CROSSJECT launches bioequivalence clinical study with ZENEO® Methotrexate

- Single bioequivalence clinical study needed to support the marketing authorization application for Zeneo® Methotrexate in Europe
- Commercialization of ZENEO® Methotrexate remains on track for 2015

Chenove, July 7, 2014, 17:45 CET – CROSSJECT (ISIN: FR0011716265, Ticker: ALCJ), creator of ZENEO®, the world's most advanced needle-free self-injection device, has launched its key single bioequivalence clinical study with ZENEO® Methotrexate. The start of enrollment of subjects in this study is an important corporate milestone for CROSSJECT.

This bioequivalence study is the only clinical study needed to support the filing of the marketing authorization (MA) application for ZENEO® Methotrexate in Europe. This novel needle-free form of methotrexate is being developed for the treatment of rheumatoid polyarthritis.

The bioequivalence study will be conducted at a single center in South Africa. It will recruit 58 subjects with the aim of generating data from 48 evaluable subjects. The aim of the study is to demonstrate that administration using the ZENEO® needle-free injection device produces the same effects as a conventional injection administration. The study will measure the blood levels of methotrexate produced by the two administration systems, regularly across a 24 hour period. The results from the bioequivalence study are expected in the fourth quarter of 2014.

The launch of this study also enables CROSSJECT to confirm that it still expects the launch of Zeneo® Methorexate in France to take place in late 2015. This short time line reflects the rapid regulatory process for generic drugs in combination with the Zeneo® needle-free system. Crossject already has a partner in place to commercialize Zeneo® Methorexate in France and is looking for partners for the commercialization of this exciting new treatment for rheumatoid polyarthritis internationally.

Patrick Alexandre, President and founder of CROSSJECT, stated: *"We are very pleased to have launched this key bioequivalence study with the first of our three current pipeline products. We are very confident that this study will deliver positive results as a pre-filled injectable presentation of methotrexate has already been approved. Furthermore, our Zeneo® device has already successfully completed a broad ranging pre-clinical program including laboratory tests on human skin. The results of the bioequivalence study will allow us to meet our objective of launching of Zeneo® Methorexate in France, in 2015, via our commercial partner."*

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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 or New Therapeutics Entities. 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 companies looking to improve the life cycle management of their key drugs or biologics.