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Corporate News

August 31, 2021

c-LEcta: Drug Master File for the use of the enzyme DENARASE® in the pharmaceutical industry accepted by the US FDA

- *Successful submission of a Master File to the U.S. Food and Drug Administration for the product DENARASE®, with assigned reference number MF 27708*
- *The Master File reduces the regulatory burden for DENARASE® customers aiming to obtain regulatory approval for pharmaceutical products in the United States*
- *c-LEcta further strengthens the market position of its best-selling product in the US market*

Leipzig, 2021-08-31 – c-LEcta, a global biotechnology company with technology leadership in enzyme engineering and bioprocess development, has announced the submission of a Master File for its best-selling product DENARASE®. The filing with the US Food and Drug Administration's Center for Biologics Evaluation and Research (CBER) is intended to assist DENARASE® customers with regulatory approvals of biopharmaceuticals, such as vaccines and advanced therapy medicinal products. The Master File demonstrates the suitable quality of DENARASE® for use in pharmaceutical products.

DENARASE®, a so-called endonuclease, is an enzyme used in the biopharmaceutical industry to remove DNA in the purification of therapeutic agents as well as vaccines. The Master File (Type II) contains detailed information on the production, processing, packaging and storage of DENARASE®.

This comprehensive documentation demonstrates to the regulatory authority that the product is of suitable quality for use in pharmaceutical products. The submission, available in eCTD format, can be used to support regulatory filings such as Biologic License Applications (BLA), Investigational New Drugs (IND), New Drug Applications (NDA), and others. "*This means the DENARASE® Master File helps to meet regulatory requirements for biopharmaceuticals, vaccines and other drugs to demonstrate their quality, safety and efficacy*," said Dr. Paula Pescador, VP of Regulatory Affairs at c-LEcta.

The FDA has accepted the submission and assigned Master File number 27708 as a reference. c-LEcta is now ready to provide its customers with a signed and designated Authorization Letter (LoA) for their product registrations with the US FDA upon request.

"*By submitting this Master File, we strengthen our customers' confidence in the quality of our product while helping to reduce the regulatory burden in their development and approval process*," commented Dr. Marc Struhalla, Founder and CEO of c-LEcta.

About c-LEcta

c-LEcta is a world-leading biotechnology company with a focus on enzyme engineering and application in regulated markets like the food and pharma industries. The company is based in Leipzig, Germany, and has established itself as a leading player in the realization of high-value biotech products, either in the form of in-house developments or in close cooperation with industry. The company currently employs more than 100 people.

c-LEcta delivers cost-efficient and sustainable production processes which open new markets and allow for better penetration of existing markets. The company is characterized by fast and efficient development of best-in-class biotech solutions and a rapid and successful market introduction and commercialization of the resulting products. This enables c-LEcta to leverage the unique potential of its core technologies. c-LEcta has a proven track record of more than ten successfully commercialized high-value industrial biotech products.

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