Crossject Reports Positive results from bioequivalence study with needle free ZENEO® Methotrexate

- The needle-free injection with ZENEO® Methotrexate produces similar blood levels to the current injectable formulation
- Study data an important milestone in the development of CROSSJECT's portfolio of ZENEO® needle-free products

Chenôve, November 24th, 2014, 8:30 – CROSSJECT (ISIN: FR0011716265 ; Mnémo: ALCJ), the creator of ZENEO®, a needle free injection system, announces the similarity between the ZENEO® Methotrexate needle-free injection system and the current injectable formulation. ZENEO®Methotrexate has met its objectives in a key bioequivalence study, enabling CROSSJECT to show the clinical effectiveness of its innovating product, also called "needle free injection".

This clinical study, also called a bioequivalence study, is the only one needed to confirm the effectiveness and the safety of the product with a view to complete the filing of the marketing authorization (MA) application for ZENEO® Methotrexate in Europe. Moreover, CROSSJECT'S clinical development plan for ZENEO® Methotrexate has received approval from the ANSM and the FDA.

ZENEO® Methotrexate, an innovative needle-free and subcutaneous auto-injection device, has been developed principally for the treatment of rheumatoid polyarthritis, a chronic inflammatory disease which can lead to deformities and deterioration of joints. Methotrexate is already registered in the form of pre-filled syringes.

The single center bioequivalence study was conducted on 52 subjects. The results demonstrate the similarity between ZENEO® needle-free administration and current needle injection systems, as the principal objectives of the study were achieved. ZENEO® delivered the desired dose of methotrexate (25 mg).

The success of this study has allowed CROSSJECT to confirm ZENEO®'s potential to offer better treatment compliance compared to current injection systems. It also promises to be better tolerated when compared to oral formulations of methotrexate.

ZENEO® Methotrexate already has a commercialization partner in France. These results should help accelerate current negotiations with potential European and international commercialization partners for this promising product.

Patrick Alexandre, President and founder of CROSSJECT, stated: "We are very pleased with the positive results of this study, which confirm the effectiveness and reliability of our ZENEO® device. These results represent an important landmark in the development of our needle-free ZENEO® device and make us more optimistic about our ability to successfully execute our strategy and build value from our portfolio of exciting supergeneric products."

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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 looking to improve the life cycle management of their key drugs or biologics.

CROSSJECT is listed on Alternext Paris (Mnemo : ALCJ, ISIN : FR0011716265)