

PRESS RELEASE

28 March 2025 18:52:00 CET

IBT IS GRANTED BREAKTHROUGH THERAPY DESIGNATION FOR ITS DRUG CANDIDATE

The U.S. Food and Drug Administration (FDA) has granted a Breakthrough Therapy designation for IBP-9414's potential to reduce gastrointestinal-related mortality. A breakthrough designation is intended to facilitate and expedite the development and review of new drugs that address unmet medical needs in treating a serious or life-threatening condition.

Last year, IBT reported the outcomes from "The Connection Study" IBT's large pivotal Phase 3 trial. The results from the study have been discussed with the FDA, allowing the FDA to conclude, based on their preliminary assessment performed, that IBP-9414 can address unmet medical needs.

"The Breakthrough Therapy designation for IBP-9414 underscores the urgent need for new and effective treatment options for reducing the high rate of mortality and morbidity in very low birthweight (VLBW) premature infants. The designation validates IBT's pharmaceutical approach to treating the underdeveloped gut, reducing severe conditions like NEC and thereby saving lives. In December 2024, the FDA and IBT agreed that IBT should submit all available clinical data enabling a full review by the FDA of the totality of evidence. IBT is now preparing for the submission in parallel with the activities for the launch of IBP-9414. With the Breakthrough Therapy Designation approved I am very hopeful that full review of the available data leads to an approval. The Breakthrough Therapy Designation from the FDA allows us to collaborate even more closely with the agency to quickly bring IBP-9414 to the market.", says Staffan Strömberg, CEO of IBT.

Contacts

Staffan Strömberg, CEO

Maria Ekdahl, CFO

info@ibtherapeutics.com

+46 76 219 37 38

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.

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 2025-03-28 18:52 CET.

Attachments

[IBT is granted Breakthrough Therapy Designation for its Drug Candidate](#)