

Press Release September 28, 2017

European Medicines Agency adopts a positive opinion on the Paediatric Investigation Plan for IBT's lead product

The Paediatric Committee (PDCO) at the European Medicines Agency (EMA) has adopted a positive opinion on the Paediatric Investigation Plan (PIP) proposed by IBT for the development of IBP-9414 for the prevention of necrotizing enterocolitis (NEC).

As part of European regulations, pharmaceutical companies must submit a Paediatric Investigation Plan (PIP) outlining the strategy for investigation of new medicines in the paediatric population. An agreed PIP is a prerequisite for filing for marketing authorization for any new medicines in Europe.

Compliance to an agreed PIP adds a two-year extension to the 10-year market exclusivity awarded to an orphan designated product (such as IBP-9414) at market approval in the European Union.

Staffan Strömberg, CEO said "We are now preparing for the Phase 3 study and the adoption by PDCO of the PIP is necessary to allow us to move forward with our clinical development plan. I am very happy that the IBT team again has shown its capability to reach a significant milestone."

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 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.
www.ibtherapeutics.com

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Publication

This information is information that Infant Bacterial Therapeutics AB is obliged to make public pursuant to the EU Market Abuse Regulation and which is to be made public according to the Nasdaq regulations for companies listed on Nasdaq First North. The information was submitted for publication, through the agency of the contact person set out above, at 8.30 CET on September 28, 2017.