

CLINICAL DEMONSTRATION OF ZENEO® EFFICIENCY FOR INTRAMUSCULAR INJECTION OF MIDAZOLAM

- **Primary endpoints met and results in line with expectations**
- **No impact of clothing on the intramuscular injection with ZENEO®**

Dijon, November 2, 2022 at 8am

CROSSJECT (ISIN: FR0011716265; Mnémo: ALCJ), a specialty pharma company that is developing and will soon be marketing a portfolio of drug / device combinations for use in emergency situations, is releasing positive headline results of its clinical study with ZENEO® midazolam. The 4-period, crossover and randomized study was conducted on 40 healthy subjects, with gender, ethnicity and BMI¹ diversity (ref ClinicalTrials.gov Identifier NCT05026567).

The primary objective was met. It was the evaluation of the relative bioavailability of midazolam after injection with the needle-free autoinjector ZENEO® (10mg midazolam in 0.625mL) compared to injection of DORMICUM® (10mg midazolam in 2mL) by a conventional syringe with a 30mm needle, into the thigh on bare skin. The bioequivalence was achieved both on Cmax² and on AUC³, with no change of Tmax⁴. The 90% Confidence Intervals were respectively of [84-98] for Cmax ratio, and [100-108] for AUC ratio.

No serious adverse events were reported, and there was no difference in safety profile between the tested conditions. Only 2 subjects dropped out before their fourth and last injection, not for safety but for personal reason.

¹ BMI : Body Mass Index, a measure of a person's thickness or thinness

² Cmax: maximum blood Concentration of the drug

³ AUC : Area Under the Curve reflecting blood levels of a drug over time, an indication of the dose received

⁴ Tmax : time to reach Cmax



As secondary objectives, the study aimed to test the intramuscular injection of midazolam with ZENEO® into thigh through clothing, compared to injection into thigh on bare skin with ZENEO® and with DORMICUM®. The 90% Confidence Intervals were respectively of [87-101] and [79-92] for Cmax ratios, and [87-95] and [91-98] for AUC ratios, with no change in Tmax. These results allow considering a much faster emergency treatment, without having to remove patient's clothing in an epileptic seizure situation.

In addition, an intramuscular injection with ZENEO® midazolam in the ventrogluteal site was shown to be bioequivalent to an injection in the thigh on bare skin either with a conventional syringe or with ZENEO®.

Finally, ZENEO® and the syringe with intramuscular needle showed a similar and low inter-subject variability of midazolam pharmacokinetics. This is an additional demonstration that an injection with ZENEO reached the muscle in the same way as an injection with a syringe and a 30 mm needle.

As a summary, the outcomes of this clinical study are a great achievement for Crossject, as they demonstrate the effectiveness of an intramuscular injection with the needle-free autoinjector ZENEO® into thigh with or without clothing, as well as into the ventrogluteal site.



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About CROSSJECT • www.crossject.com

CROSSJECT (ISIN: FR0011716265; Ticker: ALCJ; LEI: 969500W1VTFNL2D85A65) is developing and is soon to market a portfolio of drugs dedicated to emergency situations: epilepsy, overdose, allergic shock, severe migraine and asthma attack. Thanks to its patented needlefree self-injection system, Crossject aims to become the world leader in self-administered emergency drugs. The company has been listed on the Euronext Growth market in Paris since 2014; it receives funding from the United States BARDA (Biomedical Advanced Research and Development Authority) and from Bpifrance.