Press Release, August 31, 2021

Diamyd Medical's rhGAD65 manufacturing facility on track for Diamyd® vaccine production

Small-scale experimental production of the recombinant human protein GAD65, the active component in the therapeutic diabetes vaccine Diamyd®, is now established at the manufacturing facility in Umeå. Large-scale production is being set up primarily using Cytiva equipment. The future CGMP certified production process at the facility is a key part of Diamyd Medical's regulatory strategy for potential future conditional and accelerated market approvals.

"Our Umeå site has, despite an ongoing pandemic, in a short time been able to transfer the manufacturing technology to Diamyd Medical," says Ulf Hannelius, CEO at Diamyd Medical. "This is a paramount investment, giving us full control over our key asset in this pivotal development stage of the diabetes vaccine Diamyd®."

As previously communicated, the first priority of the vaccine facility will be to manufacture rhGAD65 for commercial use.

"This is a truly exciting and challenging process," says Maja Johansson, Umeå Site Manager. "We have identified and to a large extent secured the recources and competences needed to produce rhGAD65 for commercial use."

In parallel with the upcoming confirmatory precision medicine Phase III trial DIAGNODE-3, Diamyd Medical is interacting with regulatory authorities investigating the possibility for accelerated approval pathways for the diabetes vaccine Diamyd®.

About CGMP
CGMP stands for Current Good Manufacturing Practice. The extensive CGMP regulations for drugs contain requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. These regulations make sure that a pharmaceutical product is safe for use, and that it has the ingredients and strength it claims to have. The approval process for new and generic drug marketing applications includes a review of the manufacturer's compliance with the CGMPs where it will be determined if the firm has the necessary facilities, equipment, and ability to manufacture the drug it intends to market.

About Diamyd Medical
Diamyd Medical develops precision medicine therapies for type 1 diabetes. The diabetes vaccine Diamyd® is an antigen-specific immunotherapy for the preservation of endogenous insulin production. Significant results have been shown in a large genetically predefined patient group in a large-scale meta-analysis as well as in the Company's European Phase IIb trial DIAGNODE-2, where the diabetes vaccine was administered directly into a lymph node in children and young adults with recently diagnosed type 1 diabetes. Preparations for a confirmatory Phase III trial in the US and Europe are on-going, to start recruting patients later in 2021. A vaccine manufacturing facility is being set up in Umeå for the manufacture of recombinant GAD65, the active ingredient in the therapeutic diabetes vaccine Diamyd®. Diamyd Medical also develops the GABA-based investigational drug Remygen® as a therapy for regeneration of endogenous insulin production and to improve hormonal response to hypoglycaemia. An investigator-initiated Remygen® trial in patients living with type 1 diabetes for more than five years is ongoing at Uppsala University Hospital. Diamyd Medical is one of the major shareholders in the stem cell company NextCell Pharma AB.

Diamyd Medical's B-share is traded on Nasdaq First North Growth Market under the ticker DMYD B. FNCA Sweden AB is the Company's Certified Adviser; phone: +46 8-528 00 399, e-mail: info@fnca.se

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