

Press Release December 11, 2017

Infant Bacterial Therapeutics presents data from its Safety and Tolerability Study in premature infants

Infant Bacterial Therapeutics and the principal investigator Dr. Josef Neu presented data today from its Safety and Tolerability study in premature infants at the ongoing Hot Topics in Neonatology Conference in Washington, D.C., USA.

In summary, the Safety and Tolerability study showed that live bacterial therapy with IBP-9414 demonstrated similar safety and tolerability to placebo in preterm infants with birth weights 500g - 2000g, that there was exposure to the study drug demonstrated by presence of the bacterium in the feces on the last day of treatment, and that there was no evidence of cross-contamination with IBP-9414 in placebo treated infants.

The study, “A randomized, double blind, parallel-group, dose escalation placebo-controlled multicenter study to investigate the safety and tolerability of IBP-9414 administered in preterm infants” (NCT02472769 ClinicalTrial.gov) is part of the pharmaceutical development of IBP-9414 as a preventive therapy for necrotizing enterocolitis in preterm infants.

The study included 120 preterm infants with birth weights between 500 – 2,000g, who were randomized to receive either IBP-9414 (low dose or high dose) or placebo for 14 days, enterally administered daily, after which they were evaluated under 6 months follow up after the end of treatment. The study was performed at 15 neonatal centers in the US.

With these results in hand, the IBP-9414 clinical development program is now moving into the planned Pivotal Phase III trial for the prevention of NEC.

The Scientific Poster presented at the conference is available via this link:
<http://ibtherapeutics.com/wp-content/uploads/2016/03/Hot-topics-poster-1128.pdf>

About Infant Bacterial Therapeutics AB

Infant Bacterial Therapeutics AB (publ) (“IBT”) is a pharmaceutical company with a vision to develop drugs influencing the human infant microbiome, and thereby prevent or treat rare diseases affecting premature infants. Using its extensive experience in live bacterial therapeutics and its well-developed knowledge of the action of *Lactobacillus reuteri*, IBT is developing its lead drug candidate IBP-9414, to prevent necrotizing enterocolitis (“NEC”), a fatal, rare disease that afflicts premature infants. The FDA and the European Commission have granted IBT Orphan Drug Designation, and the FDA have granted Rare Pediatric Disease Designation for IBP-9414 for the prevention of NEC.

IBT is further pursuing a second rare disease programme IBP-1016 for the treatment of an unmet medical need in gastroschisis, a severe disease in infants. By developing these drugs, IBT has the

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potential to fulfil unmet needs for diseases where there are currently no prevention or treatment therapies available.

IBT is listed on Nasdaq First North Premier with Erik Penser Bank as Certified Adviser.
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