PRESS RELEASE

Biomay Launches FDA-Grade CRISPR/Cas9 Nuclease for Off-the-Shelf Purchase

Vienna, May 9th, 2025. Biomay, a leading manufacturer of recombinant proteins, today announced the commercial availability of its CRISPR/Cas9 nuclease, marking a significant addition to its off-the-shelf product portfolio for genome-editing applications.

Clients purchasing Biomay's Cas9 will benefit from the company's unparalleled track record and expertise as a market-registered GMP-manufacturer of the nuclease. Biomay is the FDA-approved manufacturer of recombinant Cas9 as the essential component of CASGEVY®, the very first CRISPR genome editing product on the market.

Biomay's Cas9 (internal code "BMC9") is based on the classical wild-type Cas9 nuclease from *Streptococcus pyogenes*. The Cas9 manufacturing process has been *de novo* developed, GMP-implemented and PPQ-validated by Biomay. GMP and RUO manufacturing is performed by fermentation with *E. coli* and by purification with chromatographic methods. By quality control with a comprehensive set of validated analytical assays, the consistent integrity, purity and potency of the product is secured.

"The addition of Cas9 to Biomay's off-the-shelf portfolio aligns with our mission to provide high-quality and scalable solutions for emerging therapeutic modalities," said Dr. Hans Huber, CEO of Biomay. *"With this launch, we are expanding access to a critical component of gene-editing workflows, backed by our proven manufacturing expertise. Biomay's off-the-shelf distributed Cas9, in combination with our made-to-order GMP services, will guarantee full scalability and GMP compliance throughout the whole product lifecycle."*

Biomay's latest addition further strengthens the company's position as a key supplier in the field of gene and cell therapies. The CRISPR/Cas system, a transformative gene-editing technology, whose discovery was honored with the 2020 Nobel Prize in Chemistry, enables precise and efficient modification of genomic sequences.

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About Biomay:

Biomay AG is a fully integrated Contract Development and Manufacturing Organization (CDMO) based in Vienna, Austria. Founded in 1984, the expression of recombinant proteins in *E. coli* has been Biomay's business focus yet from its beginning. Today, Biomay offers cGMP services for manufacturing of messenger RNA (mRNA), circular plasmid DNA, linear IVT-template DNA and therapeutic recombinant proteins.

Biomay operates a dedicated mRNA Competence Center for cGMP manufacturing and QC testing of mRNA drug substance and drug product (clinical, commercial). The company's scope of services comprises process and analytical development, cell banking, R&D material supply, cGMP manufacturing, lipid nanoparticle / LNP formulation and aseptic filling. Biomay's facilities are inspected by the US FDA.

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