

Karolinska Development's portfolio company Biosergen gets final approval to test lead candidate BSG005 in patients with invasive fungal infection

STOCKHOLM, Sweden, June 12 2024. Karolinska Development AB (Nasdaq Stockholm: KDEV) announces today that its portfolio company Biosergen has received the final permission required to test its lead candidate drug BSG005 in patients with invasive fungal infections in India.

Biosergen and its partner, Alkem Laboratories Limited, have received approval of the Clinical Trial Application (CTA) and an important import license in India. With the approval and import license in place, the first patient trial of BSG005 can now be initiated.

The clinical trial is designed to enroll patients suffering from severe fungal infections, including mucormycosis (Black fungus), aspergillosis, and candidiasis. The focus of the trial is on patient populations intolerant or resistant to amphotericin B, the current last-resort treatment for severe invasive fungal diseases. BSG005 is developed as an acute treatment and will be tested in intensive care units. The primary objective of the trial is to evaluate the potential of BSG005 as a rescue treatment.

The first approval for the trial came already in February 2024, but a delay in granting the import license postponed the start of the study. To make up for the time lost, Biosergen has decided to double the number of hospitals to recruit patients and have added additional sites as backups.

"BSG005 is addressing an unmet medical need in invasive fungal infections for patients that urgently require an alternative treatment option when the first-line therapy has failed. BSG005 has shown a promising safety and efficacy profile in preclinical studies as well as the absence of severe side effects in a Phase 1 trial, and we are now looking forward to following the continued clinical development," says Viktor Drvota, CEO of Karolinska Development.

Karolinska Development's shareholding in Biosergen, through ownership by KDev Investments, amounts to 1%.

For further information, please contact:

Viktor Drvota, CEO, Karolinska Development AB
Phone: +46 73 982 52 02, e-mail: viktor.drvota@karolinskadevelopment.com

Johan Dighed, General Counsel and Deputy CEO, Karolinska Development AB
Phone: +46 70 207 48 26, e-mail: johan.dighed@karolinskadevelopment.com

TO THE EDITORS

About Karolinska Development AB

Karolinska Development AB (Nasdaq Stockholm: KDEV) is a Nordic life sciences investment company. The company focuses on identifying breakthrough medical innovations in the Nordic region that are developed by entrepreneurs and leadership teams. The Company invests in the creation and growth of companies that advance these assets into commercial products that are designed to make a difference to patient's lives while providing an attractive return on investment to shareholders.

Karolinska Development has access to world-class medical innovations at the Karolinska Institutet and other leading universities and research institutes in the Nordic region. The Company aims to build



companies around scientists who are leaders in their fields, supported by experienced management teams and advisers, and co-funded by specialist international investors, to provide the greatest chance of success.

Karolinska Development has a portfolio of twelve companies targeting opportunities in innovative treatment for life-threatening or serious debilitating diseases.

The Company is led by an entrepreneurial team of investment professionals with a proven track record as company builders and with access to a strong global network.

For more information, please visit www.karolinskadevelopment.com