

Press Release 8 January 2016

## BioGaia's subsidiary IBT has US IND open and Swedish CTA<sup>1)</sup> approved for clinical study

Infant Bacterial Therapeutics (IBT), a subsidiary of BioGaia, today announced 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 Ethical Committee.

In November 2013 BioGaia founded the subsidiary IBT 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, President, BioGaia and 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

### For additional information please contact:

Peter Rothschild, President, BioGaia, telephone: +46 8 555 293 00  
Staffan Strömberg, President, IBT, telephone: +46 8 410 145 55

### Latest press releases from BioGaia

2015-12-01 BioGaia makes further investments in MetaboGen  
2015-10-26 BioGaia signs exclusive agreement in Sri Lanka  
2015-10-23 BioGaia AB Interim Management statement 1 January – 30 September 2015

BioGaia has published this information in accordance with the Swedish Securities Market Act. The information was issued for publication on 8 January 2016, 02:00 pm CET.

**BioGaia is a healthcare company that develops, markets and sells probiotic products with documented health benefits. The products are primarily based on the lactic acid bacterium *Lactobacillus reuteri* which has probiotic, health-enhancing effects. The class B share of the Parent Company BioGaia AB is quoted on the Mid Cap list of the NASDAQ OMX Nordic Exchange Stockholm. [www.biogaia.com](http://www.biogaia.com)**