INFANT BACTERIAL THERAPEUTICS

Press Release December 6, 2021

A BLINDED EVALUATION OF THE CONNECTION STUDY – SUSTAINED FEEDING TOLERANCE (SFT) CORRELATES TO CLINICAL OUTCOMES

A blinded evaluation of IBT's Connection Study will be presented by Professor Josef Neu, University of Florida, at the 2021 Hot Topics in Neonatology® on December 6, 2021. The evaluation reveals that even a modest reduction in time to Sustained Feeding Tolerance (SFT) correlates positively to several clinically meaningful outcomes including Sepsis and Bronchopulmonary Dysplasia, a chronic lung disease that affects premature newborns.

Given that IBT's product IBP-9414 is first in class, there were no validated endpoints established for SFT, the Connection Study's second primary endpoint. Prior to initiating the study, IBT and the FDA therefore agreed on an appropriate validation procedure, the result of which has now been presented by Professor Josef Neu.

IBT's Clinical Phase III study of the drug candidate IBP-9414 for the prevention of necrotizing enterocolitis (NEC) and improvement of SFT in premature infants, started in July 2019 (NTC02472769 ClinicalTrials.gov). The evaluation presented by Dr. Neu assessed the impact on clinical outcomes related to a 1-day reduction in time to SFT. Data was consolidated from 439 randomized preterm newborns at <32 weeks gestation. Of these, 248 (78%) reported time to SFT defined as the combination of:

- Enteral feeding at ≥120 ml/kg/day for 10 consecutive days.
- No use of parenteral nutrition for 10 consecutive days.
- Average body weight gain is ≥10g/kg/day during these days.

The evaluation confirmed that several clinically adverse outcomes correlate positively to a reduction in time to SFT. This infers that SFT may be used as a predictor for adverse outcomes in very low birthweight preterm infants.

"IBT is pioneering pharma grade probiotic development in our aim to prevent life threatening infant disease and promote healthy gastrointestinal development. We are very pleased to see the results of the validation as presented by Professor Neu, giving us two validated primary endpoints in our study." says Staffan Strömberg, CEO of IBT.

The Scientific Poster presented at the conference is available via this link:
https://ibtherapeutics.com/wp-content/uploads/2021/12/Dr.-Neu-Poster-for-Hot-Topics.pdf

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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