

Business update: Focus on progress during last summer

Dijon, 3 September 2019

CROSSJECT (ISIN: FR0011716265; Ticker: ALCJ), a specialty pharma company developing and soon to market a portfolio of drugs for use in emergency situations, provides an update of progress in its activity.

Patrick Alexandre, CEO of Crossject, said: *“The first year-half was rich in significant announcements, with the gain of pharmaceutical establishment status, loan financing and the signing of a marketing agreement in epilepsy. Since then, Crossject has continued its progress on its industrial facilities, and its discussions with the FDA¹ on ZENEO® Naloxone. I would like to thank our teams for their commitment to achieving our goal of submitting the first MA² dossiers in Europe and the United States in 2020.”*

Fresh progress on industrial facilities

The company made substantial progress in preparing the ramp-up of the capacity of its manufacturing facilities, with the automation of the tube cleaning operation, one of the three key steps in sterilising ready-to-fill tubes. The equipment has been fitted on the PARC® production module, and was successfully tested in July.

Continuation of the clinical batch production process

The quality and technical steps required for the production of clinical batches came out positive. The production of three batches of 5,000 test units demonstrates that product sterility is maintained throughout the entire production cycle.

Update on our Quality system

In preparation for the international ISO 13485 certification standard for medical equipment, complementary to pharmaceutical establishment status, Crossject called on an external firm to conduct a mock audit. The results demonstrated the soundness of Crossject’s quality approach and allowed it to embark on the certification process.

¹ FDA: Food and Drug Administration, the US regulatory authority

² MA: Marketing authorisation issued by the relevant regulatory authorities



Continuation of the dialogue engaged with the FDA on ZENEO® Naloxone

The discussions between Crossject and the FDA on the development of ZENEO® Naloxone are continuing. The FDA is keen to identify emergency treatments to address the increase in deaths due to consumption of opioid-based painkillers. Opioid overdoses are an epidemic in the United States and represent a real health crisis. With ZENEO® Naloxone, Crossject hopes to provide an innovative solution.

Next release:

9 September 2019 (after trading): First-half 2019 results

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About CROSSJECT • www.crossject.com

Crossject (ISIN: FR0011716265; Ticker: ALCJ; LEI: 969500W1VTFNL2D85A65) is developing and is soon to market a portfolio of drugs dedicated to emergency situations: epilepsy, overdose, allergic shock, severe migraine 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 benefits from Bpifrance funding.