

## **IBT continues to recruit prematurely born infants to The Connection Study following a planned safety analysis.**

In accordance with the study protocol, the independent Data Monitoring Committee (DMC) has performed the final planned safety analysis of Infant Bacterial Therapeutics AB (IBT) drug candidate IBP-9414. The analysis was based on data from 1,403 babies in the ongoing Phase III study.

The recommendation from the DMC is that recruitment can continue as planned, in accordance with the approved study protocol. The study was initiated in July 2019 and is ongoing in the USA, Bulgaria, France, Hungary, Israel, Poland, Romania, Serbia, Spain, and the United Kingdom.

"We have made significant progress and are now in the final phase of our extensive Phase III study, in which we have thus far enrolled more than 1,650 of the planned 2,158 premature babies. Based on the enormous amount of data collected, DMC has conducted the final planned safety review, and it is very gratifying that we have received approval to proceed according to plan", says CEO Staffan Strömberg.

### **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 (IBTB).

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 also 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.

### **For additional information please contact**

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