CROSSJECT receives authorization to conduct Zeneo® Midazolam bioequivalence study

- Major milestone for the payment of the second tranche (€ 2.8M) of Bpifrance's PIAVE financing to CROSSJECT
- Significant competitive edge of Zeneo® in intramuscular injection on subjects having an epileptic seizure

March 6th, 2017

Crossject, (ISIN: FR0011716265 ; Mnemo: ALCJ), specialty pharma developing a portfolio of innovative combined drugs dedicated to emergency situations, has received authorization[1] from competent health authorities to launch the bioequivalence study of Zeneo® Midazolam on healthy volunteers. This authorization is the main milestone for the € 2.8M payment of the second tranche of the PIAVE financing granted by Bpifrance.

This study will be conducted by Parexel in the course of 2017 and will be used to file for marketing authorization (MA) for Zeneo® Midazolam in the USA and in the European Union. With a proven bioequivalence to a reference drug, the efficacy of a pharmaceutical product is considered demonstrated without the need for further clinical studies.

Zeneo® Midazolam is a pioneering treatment in the management of epileptic seizure outside hospitals and medical settings. It will be the first product for adult epileptic patients to be used by caregivers to stop a seizure. There are 50 million epileptic people worldwide.[2]

Zeneo® Midazolam is administered intramuscularly, a route for which Zeneo®'s effectiveness was clinically demonstrated[3] in 2016. Although many emergency products are administered intramuscularly, allowing quick absorption of the pharmaceutical substance injected, there is a lack of solid proof that currently available auto-injectors realize an intramuscular injection for all patients, including those with a high BMI[4]. The European Medicines Agency therefore asked current manufacturers of adrenaline auto-injectors to conduct pharmacodynamic studies[5] to validate their systems, comparing them to a syringe[6] with a 25mm needle.

Besides, a needle length increase to penetrate the muscle could increase the risk of accidents such as those published in 2015[7] for auto-injectors with 15mm needles. These needle-linked accidents, are more

[1] Subject as usual to providing the Certificates of Analysis of the clinical batch to be used in the study
[2] WHO, February 2016, http://www.who.int/mediacentre/factsheets/fs999/fr/
[3] https://www.ncbi.nlm.nih.gov/m/pubmed/27928757/?i=1&from=Zeneo®
[4] BMI: body mass index
[5] http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Adrenaline_auto_injectors/human_referral_000367.jsp&mid=WC0b01ac05805c516f
[6] NB: "syringe" and not "auto-injector" as incorrectly mentioned in Crossject's press release dated 12th December 2016
[7] https://www.ncbi.nlm.nih.gov/pubmed/26452720
Lacerations and Embedded Needles Caused by Epinephrine Autoinjector Use in Children, Brown et al

likely on a subject convulsing during an epileptic seizure. Obviously they will not occur with Zeneo®, which has no needle and injects the full medication dose in 1/10th of a second.

Patrick Alexandre, President and founder of CROSSJECT, declared: "This authorization was a key milestone for the PIAVE financing. Zeneo® Midazolam is a true innovation in the field of epilepsy. We are at the heart of Crossject's strategy of high added-value emergency medications to save lives."

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About CROSSJECT • www.CROSSJECT.com

CROSSJECT (ISIN: FR0011716265; Mnemo: ALCJ) is a specialty pharma developing and conceiving a portfolio of drug candidates for emergency situations (overdoses, acute migraines, epilepsy, temporary paralysis, anaphylactic chocks, etc.). With Zeneo®, its patented needle-free injection system, CROSSJECT provides efficiency to emergency situations by allowing simple drug self-administration. CROSSJECT is listed on Alternext of Euronext Paris since February 2014.

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