Pressrelease 20 May 2026

Diamyd Medical receives GMP certification and manufacturing authorization for biological investigational medicinal products for human use

Diamyd Medical today announced a significant advancement in the company's operations related to the manufacturing of biological medicines (biologics). The company has now received GMP (Good Manufacturing Practice) certification as well as manufacturing authorization from the Swedish Medical Products Agency for the production of biological investigational medicinal products for human use.

The certification and authorization confirm that Diamyd Medical's manufacturing facility complies with current regulatory requirements and international quality standards for pharmaceutical production. The approval follows an inspection conducted by the Swedish Medical Products Agency and marks an important milestone in the company's continued development and long-term strategy within biological medicines.

"This is strategically very important for our manufacturing facility in Umeå," says Sofia Mayans, Head of Manufacturing Site. Receiving both GMP certification and manufacturing authorization for biological investigational medicinal products for human use is clear proof of the quality of our work and our technical expertise. The progress we are making in manufacturing, regulatory processes, and quality assurance lays a strong foundation for our continued development. I am extremely proud of the commitment and effort the team at the facility has invested to make this possible."

The authorizations strengthen the manufacturing facility's position and capabilities in the development and production of biological medicines and create improved conditions for the company's future activities.

About Diamyd Medical
Diamyd Medical is a Swedish biotechnology company focused on precision medicine approaches for type 1 diabetes and biological manufacturing. The company's investigational drug candidate retogatein, based on recombinant GAD65, was evaluated in the Phase 3 DIAGNODE-3 trial in recent-onset type 1 diabetes. The Company has established a facility for manufacturing of biological products in Umeå, Sweden. 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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