

PRESS RELEASE
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“THE CONNECTION STUDY” IS COMPLETED

The last patient in IBT’s global phase 3 clinical program “The Connection Study” has finished treatment. IBP-9414 is being developed to prevent serious diseases in premature infants. The study evaluates the safety and clinical efficacy of IBP-9414. As planned, the work to generate the results is underway.

This marks the achievement of another important milestone in the largest randomized controlled study ever conducted on premature infants. It means that the clinical development program is now complete and the next milestone will be to generate the study’s results. The study involved 2,158 premature infants in 10 countries at approximately 100 hospitals.

“Having now completed the clinical development program, we look forward to seeing the results of our important phase III study for this vulnerable patient group. The medical needs of premature infants are enormous, and establishing healthy gut function is crucial to prevent serious illness,” says Staffan Strömberg, CEO of IBT.

“During the past 5 years we have successfully conducted this study and look forward to presenting the study results in Q3 2024,” adds Staffan.

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About Us

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.

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 2024-07-08 16:40 CEST.

Attachments

["The Connection Study" is completed](#)