Biomay AG

29.04.2025 – 14:00 Uhr

Biomay Obtains FDA Approval for Manufacturing of Cas9 Nuclease at Headquarters Site

Vienna (ots) -

The company announced its successful approval by the U.S. Food and Drug Administration (FDA) for the manufacturing, testing and release of recombinant Cas9 nuclease from its headquarters site. Cas9 is an essential component of CRISPR-based gene editing therapies, including CASGEVY® (exagamglogene autotemcel) developed and launched by Vertex Pharmaceuticals.

Biomay's recent achievement refers to an inspection by the FDA's Center for Biologics Evaluation and Research (CBER) at Biomay's headquarters manufacturing site in Vienna, Seestadt in December 2024. No observation was found, and no Form FDA 483 was issued by the authority, allowing Biomay's headquarters site to supply Cas9 for the United States.

Biomay operates two independent cGMP manufacturing sites, a headquarters facility in Vienna Seestadt, and a second site in Vienna downtown. The authority’s approval of Biomay's headquarters site represents the company's second successful FDA inspection following the 2023 approval of Biomay's downtown facility. Biomay's headquarters site is a recently constructed, state-of-the-art biomanufacturing facility.

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 from the very beginning. Today, Biomay offers cGMP services for manufacturing of therapeutic proteins, plasmid DNA (pDNA) and messenger RNA (mRNA). The company's scope of CDMO services comprises process and analytical development, cell banking, cGMP manufacturing of drug substance and aseptic filling of drug product.

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