

Press Release July 4, 2019

Infant Bacterial Therapeutics has recruited the first patient in the pivotal Phase III clinical study

IBT has recruited the first patient in the Phase III pivotal clinical study, The Connection Study. The development program for IBP-9414, of which The Connection Study is the final planned clinical study, has now been agreed with both FDA and EMA. The study is randomized, double blind and placebo controlled to evaluate the safety and efficacy of IBP-9414 with respect to the prevention of necrotizing enterocolitis and other clinically important aspects of feeding preterm babies. The study is designed to include 2158 premature infants with a birth weight of 500-1500 grams and will be conducted at about 100 hospitals in the US, Europe and Israel.

The first patient was recruited today, July 4th, and the clinical trial applications have been approved in the United Kingdom, France, Hungary and Spain in addition to the IND that is now open in the United States. This means that IBT expects patients to be included in additional countries in the very near future.

“We are pleased to announce “first patient in” in this important Phase III study. It is a milestone for IBT and the study we are now starting marks a significant step in the development of therapies to address major medical needs facing the prematurely born babies. IBT is leading development in this field. My gratitude goes to everybody that has been involved in getting us this far” says CEO, Staffan Strömberg.

Further and more detailed information about The Connection Study can be found on www.clinicaltrials.gov with reference NCT03978000

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.

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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).

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