Press Release

CROSSJECT provides updates on the EUA filing of ZEPIZURE®

- CROSSJECT and its EUROFINS CDMO partner successfully completed the aseptic filling of all ZEPIZURE® registration batches and anticipate the delivery of the last manufacturing data needed for U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) submission in June 2025.
- CROSSJECT started the final regulatory activities for the ZEPIZURE® dossier submission under EUA.
- CROSSJECT began manufacturing EUA batches, intended as the first delivery to the CHEMPACK program, in support of U.S. national preparedness against chemical threats.

Dijon, France 07 May, 2025 (07.30 CET) -- CROSSJECT (ISIN: FR0011716265; Euronext: ALCJ), the specialty pharma company in advanced phases of development and registration for ZEPIZURE®, an emergency injectable for the management of epilepsy crises, provides an update on the process for the dossier filing of ZEPIZURE® to the FDA under the Emergency Use Authorization, in agreement with its U.S. partner, the Biomedical Advanced Research and Development Authority (BARDA) within the U.S. Department of Health and Human Services.

The critical aseptic filling steps involved in the manufacturing of ZEPIZURE® batches were completed successfully by EUROFINS, as of the date of this press release. Since the beginning of 2025, CROSSJECT has allocated extra resources to its ZEPIZURE® manufacturing process to limit any delay and swiftly process regulatory aspects. The final assembly and packaging steps and batch release data steps are on track.

The publishing activities for the ZEPIZURE® dossier submission have started, and the final manufacturing data will be inserted as soon as available. Initial feedback from the FDA, limited to confirmation of positive reception of a complete dossier, is expected within one month of the submission. Moreover, CROSSJECT began manufacturing EUA batches, intended as the first delivery to the CHEMPACK program.

Isabelle LIEBSCHUTZ, Regulatory and Quality Director of CROSSJECT said: "*We are actively working with BARDA to finalize the EUA dossier for ZEPIZURE® and are confident that we meet the expected short-term timelines for submission to the FDA. The EUA dossier will be submitted by BARDA as soon as the required manufacturing data are added. We look forward to supplying ZEPIZURE® to the U.S. CHEMPACK program, in support of U.S. national preparedness against chemical threats, upon FDA's authorization.*"

"*We are extremely grateful for BARDA's technical assistance and support toward the timely filing of ZEPIZURE®. We look forward to this important milestone as an advance toward a new solution for status epilepticus. Beyond ZEPIZURE®, this new level of validation is establishing ZENEO® as a disruptive and mainstream injectable technology. This achievement will further spur our high ambitions*

in formulating drugs with ZENEO®, satisfy our current partners, and fuel our business development activities." added Patrick ALEXANDRE, CEO of CROSSJECT.

About CROSSJECT

CROSSJECT SA (Euronext: ALCJ; www.crossject.com) is an emerging specialty pharmaceuticals company developing medicines for emergency situations harnessing its award-winning needle-free auto-injector ZENEO® platform. CROSSJECT is in advanced regulatory development for ZEPIZURE®, an epileptic rescue therapy, for which it has a $60 million contract* with BARDA. The Company's versatile ZENEO® platform is designed to enable patients or untrained caregivers to easily and instantly deliver a broad range of emergency drugs via intramuscular injection on bare skin or even through clothing. The Company's other products in development include mainly solutions for allergic shocks and adrenal insufficiencies, as well as therapies and other emergency indications.

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