

First injections of ZENEO® Midazolam for the clinical bioequivalence study

Dijon, 24 May 2022

CROSSJECT (ISIN: FR0011716265; Ticker: ALCJ), a specialty pharma company developing and soon to market a portfolio of drugs for use in emergency situations, announces the first injections of ZENEO® Midazolam for the clinical bioequivalence study.

Patrick Alexandre, Crossject CEO, said: *"We are pleased to announce that the pivotal clinical study for ZENEO® Midazolam has begun. This is an important step, as it is part of the evaluation of the marketing authorisation application. The results are expected in the autumn."*

Crossject is beginning its clinical bioequivalence study for ZENEO® Midazolam with the first injections. The resulting data will be presented in the Marketing Authorisation Application (MAA) file.

The objective of the study is to compare the plasma concentration of a ZENEO® Midazolam injection in healthy subjects with that of a syringe fitted with a conventional intramuscular needle filled with the regulatory reference drug midazolam. As a reminder, the previous clinical bioequivalence study for ZENEO® Methotrexate¹ demonstrated the equivalence of subcutaneous injection.

The two main criteria used to assess bioequivalence are (i) the area under the curve (AUC) – i.e. the dose of drug received by the subject, which must be between 80% and 125% of that observed for the reference drug – and (ii) peak plasma concentration (C_{max}).²

All injections are expected to be completed over the next two months. The full results of the bioequivalence study are expected in the autumn.

¹ <https://clinicaltrials.gov/ct2/show/NCT03103334?term=zeneo&draw=2&rank=5>

² Full study: <https://clinicaltrials.gov/ct2/show/NCT05026567?term=zeneo&draw=2&rank=1>



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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 needle-free 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, and benefits from Bpifrance funding.