

Press Release 8 October 2018

MetaboGen reaches development goal – first product ready for safety study

BioGaia's subsidiary MetaboGen has reached an important development goal. The first version of its next generation probiotic product is now ready to go in to a safety study.

MetaboGen focuses its research on the microbiome and on finding breakthrough opportunities that can be developed into novel therapeutics and the next generation of probiotics. A number of development programs are now being pursued by the company.

Management of metabolic disease

Two strains, *Faecalibacterium prausnitzii* (DSM 32379) and *Desulfovibrio piger* (DSM 32187), derived from the human gut microbiome, have been chosen in this program. Because of the oxygen sensitive properties of the strains, MetaboGen has developed, and patented, a unique production technology, allowing the bacteria to survive in a commercial product. This has been a crucial step in the product development, and one that may potentially be suitable also for other similar strains.

The two selected strains have been thoroughly investigated regarding properties, safety and antibiotic susceptibility. The strains have been produced and the product formulation successfully completed. The first version of the product is thereby ready to be used. Recently the ethical application for the first human safety trial was approved and the clinical study starts in the beginning of October.

Future products based on these strains aim to be used in the management of metabolic diseases, such as type 2 diabetes, gestational diabetes and non-alcoholic fatty liver disease.

Patient stratification

A person's microbiome composition may influence how that person tolerates or responds to certain pharmaceutical treatments. MetaboGen is looking into different patient stratification opportunities using its proprietary analytical tool MeduzaGen™, which provides detailed information about the composition of the microbiota, and its function. The tool offers MetaboGen possibilities to develop companion products to existing drugs, in order to shift the microbiome to achieve improved response to treatment, or less side-effects.

Microbiome restoration

Antibiotics are known to disrupt the microbial ecology. This shift in gut composition may persist for a long time and may even never return to its initial state. Thus, it may be essential to "help" the microbiome to recover after treatment with antibiotics.

Together with BioGaia, MetaboGen has initiated a project with the goal to identify, isolate, and propagate members of the human microbiota into product(s) that can be administered simultaneously with, or after, antibiotic treatment.

BioGaia is an innovative Swedish healthcare company that develops, markets and sells probiotic products with documented health benefits. The products are sold through local distribution partners in 100 countries worldwide. The class B share of the Parent Company BioGaia AB is quoted on the Mid Cap segment of Nasdaq Stockholm. biogaia.com



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Intrahepatic cholestasis of pregnancy (ICP)

In 2016 MetaboGen initiated the development of a bacterial intervention product for ICP, in collaboration with Ferring Pharmaceuticals. This disease is not only stressful for the expecting mother but may also cause serious health-problems for the unborn baby. An exploratory clinical trial is presently ongoing, recruiting pregnant women in Stockholm and Lund.

“We are very satisfied to have reached such an important milestone in product development and look forward to coming studies and continued work together with BioGaia and our partners”, says Sara Malcus, CEO MetaboGen.

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