CombiGene expands its operation into metabolic diseases through an inlicensing agreement with Lipigon Pharmaceuticals, thereby strengthening CombiGene's position as Sweden's leading gene therapy company

CombiGene AB (publ) ("CombiGene") has today entered an inlicensing and collaboration agreement with Lipigon Pharmaceuticals AB's ("Lipigon") regarding treatment of the rare disease lipodystrophy through advanced gene therapy. Under the agreement, CombiGene and Lipigon agree to collaborate during the early development phases of the project. Through this agreement, CombiGene reinforces its position as Sweden's leading gene therapy company.

Under the license agreement, payment to Lipigon consists of upfront payment, pre-defined milestone payments and royalty on future commercial sales. The royalty percentage on commercial sales is dependent on sales volume. In the event of an outlicensing of the project by CombiGene, the revenue from this outlicensing will be shared between CombiGene and Lipigon. The revenue split between the companies is dependent on how far the project has been developed. With regards to upfront payment and milestone payments, CombiGene has the possibility to use shares in the company as payment. The agreement is exclusive and without limitations in time.

The agreement also regulates the collaboration between CombiGene and Lipigon, and during the agreements first two years, the cost for CombiGene for continued development of the project will amount to approximately MSEK 10. This development will primarily be conducted in collaboration with Lipigon.

Lipigon has brought the lipodystrophy project from discovery phase to the current early development phase. The aim of the project is to break the vicious cycle of liver lipid accumulation and normalize liver lipid levels and restore normal liver function.

"The development of this very exciting project will in many ways resemble the way we are running our epilepsy project CG01," says Jan Nilsson, CEO at CombiGene. "At CombiGene, we are focused on project management and we have people with perfect skillsets, networks and experience to take research assets through the pre-clinical phase into clinical studies. In the lipodystrophy project, we will work in close collaboration with Lipigon to ensure project continuity and access to Lipigon's vast expertise within lipodystrophy and their extensive network. We will also draw upon the expertise of the network of international experts CombiGene has established during the development of CG01. In this way, there will be substantial synergies between CG01 and the lipodystrophy project. The lipodystrophy project will in no way take away any of our focus on CG01."

"We are very happy to enter this agreement with CombiGene ," says Stefan K Nilsson, CEO at Lipigon. "Through the development of their epilepsy project, CombiGene has demonstrated a fantastic ability to handle the complexities of gene therapy. With our expertise in lipid biology this collaboration is a perfect match, ultimately aiming at improving the treatment for a patient group with few or no treatment options."

During the upcoming two years, the development of the lipodystrophy project will intensify. The main part of the work will be done at Lipigon and in close collaboration between the two companies.

About lipodystrophy
Lipodystrophy is a rare condition affecting about 1 in 1,000,000, which means that there approximately are 1,000 patients in Europe and the US. The disease is characterized by complete or partial lack of functional fat tissue and in the absence this, different organs begin to accumulate fat. Central for the disease is accumulation of liver fat. This leads to severe complications, such as hard to treat diabetes, cardiovascular diseases, acute pancreatitis, and inflammation in the liver.

Lipodystrophy patients have high unmet medical needs as there are very few therapies available in the market. Patients who receive treatment take several medications that only target the associated risk factors. The only treatment indicated for lipodystrophy is metreleptin, which is very expensive and ineffective against the most common type of lipodystrophy.

Opportunity of obtaining Orphan Drug Designation
CombiGene's ambition is to develop the gene therapy asset for partial lipodystrophy. Since lipodystrophy is a rare disease, the therapy has the opportunity of obtaining Orphan Drug Designation (ODD) in several geographical markets (e.g. US and EU). This means that CombiGene could obtain incentives such as regulatory assistance, tax credit, grants, fee reduction, longer market exclusivity times (7 years in the US and 10 years in the EU) and many more. Thus, based on the incentives and benefits provided by ODD, CombiGene could potentially develop this project internally towards commercialization or, alternatively, in collaboration with external partners.

About Lipigon
Lipigon Pharmaceuticals is a spin-off company from Umeå University, Sweden. Based on five decades of research, the company develops drugs targeting lipid related diseases. Lipigon aims at building a sustainable research-based company by bringing our programs to major inflection points. In addition to the agreement with CombiGene, Lipigon's pipeline comprises one project for the treatment of high blood lipids through the use of antisense technology and a project that aims to activate an enzyme that breaks down fat. The latter project is based on a small molecule. For further information, please visit www.lipigon.se.

Lipigon Pharmaceuticals AB
Stefan K Nilsson, CEO
Phone: +46 70 578 1768
stefan@lipigon.se

About CombiGene AB
CombiGene's vision is to provide patients affected by severe life-altering diseases with the prospect of a better life through novel gene therapies.

CombiGene's business concept is to develop effective gene therapies for severe life-altering diseases where adequate treatment is currently lacking. Development assets are sourced from an external research network and developed to achieve clinical proof of concept. Drug candidates for common diseases will be co-developed and commercialized through strategic partnerships, while the company may manage this process on its own for drugs targeting niched patient populations.

CombiGene is a public company and listed on Nasdaq First North Growth Market. The company's Certified Advisor is FNCA Sweden AB, +46 (0)852 80 03 99 info@fnca.se.

For further information, please visit www.combigene.com.

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Contacts

Jan Nilsson, CEO
Phone: +46 (0)704 66 31 63
jan.nilsson@combigene.com

Arne Ferstad, Chairman of the board
Phone: +447496526142
arne.ferstad@combigene.com

www.combigene.com
CombiGene AB (publ) Medicon Village, SE-223 81 Lund, Sweden
info@combigene.com

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Attachments

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