Press Release May 19, 2019

FDA and Infant Bacterial Therapeutics agree on the design of Phase III study

IBT has for an extended time consulted with the US Food and Drug Administration (FDA) on how the company's planned Phase III study should be designed. The FDA has now informed IBT in writing that IBT has responded satisfactorily to the comments that the FDA had regarding the study design and that there are currently no additions from the FDA's side. As a consequence of the FDA's comments, an evaluation of the effects of IBP-9414 on the digestive system of premature infants in the forthcoming Phase III study is now planned, as a serious medical problem for premature infants is that they cannot take up nourishment in an adequate way.

As previously announced, IBT has discussed the clinical development plan PIP (pediatric investigation plan) with the EMA (European Medicines Agency), which resulted in IBT's PIP being approved in 2017.

The coming days at IBT's office will be intensive in order for the company to as soon as possible, before the first half of the year, receive the formal clinical trials approval required before the first patient can be dosed in the study. As previously announced, IBT plans to start the study in hospitals in France, Hungary, Israel, Spain, the United Kingdom, and the United States.

“Receiving the FDA's comments took longer than we expected, but now we have a greatly improved protocol compared to what we had 6 months ago. Previously, our only focus was on preventing NEC (necrotizing enterocolitis), that in itself is a terrible intestinal disease which impacts premature infants and too often leads to fatal outcomes. During the spring of 2019, through consultation with the FDA, we have broadened the disease indications on which our drug candidate can hopefully demonstrate an effect,” says CEO Staffan Strömberg.

About Infant Bacterial Therapeutics AB
Infant Bacterial Therapeutics AB (publ) is a pharmaceutical company with a product in clinical stage 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, for the prevention of necrotizing enterocolitis (“NEC”) and improvement of so called *feeding tolerance* 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 fulfil unmet needs for diseases where there are currently no prevention or treatment therapies available.

Infant Bacterial Therapeutics AB (“IBT”) is a public company domiciled in Stockholm. The company’s class B-shares shares are listed on Nasdaq Stockholm, Mid-cap (IBT B).

For additional information please contact
Staffan Strömberg, CEO
Daniel Mackey, CFO
Infant Bacterial Therapeutics AB
Bryggargatan 10
111 21 Stockholm
Phone: +46 70 670 1226
info@ibtherapeutics.com
www.ibtherapeutics.com

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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 which is to be made public according to the Nasdaq regulations for companies listed on Nasdaq Stockholm. The information was submitted for publication, through the agency of the contact person set out above, at 20.00 CET on May 19, 2019.