

FDA approves BioGaia's request for orphan drug designation

Necrotizing enterocolitis (NEC) is a rare and extremely severe disease that affects premature infants. BioGaia is in a very early stage of investigating the possibilities of developing a drug within this field and has submitted a request for orphan drug designation in the USA. The FDA Office of Orphan Product Development has now approved BioGaia's request.

Orphan drugs are either drugs or biologics intended for the treatment, diagnosis or prevention of rare diseases or disorders affecting less than 200 000 patients in the USA per year. An orphan drug designation qualifies the company applying for it to receive certain benefits from the US government, such as tax reductions and marketing incentives, in exchange for developing the drug.

The approval does not change the standard regulatory requirements and processes for obtaining marketing approval for a product. Consequently, all aspects of the development must be investigated, including the clinical safety and efficacy documentation required for a market authorisation.

As pharmaceuticals are not within BioGaia's current business activities the company is exploring how a possible development process should continue in order not to deflect attention from the core business. For this purpose all business related to this field is handled by the subsidiary Infant Bacterial Therapeutics AB.

"We are pleased to see that the FDA has granted the product orphan drug designation. NEC is a very serious disease that affects a vulnerable patient group. We are now investigating if, and in such case how, we can contribute in the care of these infants in the future without incurring unnecessary financial risks", says Peter Rothschild, Chief Executive Officer, BioGaia.

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BioGaia has published this information in accordance with the Swedish Securities Market Act. The information was issued for publication on 6 August 2013, 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