaths, same AE's of mild to moderate severity-disappeared on next infusion. Phlebitis of infusion vein in 4 subjects.
Overall top line conclusion	In total 36 HV included, 24 on BSG (16 in SAD, 8 in MAD). No SAE at all, expected infusion related reactions and some HV's with infusion site reactions and phlebitis. No notable changes in post baseline laboratory parameters – including kidney, liver and potassium – and no clinically relevant ECG changes. PK in HV established with BSG exposure at or approaching NOAEL level. BSG005 was safe and well tolerated in healthy male and female volunteers. Report in May 23.

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Biosergen has made strong progress

- With these results from our clinical phase I trial, we have:
  - Confirmed what we showed in our tox studies – **BSG005 does not have any impact on the kidney function!!!**
  - Confirmed that there in HV also is no impact on liver function.
  - Confirmed that there in HV there was no notable changes in any laboratory parameters.

- These results is backing up (together with non clinical data) that BSG005 is ready to go into Phase II in patients with Invasive Fungal Infections.
- Passing phase I with such positive outcome is a major milestone in any drug development program.

- **Biosergen has a new anti-fungal polyene drug in clinical Phase II !!!**

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The first Phase IIA clinical trial

The overall clinical phase II program consist of a Phase IIA trial and 2-3 Phase IIB trials in the indications previously stated.

Phase IIA trial will be in 10 - 15 patients who have failed on Amphotericin B due to toxicity – typically kidney toxicity. About 30% of patients on AmpB have to stop treatment.

Study design	**Indication:** Patients with an invasive fungal infection that would benefit from a polyene treatment but have failed on Amphotericin B/Ambisome due to toxicity. **Treatment:** BSG005 as add on to preferred alternative standard of care. Dose escalation every 3.rd day, starting dose of 0.1 mg/kg, treatment duration 2 weeks. Cohorts of 5 patients. Next cohort start on highest tolerated dose from previous cohort. **Outcome:** Safety in patients at higher doses. Clinical efficacy on treatment with measurable endpoints (Imaging such as X-ray, MR/CT scans, clinical). PK collection for continued clinical development
Phase II A objective	Optimize dose selection for phase IIB (incl. confidence building) Be indicative of the safety and efficacy in patients with IFI If promising results expand the indication of rescue therapy Potential gateway to compassionate use program
Timing	▪ Awaiting Phase I clinical study report (May) ▪ CTA in May – EC and agency approval in August ▪ First trial patient recruited/treated in September 2023 ▪ Last patient completed in February 2024 ▪ Top line data in March 2024

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The global antifungal drug market is approx. USD 16 billion

Biosergen aims to become first line treatment for patients with invasive fungal infections and thereby capture significant 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

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Management has led listed companies before and has extensive drug development experience

Peder M. Andersen, MD
Chief Executive Officer

CEO, Forward Pharma

- 2012-2017, CEO Forward Pharma A/S
- Heading all development and IP activities and was instrumental in the IPO on the NY Nasdaq (USD 235m)
- Managing director at Forward Pharma GmbH from 2009-2016

VP, Astion Pharma

- Vice President of clinical development at Astion Pharma from 2010-2012

Niels Laursen, MBA
Chief Financial Officer

CFO, Oncology Venture

- 2018-2020 CFO at Oncology Venture A/S, Nasdaq First North Growth Market Stockholm

CFO, MPI

- 2014-2018: CFO at Medical Prognosis Institute A/S, Nasdaq First North Growth Market Copenhagen

VP, SSP Technology

- 2011-2012:
- Vice President, at SSP Technology A/S

Tine Kold Olesen, PhD
Chief Operational Officer

VP, Alvotech

- 2020-2021, VP Program and Aliance Management, Alvotech Holdings S.A

Ferring Pharmaceuticals

- 20 years in various positions:
- 2009-2021, Senior Director Global project and Portfolio Management
- Responsible for the urology and oncology portfolio located in DK and US
- 2001-2009, Clinical Science Director, R&D

Torsten Goesch MD, MBA. PhD, Chairman of the board

Professional experience

- Partner at Rosetta Capital
- Chairman at Dilafor

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In brief about BSG005

Invasive fungal infection is an emerging global health problem

BSG005 is a polyene with very broad anti-fungal activity – is killing the fungus – meaning no resistance development

BSG005 have in pre-clinical testing shown superior performance and higher potency than competitors and in clinical phase I shown it is safe and well tolerated

BSG005 is now in a Phase II clinical development

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