Press Release November 21, 2018

The Phase III study protocol is modified after IBT's meeting with the FDA

Yesterday afternoon (EST) Infant Bacterial Therapeutics had a meeting with the US Food and Drug Administration (FDA) in Washington DC to discuss the design of the company's clinical development program. As a consequence of these discussions, IBT has chosen to modify its Phase III study for the prevention of necrotizing enterocolitis (NEC) in premature infants.

Following the guidance from the FDA, IBT will improve the protocol which may allow additional claims such as reduction in "feeding intolerance", that could increase the market potential of the product and the chances of success in the company's Phase III study.

The process to modify the study protocol has already been started. Because of these changes, the Phase III study protocol will not start in 2018 as previously communicated but is expected to start during the first half of 2019. Preparations for this study, including the production of clinical trial material and the initiation of clinical sites in Europe and the US, continue and are unaffected by this FDA meeting.

"We do not want delays to our development program, especially with the unmet medical need that necrotizing enterocolitis represents, but we feel that the FDA guidance will have a positive effect on our program by improving our Phase III study, allowing us ultimately to bring significant benefits to premature babies. The company's current financial position is sufficient to finance the IBTs continued operations and finalize the development program " says Staffan Strömberg, CEO of IBT.

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

IBT is developing drug candidate IBP-9414 to prevent necrotizing enterocolitis (NEC), a devastating and often fatal disease in premature infants. IBP-9414 contains the active substance *Lactobacillus reuteri*, which is a human bacterial strain naturally present in breast milk. IBT has an additional project in its portfolio, a second rare disease program, IBP-1016, for the treatment of an unmet medical need in gastroschisis, a severe disease in 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.

Infant Bacterial Therapeutics (IBT B) shares are listed on Nasdaq Stockholm.

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