INFANT BACTERIAL THERAPEUTICS

Press Release 8 January 2016

Infant Bacterial Therapeutics has U.S. IND open and Swedish CTA[1)] approved for clinical study

Infant Bacterial Therapeutics (IBT) announces today that the IND (Investigational New Drug) for the prevention of necrotizing enterocolitis (NEC), has been accepted by the FDA (U.S. Food and Drug Administration). Furthermore, IBT has received approval from the MPA (Medical Product Agency) to conduct its clinical trial in Sweden.

IBT now has an open IND accepted by the FDA, which is an important step in allowing IBT to start clinical studies in the US.

Furthermore, the Swedish MPA has given approval to IBT to conduct its clinical trial in Sweden. In addition to the approval by MPA, IBT has also received approval from the

IBT was founded in November 2013 as a subsidiary of BioGaia to manage the development of a pharmaceutical for the prevention of NEC, as this was not within BioGaia's core business activities. IBT will now commence clinical development of its drug to prevent necrotizing enterocolitis (NEC) in Sweden and the US. NEC is a bowel disease, which affects premature infants and often is fatal.

"We are very happy to see that IBT has reached these important milestones. This confirms that IBT:s drug development to date meets the requirements of both agencies to begin clinical trials in premature infants, the most vulnerable of all humans", says Peter Rothschild, Chairman of the IBT board.

"We are now able to conduct clinical trials both in the US and in an EU country and we are naturally excited to move on with our drug development with the aim of satisfying the global need to find a preventive therapy for NEC", says Staffan Strömberg, President, Infant Bacterial Therapeutics.

1) Clinical Trial Application

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