Biomay AG

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# Biomay Announces its Successful Support of Approval of First CRISPR/Cas9-based Therapy

*Vienna (ots) -*

**Biomay, a biotech contract development and manufacturing organization based in Vienna, Austria, announces successful completion of an FDA inspection qualifying Biomay as a cGMP manufacturer and supplier of recombinant nuclease Cas9 for use in gene editing therapies.**

As part of an ongoing cooperation initially dating back to 2017, Biomay has manufactured and delivered Cas9 in the course of Vertex´and CRISPR Therapeutics' clinical development of exagamglogene autotemcel (CASGEVY®), a gene edited therapy for the treatment of sickle cell disease (SCD) and transfusion dependent beta-thalassemia (TDT). CASGEVY® is the first CRISPR/Cas9-based therapy to receive marketing approval from the FDA, MHRA and positive CHMP opinion from the EMA.

Biomay has developed and validated a Cas9 manufacturing process together with the associated analytical quality control methods. This included the construction of an E. coli expression system, GMP cell banking, upstream and downstream development, as well as the establishment of a comprehensive set of analytical quality control methods. An in-depth product and process characterization program, analytical method validation, as well as full manufacturing process validation have been performed. Recently, the U.S. FDA completed a Pre-License Inspection of Biomay´s facilities and systems in the context of Vertex's Biologics License Applications (BLAs) for exagamglogene autotemcel (CASGEVY®).

Biomay´s Chief Executive Officer, Hans Huber, PhD, stated: "We are pleased that Biomay has successfully completed the inspection by the FDA. This inspection represents a significant milestone for Biomay. It underscores our unwavering commitment to quality, continuous improvement, and the highest standards in all our operations.

Angela Neubauer, SVP Client Business at Biomay added: "We are very excited about the news of the first CRISPR/Cas9-based gene editing therapy entering the market. We are proud of having successfully supported our clients in reaching that goal, for the benefits of numerous patients."

About Biomay

Biomay AG is a privately owned and fully integrated Contract Development and Manufacturing Organization (CDMO) based in Vienna, Austria. Founded in 1984, the expression of recombinant proteins by utilizing E. coli has been Biomay´s business focus yet from its beginning. Today, Biomay offers cGMP services for manufacturing of therapeutic proteins, plasmid DNA (pDNA) and messenger RNA (mRNA). The company´s scope of services comprise process and analytical development, cell banking, cGMP manufacturing of drug substance and aseptic filling of drug product.

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Medieninhalte

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