INFANT BACTERIAL THERAPEUTICS

Press Release September 30, 2021

Next recruitment milestone reached in IBT's Phase III Study.

Infant Bacterial Therapeutics (IBT) announces that the company has reached the next important milestone after recruiting 600 premature infants in the ongoing Clinical Phase III study of IBP-9414. According to the study protocol, a safety and futility analysis will now be performed during which the recruitment will continue. On September 22nd the company announced the reopening of stratum A (weights 500 to 749 grams) after the independent Data Monitoring Committee (DMC) completed an additional safety review. The DMC had no objections for the continuation of the study.

IBT's Clinical Phase III study of the drug candidate IBP-9414 for the prevention of necrotizing enterocolitis (NEC) and improvement of feeding tolerance in premature infants, the Connection Study, started in July 2019. There are currently 79 neonatal intensive care units (NICUs) open for recruitment in the study. These NICUs are located across 10 countries: Bulgaria, France, Hungary, Israel, Poland, Spain, the UK, the US, as well as in the recently approved Romania and Serbia.

"Currently, we do not expect any safety signals to occur at the 600 patient review, as the DMC recently looked at 571 patients corresponding to approximately 25,000 patient days. In addition, it is good to see that recruitment is many times greater than observed during the spring of 2021. We also see that centers are motivated to accelerate recruitment in order to develop a pharmaceutical-grade-probiotic for the prevention of NEC and improving feeding tolerance in preterm infants." says Staffan CEO, 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 listed on Nasdaq Stockholm, Mid-cap (IBT B).

Infant Bacterial Therapeutics AB (publ) (IBT) is a pharmaceutical company with a product in clinical phase III with a vision to develop drugs influencing the infant microbiome, and thereby prevent or treat rare diseases affecting infants.

IBT is currently developing the drug candidate IBP-9414. The ambition for IBP-9414 is to become the world's first approved probiotical drug with the goal to prevent life threatening diseases in premature infants including NEC and sepsis by promoting healthy stomach-and bowel development in premature infants. IBP-9414 contains the active compound Lactobacillus reuteri, which is a human bacterial strain naturally present in breast milk. The product portfolio also includes another project, IBP-1016, for the treatment of gastroschisis, a severe and rare disease affecting infants. By developing these drugs, IBT has the potential to fulfill unmet needs for diseases where there are currently no prevention or treatment therapies available.

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Publication
This information is information that Infant Bacterial Therapeutics AB is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act.

The information was submitted for publication, through the agency of the contact persons set out above, at 19.00 CET on September 30, 2021.