Business update

Confirmation of the schedule of marketing authorisation filings

Dijon, 8 June 2017

CROSSJECT (ISIN: FR0011716265; Ticker: ALCJ), a specialty pharma company developing a portfolio of innovative combined drugs for use in emergency situations, provides a business update in line with its financial calendar.

Crossject is continuing its strategy announced in November 2016, focusing on the development of emergency drugs and the signing of distribution licensing agreements, particularly in the United States.

A financial structure in line with development needs

The company's cash position was reinforced by the success of the recent capital increase (€5 million raised). It will be further strengthened by payments related to ongoing public aid programmes (PIAVE, RAPID, Eurostars, Research Tax Credit) and revenue from possible new partnerships and grants.

This puts the company in a position to continue its development efforts focused on the production of clinical batches,[1] the conduct of bioequivalence studies and the production of commercial batches, which are essential for the filing of marketing authorisation[2] dossiers. The company also plans to continue work to establish licensing agreements, particularly in the United States.

Continued product development

Crossject plans to launch clinical studies for Zeneo® Sumatriptan (severe migraine), Zeneo® Adrenaline (anaphylactic shock) and Zeneo® Midazolam (epilepsy) by the end of the year. As announced earlier, the company is also set to launch the production of Zeneo® Sumatriptan registration batches[3] in 2017.

Crossject confirms its schedule for the filing of marketing authorisation dossiers announced in November 2016.

Extension of production capacity

A dozen people are already working on production lines using innovative processes[4] at Crossject's two sites: the glass tubes containing the medicated solution are toughened in Gray and then prepared in Dijon (washing, siliconisation, sterilisation), in the manufacturing unit inaugurated on 13 April. They will be routed ready to fill to Cenexi, where work continues to install two production lines. The first, known as the fast-track line, has been delivered and is in the process of qualification in order to be able to produce clinical

[1] Clinical batch: batch intended for therapeutic trials on humans.
[2] Marketing authorisation: all medicinal products must be authorised for marketing by the authorities of the relevant country (ANSM in France, FDA in the United States) before they can be brought to market.
[3] Registration batch: produced in line with the quantity and quality conditions required for marketing.
[4] Several patents granted or in process of being obtained.

and commercial batches starting in autumn 2017. The second, known as the scale-up line, is scheduled to open in 2018. It is intended for mass production.

Commercial negotiations

Crossject reaffirms its objective of negotiating licensing agreements in the United States in 2017. The search for partnerships for Zeneo® Sumatriptan in the United States, initiated in the first quarter, is going to plan. As the study carried out by Bionest Partners on the commercial potential of Zeneo® Midazolam in the United States produced very positive conclusions, Crossject plans to launch a specific tendering process by the end of the year so as to get full value from the potential of this drug.

Next release:

Thursday 21 September 2017 (after trading): interim 2017 results

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About CROSSJECT • www.crossject.com

Crossject (ISIN: FR0011716265; Ticker: ALCJ) is a specialty pharma company developing a portfolio of drugs for use in emergency situations (severe migraines, epilepsy, temporary paralysis, anaphylactic shock, overdoses, etc.). With Zeneo®, its patented needle-free injection system, Crossject provides an efficient response to emergencies by enabling the simple self-administration of drugs. Crossject has been listed on Alternext since February 2014.

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