PRESS RELEASE
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REGISTRATION WORK FOR IBT'S DRUG CANDIDATE IBP-9414 CONTINUES IN THE US AND EUROPE

Communication with the FDA continues, and IBT is focused on obtaining drug approval for IBP-9414 in the US as soon as possible. The next step is a Pre-BLA (Biologics License Application) meeting with the FDA. The purpose of the meeting is for the company and the agency to review important issues to ensure that the BLA meets all regulatory requirements, as well as the timing of the submission. At the Pre-BLA meeting, we expect discussions on the clinical data previously received by the FDA and outstanding manufacturing-related documents. The company expects that after the Pre-BLA meeting, it will be in a better position to estimate the point of time when a possible market authorization will be in place..

The validation of the manufacturing process for IBP-9414 is proceeding according to plan. We expect to complete our last analysis method shortly and plan to run a full-scale production as part of the validation work.

In addition to the work on registration in the US, IBT has initiated contact with the EMA regarding the application for market approval in the EU.

“We are working intensively to compile all the documentation required for market approval in both the US and Europe and estimate that we have completed approximately 90% of this work,” says Staffan Strömberg, CEO of Infant Bacterial Therapeutics.

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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

Registration work for IBT's drug candidate IBP-9414 continues in the US and Europe