PRESS RELEASE
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FDA GRANTS INFANT BACTERIAL THERAPEUTICS AB'S REQUEST FOR A TYPE B PRE-BLA MEETING

Infant Bacterial Therapeutics AB (IBT) announced today that the U.S. Food and Drug Administration (FDA), has granted the company's request for a Type B Pre-BLA (Pre-Biologics License Application) meeting regarding IBP-9414, IBT's drug candidate for premature infants. The meeting will take place on October 29, 2026, in Washington.
Staffan Strömberg, CEO of IBT, says:
"The FDA's approval of the Type B Pre-BLA meeting is a significant step toward our goal of obtaining marketing approval for IBP-9414 in the U.S."

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About IBT

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

IBT is a pharmaceutical company whose mission is to develop and commercialize drugs for diseases affecting premature babies.
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 development of IBP-9414 is currently in its final stages.

In the recent Phase III Connection study in premature infants that was completed in July 2024, the group treated with IBP-9414 demonstrated a significant 27% reduction in all-cause mortality compared with the placebo group, meaning that widespread use of IBP-9414 could save more than 1000 patients annually in the US alone. The therapy has received both Breakthrough Therapy Designation (March 2025) for gastrointestinal related mortality and Rare Paediatric Disease Designation, reflecting its potential to address a significant unmet medical need.

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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