

PRESS RELEASE

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MAJOR MILESTONE ACHIEVED - LAST PATIENT ENROLLED IN INFANT BACTERIAL THERAPEUTICS' PHASE 3 STUDY

The last patient of 2158 premature babies has been enrolled in the global phase 3 clinical program ("The Connection Study") for the development of IBP-9414. "The Connection Study" aims to assess the safety and efficacy of the drug IBP-9414, a Live Biotherapeutic Product developed to prevent severe diseases associated with prematurity.

The final patient participating in "The Connection Study" is expected to leave the study during July 2024. The results from the study are anticipated during Q3 2024.

"We are delighted to announce the completion of patient recruitment for IBT's large phase 3 study," says Staffan Strömberg, CEO of IBT. "The unmet medical needs of preterm infants are enormous, and establishing healthy gut function is essential to prevent severe illness among this vulnerable patient group. I would like to express my sincere gratitude to the IBT team for their dedication in successfully completing recruitment for the largest randomized controlled study ever conducted in premature infants," Staffan adds. "This study spans nearly 100 centers across 10 countries, and the recruitment of patients has taken almost 5 years. This represents a monumental operational achievement, which we celebrate with this announcement."

About IBT

Infant Bacterial Therapeutics AB ("IBT") is a public company domiciled in Stockholm. The company's Class B shares are since September 10, 2018, listed on Nasdaq Stockholm (IBTB).

IBT is a pharmaceutical company whose purpose is to develop and commercialize drugs for diseases affecting premature babies. During the 12 years of drug development IBT has gained unique expertise in the field of drugs using live bacteria as active substances, this is a key competitive factor for our development programs.

IBT's main focus is the drug candidate IBP-9414, a formulated bacterial strain naturally found in human breast milk. The development program is designed to show a reduced incidence of necrotizing enterocolitis ("NEC") and improved gastrointestinal function ("SFT"). IBP-9414, is expected to be the first product in the new class of biologics called "Live Biotherapeutic Products" for premature infants. Upon approval, it would be the first product to prevent NEC and improve Sustained Feeding Tolerance ("SFT") in newborns. The drug development of IBP-9414 is currently in its final stages and IBT expects to receive regulatory approval in 2025 for this important product for premature babies.

The portfolio also includes additional drug candidates, IBP-1016, IBP-1118 and IBP-1122. IBP-1016,

for the treatment of gastroschisis, a life-threatening and rare disorder in which children are born with externalized gastrointestinal organs. IBP-1118 to prevent retinopathy of prematurity (ROP), one of the leading causes of blindness in premature babies, and IBP-1122 to eliminate vancomycin-resistant enterococci (VRE), which cause antibiotic-resistant hospital infections.

Through the development of these drugs, IBT can address medical needs where no sufficient treatments are available.

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This information is information that Infant Bacterial Therapeutics is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2024-04-04 19:32 CEST.

Attachments

[Major Milestone Achieved - Last Patient Enrolled in Infant Bacterial Therapeutics' Phase 3 Study](#)