PRESS RELEASE
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IBT SUBMITS CLINICAL STUDY REPORT FOR 'THE CONNECTION STUDY' TO THE FDA

In accordance with the agreement reached with the FDA on 19 December 2024, IBT has today submitted the Clinical Study Report (CSR) for 'The Connection Study' to the FDA. The CSR contains data from the Phase 3 clinical trial that IBT completed in 2024 and which the FDA will now review. This is the first of several submissions to the FDA that IBT plans during the year.

Since IBT has been granted 'Break Through Designation', there is the possibility of a rolling review. IBT continues to work on other documentation that must be included for a biological registration application to be complete, a so-called Biologics Licence Application (BLA).

"We are pleased that we have now come so far that we can submit the clinical study report and continue the ongoing dialogue with the FDA" says Staffan Strömberg, CEO of IBT

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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. IBP-9414, is expected to be the first product in the new class of biologics called "Live Biotherapeutic Products" for premature infants. The drug development of IBP-9414 is currently in its final stages 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.

Attachments

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