CROSSJECT

Press release

February 2018

ZENEO® Midazolam earns the FDA orphan drug designation for the treatment of status epilepticus

The American Food and Drug Administration (FDA) has granted Orphan Drug Designation to ZENEO® Midazolam for the treatment of status epilepticus (epileptic seizure lasting longer than 5 minutes).

Epilepsy is a neurological disorder that affects **50 million people worldwide**[1]. Epileptic seizures can have serious neurological and physical consequences. **Through its ease-of-use, ZENEO® Midazolam enables the rapid treatment of those seizures**, and thus constitutes a major, life-saving advance in the treatment of the disorder.

The orphan designation for ZENEO® Midazolam improves Crossject's international visibility and gives impetus to its current negotiations for partnerships with pharmaceutical laboratories. The designation also reinforces **Crossject's ambition of becoming the world's leading pharmaceutical laboratory for self-administered emergency products.**

Epilepsy: one of the most severe neurological disorders

Epilepsy is a neurological disorder that can develop at any age. Epileptic seizures are caused by a sudden, abnormal increase in the electrical activity of thousands of cerebral nerve cells, resulting in the disruption of inter-neuron communication.

Epilepsy affects 50 million people worldwide, including 6 million in Europe[1]. Today still, a significant number of epileptic seizures are fatal. For example, estimates suggest that between 2,270 and 7,000 deaths could be prevented every year in the European Union[2].

Seizure treatment: a vital necessity

Currently, t**here is no practical rescue treatment to stop a seizure in adults before the arrival of an emergency medical team.** Once there, the latter will usually administer lorazepam, diazepam or midazolam intravenously[3].

However, status epilepticus can cause **severe neurological damage or even become life-threatening:** in the absence of rapidly-initiated treatment, the death rate reaches 20%[4].

ZENEO® Midazolam: a breakthrough in saving lives

ZENEO® Midazolam takes effect in an average of 1.2 minutes[5], rapidly stopping an epileptic seizure. By making emergency treatment immediately available, it radically changes the management of epileptic seizures.

ZENEO®: a technology unique worldwide

ZENEO® is a prefilled, single-use device capable of propelling a medical formulation through the skin in only 50 milliseconds. Its injection parameters are entirely tailor-made according to the viscosity, dosage and injection route (subcutaneous or intramuscular) of the drug formulation. For a needle-free auto-injector, this versatility is unmatched anywhere in the world.

The novel technology and revolutionary design of ZENEO® make it particularly well-suited for patients facing emergency situations, and resultantly, Crossject has chosen to focus its efforts on that segment. Today, the company's portfolio contains eight products in advanced stages of development, **including 7 emergency treatments, 5 of which are intended for life-threatening situations.**

THE CROSSJECT PORTFOLIO

- **ZENEO® Midazolam** for epileptic seizure
- **ZENEO® Sumatriptan** for migraine
- **ZENEO® Naloxone** for opioid overdose
- **ZENEO® Hydrocortisone** for acute adrenal crisis
- **ZENEO® Apomorphine** for off episodes in Parkinson's disease
- **ZENEO® Adrenaline** for anaphylactic shock
- **ZENEO® Methotrexate** for rheumatoid arthritis
- **ZENEO® Terbutaline** for severe asthma crisis

About Crossject

ZENEO® is the manifestation of Crossject's expertise in the needle-free injection of therapeutic formulations, an expertise unmatched elsewhere in the world. ZENEO® is the result of nearly 20 years of R&D and has been granted close to 400 patents.

The company's portfolio currently contains eight products in advanced stages of development, including 7 emergency treatments, 5 of which are intended for life-threatening situations. Crossject aims to become the world leader in self-administered emergency treatments.

Crossject has been listed on the Euronext Growth market since February 2014. The company has completed three fund raising campaigns and furthermore received financing from the French Ministry of Defense and grants from Bpifrance as part of the Investissements d'Avenir program.

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