



Press Release 23 February 2015

BioGaia subsidiary Infant Bacterial Therapeutics gets Orphan Drug Designation in Europe

Infant Bacterial Therapeutics (IBT), subsidiary of BioGaia, is in the early stages of developing a drug to prevent necrotizing enterocolitis (NEC) which is a rare and fatal disease that affects premature infants. IBT has now obtained the Orphan Drug Designation for the prevention of NEC in Europe, which complements the corresponding designation in the US from FDA, granted in August 2013.

Orphan drugs are either drugs or biologics intended for the treatment, diagnosis or prevention of rare diseases which are defined as life-threatening or chronically debilitating conditions affecting less than five in 10,000 people in the European Union per year. The Orphan Drug Designation allows IBT to obtain assistance with development of the drug, fee reductions and marketing incentives.

In 2013 BioGaia founded the subsidiary IBT to manage all business related to the development of a pharmaceutical for the prevention of NEC, as this was not within BioGaia's normal business activities.

"We are pleased that the European Commission have granted the Orphan Drug Designation. We are confident that our subsidiary IBT can significantly contribute in the care of premature infants in the future", says Peter Rothschild, CEO, BioGaia.

"The US and European approvals of the Orphan Drug Designations are important steps in our efforts to develop this preventive therapy to save the lives of premature infants from one of the most deadly diseases occurring in the most vulnerable human population", says Staffan Strömberg, CEO, Infant Bacterial Therapeutics.

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BioGaia has published this information in accordance with the Swedish Securities Market Act. The information was issued for publication on 23 February 2015, 9:30 am 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



