



## Press Release

# Crossject announces publication of clinical data on ZEPIZURE<sup>®</sup> in *Neurology and Therapy*

Clinical study performed in 2022 now published in peer-reviewed *Neurology and Therapy*

Further elaborates on bioequivalence demonstrated versus European listed drug Dormicum<sup>®</sup>

Early onset can be expected thanks to early blood concentration of midazolam with ZEPIZURE<sup>®</sup>

Low variability confirmed, a key advantage vs other forms of administration, such as intranasal

**Dijon, France May 30, 2024 -1030 am CET- Crossject (ISIN: FR0011716265; Euronext: ALCJ), a specialty pharma company in advanced phases of development and registration for ZEPIZURE<sup>®</sup>, its emergency treatment for the management of epileptic crises based on its award-winning needle-free auto-injector ZENEO<sup>®</sup>, announces the publication of clinical data in the peer-reviewed journal *Neurology and Therapy*.**

Seizures require urgent treatment when they last longer than 5 minutes and when prolonged, can lead to damage to the brain, coma, and ultimately death. Midazolam injected in the muscle has become the first-line treatment of choice for long-lasting seizures. ZEPIZURE<sup>®</sup>, based on the ZENEO<sup>®</sup> autoinjector and previously known as ZENEO<sup>®</sup> Midazolam, provides for needle-free delivery of midazolam with significant associated advantages.

The article now published outlines full results of a clinical study conducted in 2022, demonstrating that ZENEO<sup>®</sup> allows injecting midazolam intramuscularly, on bare skin or through clothing, to the same extent as a syringe equipped with a 30mm needle (Dormicum<sup>®</sup>), and with a 2-fold lower variability as compared to that usually observed for routes of administration such as intranasal. In addition, ZEPIZURE<sup>®</sup> enhanced the midazolam absorption during the first minutes post-injection, suggesting that seizure treatment may be efficient sooner. The safety profile, level of pain and sedation were comparable to intramuscular syringe injection. The maximum blood concentration reached with ZEPIZURE<sup>®</sup> is not above that with Dormicum<sup>®</sup>, which is a good indication in terms of safety.

*“The ZENEO<sup>®</sup> needle-free auto-injector is an innovative, prefilled, single-dose, ready-to-use, two-step device that could become the best in-class device for midazolam intramuscular administration in emergencies. Delivery of the full, 10mg dose in a safe manner, with low variability and in convenient conditions, is a decisive advantage in emergency situations,”* said **Olivier Lacombe, PhD, Director Pharmaceutical Development of Crossject and lead author of the article.**

The 4-period, crossover and randomized study was conducted on 40 healthy subjects, with gender, ethnicity and body mass index diversity (ClinicalTrials.gov NCT05026567). Data reported in November

2022 showed that the primary objective was met in the trial, with the evaluation of the relative bioavailability of midazolam after injection with the needle-free autoinjector ZENEO® (10mg midazolam in 0.625mL). This was compared to injection of Dormicum® (10mg midazolam in 2mL) by a conventional syringe with a 30mm needle, into the thigh on bare skin.

*“The detailed clinical results published today in Neurology and Therapy on ZEPIZURE® are exciting, as they outline quick delivery of a life-saving medicine,”* said **Patrick Alexandre, CEO of Crossject.**

Click [here](#) for the full article.

### **About Crossject**

**Crossject SA** (Euronext: ALCJ; [www.crossject.com](http://www.crossject.com)) is an emerging specialty pharma company. It 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). 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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