Press Release

Crossject reports successful completion of European and U.S. audits for manufacturing of ZENEO® Midazolam for epileptic seizures

ISO 13485 certification renewed for manufacturing sites at Gray and Dijon

French Health Agency upgrades GMP certification to commercial use

U.S. audit readiness of Crossject Dijon and Gray manufacturing sites for a potential FDA audit

Dijon, France, September 5, 2023 -- Crossject (ISIN: FR0011716265; Euronext: ALCJ), a specialty pharma company developing needle-free autoinjectors for emergency situations, announces that its manufacturing sites in Dijon and Gray (France) have passed an annual ISO certification audit, expanded their scope of certification by French Health Agency, and received positive feedback after an audit by 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, on compliance of manufacturing ZENEO® Midazolam for the U.S. market.

''*These positive reports from both sides of the Atlantic are an important demonstration of Crossject's stringent manufacturing and quality systems standards. These are essential for Crossject to ensure quality and bring our products to market in Europe and the United States,"* **said Patrick Alexandre, CEO of Crossject.** "*ZENEO® Midazolam will provide a new, simple and reliable method of administering emergency treatment of status epilepticus seizures, delivering life-saving medicine rapidly and accurately. These certifications will enable Crossject to continue to expand manufacturing capacity as we aim to be a world leader in the self-administration of emergency needle-free injectables."*

Preparatory audits have been carried out as part of the contract with BARDA (#75A50122C00031) to evaluate compliance with cGMP required by U.S. Food and Drug Administration (FDA) rules and to assert readiness for a potential FDA audit. The audit found no critical or major observations. Crossject Dijon and Gray sites met all the requirements for manufacturing and control of its auto-injector device under Quality Systems and CGMPs. The Company previously signed a $60 million contract with the Biomedical Advanced Research and Development Authority (BARDA) to procure ZENEO® Midazolam upon receiving FDA clearance. According to the contract terms, BARDA also has options to procure additional units for up to $59 million. The total contract value if all options are exercised is $155 million.

Furthermore, the British Standards Institution (BSI) Notified Body conducted an annual audit of Crossject's quality systems and renewed its ISO 13485 certification, demonstrating compliance with internationally recognized standards across the entire life cycle of the ZENEO® needle-free injection system for its two France-based manufacturing sites in Dijon and Gray.

In addition, the French National Agency for the Safety of Medicines and Health (ANSM) has upgraded Crossject's manufacturer's authorization to allow the transition from initial clinical to commercial medicinal product use.

About Crossject

Crossject SA (Euronext: ALCJ; www.crossject.com) is developing and will soon market a portfolio of drugs for use in emergency situations (epilepsy, overdose, allergic shock, severe migraine and asthma attack). With its patented needle-free self-injection system, Crossject aims to become the world leader in self-administered emergency medications. The company has been listed on the Euronext Growth market in Paris since 2014, and benefits from Bpifrance funding.

For further information, please contact:

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