PRESS RELEASE
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IBT HAS SUBMITTED AN APPLICATION FOR MARKETING AUTHORISATION FOR THE EU/EEA

IBT has today submitted a Marketing Authorisation Application (MAA), i.e. an application for marketing authorisation for medicines, to the European Medicines Agency (EMA) for the company's drug candidate IBP-9414. The application is handled through a centralised procedure which, if approved, gives IBT the right to market the medicine throughout the EU as well as in Norway, Iceland and Liechtenstein (EEA). EMA has appointed a rapporteur and co-rapporteur to lead the approval process. The first step in EMA's work is to assess whether IBT's application is complete by validating it. Once validation is completed, the review of the application begins. A marketing authorisation (or rejection of the application) usually takes place approximately 18 months after the application has been submitted. The European Commission gives final approval. IBT has previously received Orphan Drug Designation for IBP-9414 from EMA.

Staffan Strömberg says: "Another important step has been taken towards approval, this time for the large EU market. In the EU, an estimated 100,000 children are born per year who could be treated with IBP-9414. According to the results of IBT's Phase 3 study, 44 children need to be treated to save one life. Therefore, IBP-9414 could save the lives of thousands of premature babies. I am very grateful that our small team has managed to develop the European application while we are working hard to complete the application for the US market."

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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.

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 2026-11-26 08:56 CET.

Attachments
IBT has submitted an application for marketing authorisation for the EU/EEA