

Press Release January 19, 2022

The Connection Study continues after pre-scheduled Data Monitoring Committee (DMC) review

On September 30, 2021 Infant Bacterial Therapeutics (IBT) announced that the company had reached a key milestone in the development of IBP-9414, after having recruited 600 premature infants to The Connection Study. The DMC has completed its pre-scheduled safety analysis without any concerns. At the same time a futility analysis was performed. Based on DMC recommendations and futility outcome, IBT is continuing the recruitment to the study as planned.

The phase III study, which started July 2019, is open for recruitment of prematurely born infants between 500g and 1,000g across the US, Bulgaria, France, Hungary, Israel, Poland, Romania, Serbia, Spain, and the UK.

“With more than 750 patients recruited to date, we are pleased to receive this favorable outcome. It is also reassuring that the futility analysis demonstrates statistical support for the continuation of the study”, 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 listed on Nasdaq Stockholm, Small Cap (IBT B).

IBT is a pharmaceutical company with a product in clinical phase III with a vision to develop drugs influencing the infant microbiome, and thereby preventing or treating 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 probiotic 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 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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For additional information please contact

Staffan Strömberg, CEO
Infant Bacterial Therapeutics AB
Bryggargatan 10
111 21 Stockholm
Telefon: +46 8 410 145 55
info@ibtherapeutics.com
www.ibtherapeutics.com

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 23:30 CET on January 19, 2022.