

BioGaia subsidiary IBT takes rapid steps in development of a drug for premature infants

Infant Bacterial Therapeutics (IBT) aims to develop a unique orphan drug to prevent the fatal disease necrotising enterocolitis (NEC). The project has proceeded faster than previously scheduled and according to the updated development plan IBT expects to run two clinical trials within the next three years.

As announced earlier the IBT drug candidate IBP-9414 has been granted Orphan Drug Designation for the prevention of NEC by the FDA (August 2013) and the European Commission (February 2015).

First clinical trial to start already this year

The clinical development plan is designed with input from the FDA, EMA and US/EU key opinion leaders.

	Safety and tolerability trial	Pivotal trial
Expected duration	<ul style="list-style-type: none"> December 2015 – December 2016 	<ul style="list-style-type: none"> 2017 –2018
Clinical trial details	<ul style="list-style-type: none"> ClinicalTrial.gov identifier: NCT02472769 A randomised, double blind, parallel-group, dose escalation placebo-controlled multicenter study to investigate the safety and tolerability of IBP-9414 administered in preterm infants. Requested by FDA prior to the pivotal study to assess safety and tolerability of the new formulated IBP-9414 in a small sample of the target population of premature infants intended to be used in the pivotal trial. 	<ul style="list-style-type: none"> A randomised, double blind, parallel-group, placebo-controlled study to evaluate the efficacy of IBP-9414 in premature infants, ≤1,500 grams, in the prevention of NEC.

New Drug Application

What is NEC?

Necrotising enterocolitis (NEC) kills approximately 3,700 European and 1,500 US infants per year. NEC has an unpredictable, spontaneous, and acute onset and is untreatable, except through major surgery. The long-term clinical sequelae for infants who survive NEC are variable and include impairment such as short bowel syndrome, prolonged neonatal hospitalisation and adverse neurodevelopmental outcomes, including cerebral palsy, cognitive impairment, visual impairment, and hearing impairment.

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

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There is no definitive treatment for NEC. Approximately 20-40 per cent of patients with NEC will require surgery. None of the currently available treatments for NEC modify the underlying risk factors for the disease.

According to published literature, NEC is the leading cause of death among all premature infants with an average mortality rate of 20-30 per cent.

High incidence and mortality among premature infants

Infants birth weight (g)	NEC incidence rate (%)	NEC mortality rate (%)
501-750g	12.0%	42.0%
751-1,000g	9.2%	29.4%
1,001-1,250g	5.7%	21.3%
1,251-1,500g	3.3%	15.9%
1,501-2,500g	0.4%	8.2%-17%
>2,500g	0.1%	0-20%

External financing solution evaluated

Due to the fast progression of the project, BioGaia decided in March 2015 to supply IBT with an additional USD 520 000. In total BioGaia has provided financing of SEK 24 million to the project (as of June 2015), of the total decided amount of approximately SEK 47 million.

To finance the first planned clinical trial, expected to start already this year, IBT has an estimated capital need of SEK 130 million. In June 2015, BioGaia announced that the management team will evaluate the possibility of a separate listing of IBT during the second half of 2015.

"After two years of preparatory work in our efforts to save the lives of fragile premature infants, we are pleased to move into the first clinical trial within the coming months", says Staffan Strömberg, President, IBT.

"This project is a unique opportunity for investors to be involved in the drug development of a life saving therapy", says Peter Rothschild, President, BioGaia.

Read more at ibtherapeutics.com.

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2015-05-08 Annual General Meeting of BioGaia
2015-05-07 BioGaia AB Interim Management Report 1 January – 31 March 2015

BioGaia has published this information in accordance with the Swedish Securities Market Act. The information was issued for publication on 24 June 2015, 3:30 pm CET.

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