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Diamyd Medical deepens long-term manufacturing collaboration for retogatein

Diamyd Medical is taking the next step in a long-term manufacturing collaboration with APL and, in parallel, is initiating a strategic collaboration with NorthX Biologics to further develop and scale the manufacturing of retogatein (rhGAD65) ahead of commercialization.

“This is a natural next step in work that has been built up over time,” says Ulf Hannelius, CEO of Diamyd Medical. By combining Diamyd Medical’s in-house drug substance manufacturing with APL’s long-standing fill and finish expertise and now adding the validation capabilities of NorthX Biologics, we are creating a sustainable structure for continued development, while strengthening Sweden’s manufacturing capabilities within biologics.”

Diamyd Medical is responsible for manufacturing retogatein (rhGAD65) drug substance at its biologics manufacturing facility in Umeå, Sweden, currently undergoing GMP certification. The collaboration with APL, also in Umeå, on GMP fill and finish activities of retogatein has been ongoing for several years and continues to evolve in line with the needs of the program.

“Our collaboration with Diamyd Medical has developed step by step. We view this as a long-term partnership focused on quality, flexibility, and progressively meeting the higher regulatory requirements of later development phases and commercial manufacturing,” says Erik Haefller, CEO of APL.

NorthX Biologics is joining the collaboration to support preparatory work for the process validation of the drug substance, while the manufacturing operations in the Umeå site move towards commercial scale manufacturing.

“Our role is to contribute with manufacturing experience, validation, and regulatory readiness as the process matures, says Janet Hoogstraate, CEO of NorthX Biologics. This is a partnership designed to evolve over time, through close dialogue between all parties, and to reinforce Sweden as a strong base for biopharmaceutical manufacturing”.

The collaboration enables controlled scale-up, reduces manufacturing risk, and supports regulatory readiness as the clinical programs advance.

About APL

Apotek Produktion & Laboratorier (APL) is one of Europe’s leading companies manufacturing extemporaneous drugs and stock preparations. We have a public policy assignment from the Swedish government, but also work together with other pharmaceutical companies to create the greatest possible patient benefit. The assignment also comprises preparedness to maintain operations in times of crisis and ultimately war.

Our vision is that we will make a difference for patients with additional needs. We are also an established contract manufacturer within life science in Scandinavia, where we deliver services within development and analysis. With more than 500 employees and five manufacturing units in Malmö, Gothenburg, Stockholm and Umeå, we develop drugs that improve and save lives.

About NorthX Biologics

NorthX Biologics is a leading contract development and manufacturing organization (CDMO) and Sweden’s national innovation hub for advanced biologics, enabling next-generation therapies beyond traditional manufacturing. With over 30 years of GMP experience, NorthX Biologics offers end-to-end services including process development, recombinant proteins, vaccines, personalized medicine, viral vectors, cell therapies, and aseptic fill & finish. With its headquarters in Matfors, Sweden, and a facility in Stockholm, NorthX Biologics serves customers worldwide.

<https://www.nxbio.com/>

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About Diamyd Medical

Diamyd Medical develops precision medicine therapies to prevent and treat type 1 diabetes. Retogatein (rhGAD65) formulated with alum is an investigational antigen-specific immunotherapy, designed to induce antigen-specific immune tolerance to GAD65 and preserve endogenous insulin production in individuals with type 1 diabetes who carry the HLA DR3-DQ2 gene. Retogatein has been granted Orphan Drug Designation in the U.S. as well as Fast Track Designation by the U.S. FDA for the treatment of Stage 3 (clinically diagnosed symptomatic) type 1 diabetes. Fast Track Designation has also been granted for the treatment of Stage 1 and 2 (pre-symptomatic) type 1 diabetes. DIAGNODE-3, a confirmatory Phase 3 trial with potential for an accelerated approval pathway in the US, is being conducted at 57 clinics in eight European countries and in the US in patients with recent-onset (Stage 3) type 1 diabetes. Significant results in preserving endogenous insulin production have previously been shown in a large genetically predefined patient group – both in a large-scale meta-analysis as well as in the Company's prospective European Phase 2b trial. The DIAGNODE-3 trial has only included patients from this specific patient group that carries the common genotype known as HLA DR3-DQ2, which constitutes approximately 40 % of patients with type 1 diabetes in Europe and the US. A biomanufacturing facility is under development in Umeå, Sweden, for the manufacture of retogatein (recombinant GAD65 protein), the active ingredient in the antigen-specific immunotherapy. Diamyd Medical is a major shareholder in the stem cell company NextCell Pharma AB and in the artificial intelligence company MainlyAI 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.

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