CROSSJECTconfirms the development plan for ZENEO® Sumatriptan

Ongoing consultation with FDA – Pre IND meeting n°127,044
Launch of stability tests
Confirmed calendar of the bioequivalence study

Chenôve, July 16th 2015, 05:35pm CET - CROSSJECT (ISIN: FR0011716265 ; Mnemo: ALCJ), the creator of Zeneo®, the world most advanced needle-free injection system, confirms the correct execution of the clinic and regulatory development plan of Zeneo® Sumatriptan. In the USA, CROSSJECT began dialogue with the FDA (*Food and Drug Administration*) as part of a Pre-IND meeting (*Pre-investigational New Drug Application*) procedure. Stability tests of sumatriptan within the Zeneo® device will be starting in July. Following the selection of the CRO, announced on June 9th 2015, CROSSJECT confirms the calendar of the bioequivalence study of Zeneo® Sumatriptan which is expected in the second half of 2015.

Patrick Alexandre, CEO and founder of Crossject declared: *"By confirming the clinical development plan of Zeneo® Sumatriptan, CROSSJECT meets its objectives for 2015 regarding this product. This further confirms our capacity to implement CROSSJECT's development plan. In line with our strategy, we develop our supergeneric proprietary products portfolio based on a unique needle-free injection system. We aim to present these products to our potential partners at an advanced development stage, to better benefit from the potential of our portfolio."*

Zeneo® Sumatriptan's bioequivalence study will begin in the next fall, and is considered as the only study needed to complete the product filing for market authorization (AMM) in Europe. The clinical study will be conducted in South-Africa on 72 eligible patients by Parexel, the CRO (Contract Research Organisation) chosen by CROSSJECT. The aim of this study is to show that administration with the Zeneo® needle-free injection system in the treatment of facial algia and acute migraine has the same effect than administration with injector pens. In parallel, CROSSJECT is launching the stability tests of sumatriptan in July 2015; they are required to file for market authorization.

CROSSJECT is currently consulting with the FDA on Zeneo® Sumatriptan's development plan in the USA as part of a Pre-IND procedure with the 127,044 number.
European and American markets of facial algia and acute migraine treatment concern a patient population of about 19 million. Under its oral form, sumatriptan can lead to serious side effects and the time needed for it to be effective can be up to 2 hours. Furthermore, sumatriptan absorption is almost impossible during nausea or vomiting crisis. Marketing efforts done on its injectable form during many years show that patients are happy to use this form as long as there is no needle. The proof of concept for the Zeneo® device has already been established during a bioequivalence study conducted on Zeneo® Methotrexate in 2014. The patient benefit from

an unequalled level of comfort during the period of treatment, thanks to Zeneo® and the ease of self-injection it provides.

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About Crossject • www.crossject.com

Crossject is using its world-leading needle-free injection system, ZENEO™ to develop an attractive pipeline of high value SUPERGENERICS These needle-free products, which are based on well-known injectable drugs (chemicals & biologics), are designed to enhance patient safety, compliance and comfort.
Crossject's needle-free, pre-filled, single-use ZENEO™ injection systems are unique in that they can be tailored to deliver drugs intra-dermally, subcutaneously and intramuscularly. This means that ZENEO™ can allow a wide range of drugs and vaccines for a broad range on indications to be developed and approved in a very short period of time. Outside its own portfolio of SUPERGENERICS, Crossject anticipates partnering ZENEO with other pharma/biotech looking to improve the life cycle management of their key drugs or biologics.
CROSSJECT is listed on Alternext Paris (Mnemo: ALCJ, ISIN: FR0011716265)

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