

## **Press Release**

## Crossject provides strategic update on priorities for 2024

Focusing on regulatory filings and accelerating U.S. commercialization efforts

Contract of up to \$155 million with BARDA for U.S. stockpiling continues to advance

Dijon, France February 6, 2024 –530 pm CET Crossject (ISIN: FR0011716265; Euronext: ALCJ), a specialty pharma company developing needle-free auto-injectors for emergency situations, provides a summary of recent milestones reached and an update on its strategic priorities for 2024.

In January 2024, Crossject engaged Syneos Health, a leading fully integrated biopharmaceutical solutions organization, to prepare for the commercial launch of its ZENEO-midazolam autoinjector, proposed name ZEPIZURE®, an innovative rescue therapy for epileptic seizures, including those caused by nerve agent exposure, in the United States. Syneos Health has a strong U.S. presence and significant expertise in commercializing new therapies for Crossject, as it approaches filing for regulatory approval.

Crossject is also advancing its licensing and commercialization efforts for ZEPIZURE® in other strategic markets and signed in 2023 a licensing agreement with AFT Pharmaceuticals for Australia and New Zealand and a new commercialization agreement for northern Europe.

In 2024, Crossject will especially focus on regulatory approvals for ZEPIZURE® and accelerating market access efforts in the United States. Crossject has a senior team in the U.S. and is working in close collaboration with Syneos Health to ensure a smooth and rapid launch of ZEPIZURE® upon receiving regulatory approval.

The Company previously signed a \$92 million contract with the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR) in the U.S. Department of Health and Human Services (HHS), under contract number 75A50122C00031. The contract includes \$32 million to advance the development of ZEPIZURE®, through U.S. Food and Drug Administration (FDA) approval for status epilepticus. The agreement also includes procurement of \$60 million of ZEPIZURE®, which will be delivered to the U.S. government (USG), once it is authorized for emergency use by the FDA. Delivery of ZEPIZURE will fulfill a USG requirement for an improved anticonvulsant to treat status epilepticus seizures caused by nerve agent exposure. According to the contract terms, BARDA also has options for post-marketing commitment activities and procurement of additional ZEPIZURE® units for up to \$63 million. The total contract value, if all options are exercised, is \$155 million. The Company is

actively engaged with BARDA and the FDA, and discussions are fully focused on ensuring fulfillment of requirements to file for Emergency Use Authorization (EUA) of ZEPIZURE®.

Crossject cashed in early 2023 €8 million, in addition to €4 million at the end of 2022, from a combined non-dilutive financial transaction of €14 million to accelerate the company's development. The transaction includes various loans granted by its long-standing banks (Caisse d'Epargne and BNP), Société Générale and BPI, with amortization periods ranging from 5 to 10 years.

The company also secured a total sum of around EUR 5 million over several years through the leaseback of several of its buildings.

According to the BARDA agreement terms, Crossject was reimbursed \$3.2 million for the advanced US regulatory development expenses in the first half of 2023, an increase from \$1.8 million in 2022. The company has continued its monthly regulatory development billing for this matter.

Henri de Parseval is leaving his position as Chief Operating Officer of Engineering & Industry at Crossject, with a strong organization in place to support the company's drive for approvals and commercialization of ZEPIZURE®. Didier Morin, who joined Crossject in mid-2023 as Industrial Director, assumes those responsibilities.

"Crossject is starting 2024 with strong momentum as our discussions with FDA related to the requirements necessary for Emergency Use Authorization of ZEPIZURE® continue moving forward on a good track. In parallel, we are preparing for regulatory filings of ZEPIZURE®, our unique treatment which can be administered by anyone in seconds, to save lives in emergencies. We are working closely with our strategic partners market access activities in the US," said Patrick Alexandre, CEO of Crossject.

"I would like to thank Henri de Parseval for his contributions to Crossject, providing a strong foundation for our future work, and I wish him all the best for the future."

## **About Crossject**

**Crossject SA** (Euronext: ALCJ; www.crossject.com) is an emerging specialty pharma company. It is in advanced regulatory development for ZEPIZURE®, an epileptic rescue therapy, for which it was awarded a \$92 million contract with the U.S. Biomedical Advanced Research and Development Authority (BARDA) for the FDA Approval and procurement of ZEPIZURE® for the US government.

ZEPIZURE® is based on the Company's award-winning needle-free autoinjector ZENEO®, designed to enable patients and untrained caregivers to easily and instantly deliver emergency medication via intramuscular injection on bare skin or even through clothing. The Company's other products in development include rescue therapies for allergic shocks, adrenal insufficiencies, opioid overdose and asthma attacks.

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