Additional Infant Bacterial Therapeutics product receives FDA orphan drug designation

The FDA has granted orphan drug designation for IBT's product IBP-1016 for gastroschisis.

Infants suffering from gastroschisis suffer from risks of growth retardation, sepsis and NEC which leads to increased mortality. Hospital stays for these infants are commonly long and costly.

Orphan drugs are either drugs or biologics intended for the treatment, diagnosis or prevention of rare diseases or disorders affecting less than 200 000 patients in the USA per year. An orphan drug designation qualifies the company applying for it to receive certain benefits from the US government, such as tax reductions and long term market exclusivity, in exchange for developing the drug.

The approval does not change the standard regulatory requirements and processes for obtaining marketing approval for a product. Consequently, all aspects of the development must be investigated, including the clinical safety and efficacy documentation required for a market authorisation.

"This is the first time the FDA has granted orphan drug designation for gastroschisis. This is important as there are no treatments available for this serious disease. We are now investigating the optimum development pathway to obtain market authorization", says Staffan Strömberg, Chief Executive Officer, IBT.

About Infant Bacterial Therapeutics AB

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 (IBT B).
IBT is a pharmaceutical company whose purpose is to develop and market drugs targeting diseases affecting prematurely born infants or caused by antibiotic-resistant bacteria.

IBT's main focus is on its drug candidate IBP-9414, whose development program is designed to demonstrate a reduced incidence of necrotizing enterocolitis (NEC) and whether prematurely born infants achieve improved sustained feeding tolerance (SFT) when treated with the active substance Lactobacillus reuteri, a bacterial strain naturally found in human breast milk. IBP-9414 is currently in an ongoing registration-enabling pivotal Phase III study and is the company's most advanced development project.

The portfolio includes drug candidates, IBP-1016, IBP-1118, and IBP-1122. IBP-1016 is for the treatment of gastroschisis, a life-threatening and rare condition where the child is born with externalized abdominal organs. IBP-1118 aims to prevent ROP (retinopathy of prematurity), a leading cause of blindness in premature infants, while IBP-1122 aims to eliminate vancomycin-resistant enterococci (VRE), which cause antibiotic-resistant hospital acquired infections.

By developing these drugs, IBT has the opportunity to address medical needs where no available treatments currently exist.

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