

Press release

## **Business update November 2018**

# Resumption of production First Marketing Authorisation¹ applications to be filed in 2020

Dijon, 21 November 2018

CROSSJECT (ISIN: FRoo11716265; Ticker: ALCJ), a specialty pharma company developing and soon to market a portfolio of drugs for use in emergency situations, provides a business update.

Patrick Alexandre, CEO of Crossject, said: "I am pleased to see the resumption of production of the component that caused the incident this summer, in perfect technical conditions and a demanding quality environment. It is the culmination of weeks of intensive work by Crossject's teams, whom I thank. The production of ZENEO® will resume in early 2019, in line with our goal of filing our first MA applications in 2020. The resumption of production will also allow us to continue our commercial negotiations, and we expect to sign licensing agreements in 2019."

#### Resumption of production

Production of the component for which a supplier encountered difficulties has resumed. Our entire industrial chain is once again fully operational, backed up by the very good quality of early tests carried out upstream.

After a few weeks of standard tests and verifications, production of clinical batches will start again in the spring of 2019.

A total of 350,000 glass tubes intended to contain the drug solution included in the ZENEO® system have been produced to date. Some 25,000 actuators have been produced since the pyrotechnic production line was insourced.

In addition to the measures already taken to secure certain equipment (preventive maintenance, spare parts), we intend to launch the duplication of key equipment so as to further reduce our

<sup>&</sup>lt;sup>1</sup> MA: Marketing authorisation issued by the relevant regulatory authorities



sensitivity to unforeseen events and help ramp up production.

#### First Marketing Authorisation applications to be filed in 2020

Our MA application filing priorities are ZENEO® Midazolam in Europe, and ZENEO® Naloxone and ZENEO® Adrenaline in Europe and the US.

Industrial transfer to production sites (a key step prior to the completion of clinical batches and registration with a drug) is underway for ZENEO® Naloxone and nearly complete for ZENEO® Midazolam.

#### Progress in commercial negotiations

Crossject is still in talks with several potential partners with a view to signing licensing agreements in 2019. They bear chiefly on ZENEO® Midazolam, ZENEO® Naloxone and ZENEO® Sumatriptan, and mainly concern the United States and/or Europe, depending on the drug in question. Ongoing commercial negotiations and the FDA's confirmation last August of the priority need for opioid overdose rescue kits comfort Crossject in its decision to position ZENEO® Naloxone at the top of its pipeline.

Crossject has published a booklet (in French) entitled "2017-2018: two key years marking our transformation from medtech to pharmaceutical company". It describes progress made over the last two years, illustrated by interviews. You can find it here.



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### About CROSSJECT · www.crossject.com

Crossject (ISIN: FRoo11716265; Ticker: ALCJ; LEI: 969500W1VTFNL2D85A65) is developing and is soon to market a portfolio of drugs dedicated to emergency situations: epilepsy, severe migraine, allergic shock, overdose 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 has notably received financing from Bpifrance.