Press Release

Crossject reports strong manufacturing progress with its epilepsy rescue therapy ZEPIZURE® ahead of filing U.S. Emergency Use Authorization

- Product batch announced in July yielded new regulatory stability data. These results will directly support the requested 6-month stability data in the first quarter of 2025
- Crossject expects to file for EUA early next year and to receive a positive FDA response shortly thereafter
- Crossject will manufacture additional product batches, including first commercial batches in early 2025, in anticipation of first BARDA deliveries later that year

Dijon, France, October 22 2024 (07:30 CET) - Crossject (ISIN: FR0011716265; Euronext: ALCJ), a specialty pharma company developing the award-winning needle-free ZENEO® auto-injector to deliver life-saving medicines in emergency situations, is reporting strong progress in producing the manufacturing batches of its ZEPIZURE® epilepsy rescue therapy that are required to meet the stringent standards for its upcoming anticipated authorization by the U.S. Food and Drug Administration (FDA) under Emergency Use Authorization (EUA).

Granting of the EUA will mark a major value creation milestone for Crossject and allow the company to fulfil its first sales order of ZEPIZURE® from the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response within the U.S. Department of Health and Human Services, for the CHEMPACK program. The company expects to file its EUA for ZEPIZURE® early next year and to receive a positive response from the FDA shortly thereafter.

On July 18, the company announced a significant step forward in completing the production of a new batch for its EUA. This batch will generate six months' worth of International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) stability data, allowing the determination of the shelf life of the product. The company has now successfully manufactured several product batches since December 2023. Such batches are a critical part of the data which Crossject will submit to the FDA to support its EUA.

Together with Crossject's upcoming U.S. bioequivalence study, the manufactured batches and the new registration batches Crossject will produce during the first quarter of 2025 will also represent an essential part of the company's future New Drug Application filings from 2025 onward.

"I am very pleased with the strong manufacturing progress Crossject is continuing to make in preparing for the commercialization of ZEPIZURE® epilepsy rescue therapy. Through hard work from our dedicated teams, we are now close to gathering all the data required for a successful EUA in the U.S. This crucial

regulatory step will enable us not only to start delivering orders for national preparedness efforts under our contract with BARDA but also form the bedrock for our commercial strategy in the U.S.," said Patrick Alexandre, Chief Executive Officer of Crossject.

Earlier analysis performed on clinical batches of ZEPIZURE® showed excellent stability data after 36 months, raising strong expectations for future production. The steady manufacturing progress that Crossject has been demonstrating over 2024 also shows that the transition to the laboratories of Eurofins CDMO, which executes fill-and-finish activities for ZEPIZURE® for supply to BARDA, has been flawless and has not in any way affected the data gathered about manufacturing batches so far.

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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 the U.S. Biomedical Advanced Research and Development Authority (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 medicines 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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