PRESS RELEASE
25 November 2025 18:41:00 CET

IBT CHANGES THE IBP-9414 PATHWAY FOR APPROVAL FOLLOWING DISCUSSIONS WITH THE FDA

Following today's meeting with the FDA concerning IBT's live biotherapeutic product, IBT has decided to pursue an accelerated approval pathway for IBP-9414.

The FDA's Accelerated Approval Program allows expedited approval of drugs that treat serious or life-threatening diseases with an unmet medical need. To obtain an accelerated approval, a postmarketing clinical trial is expected.

“It is too early to state exactly what will be required. Our plan to apply for a marketing authorization in the USA remains in the first half of 2026. This means that instead of the planned Pre-BLA meeting, IBT now anticipates having interactions with the FDA to discuss the details of the accelerated approval pathway. The validation of the manufacturing process for IBP-9414 is proceeding as planned and must be completed before the product can be launched. Our plans for Europe remain as communicated earlier, with MAA submission in 2026” says Staffan Strömberg, CEO.

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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 listed on Nasdaq Stockholm (IBTB) since September 10, 2018.
IBT is a pharmaceutical company whose purpose 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 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.

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 2025-11-25 18:41 CET.

Attachments
IBT changes the IBP-9414 pathway for approval following discussions with the FDA