Press Release

Crossject confirms ZEPIZURE® supply chain readiness with another successful ISO audit for Quality Management System

- Crossject successfully passes another ISO 13485 audit for sites in Dijon and Gray (France)
- Company is ramping up supply chain to prepare for commercialization in U.S.

Dijon, France, December 19, 2024, 07:30 CET -- Crossject (ISIN: FR0011716265; Euronext: ALCJ), a specialty pharma company preparing to commercialize its epilepsy rescue therapy ZEPIZURE®, has successfully concluded a surveillance audit of its manufacturing sites, delivering new evidence its supply chain is ready to move ZEPIZURE® towards regulatory approvals and market entry.

The company maintained its ISO13485 certification after an annual audit of Quality Management System by the British Standards Institution (BSI) notified body. The certification demonstrates compliance with internationally recognised manufacturing standards of the award-winning ZENEO® needle-free auto-injector, which ZEPIZURE® is based on.

"The ISO 13485 certification confirms that our manufacturing sites and processes are fully aligned with the highest international standards. The positive results demonstrate Crossject's stringent manufacturing and quality standards, which are essential to delivering our products to market. It provides a solid foundation as we ramp up production of ZEPIZURE® in preparation for commercialization in the United States and continue to expand manufacturing capacity as necessary," said Patrick Alexandre, Chief Executive Officer 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 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.

** Contract no: 75A50122C00031 with the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Research and Development Authority*

For further information, please go to www.crossject.com, or contact:

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