Provepharm Receives Favorable EMA Review of its Methylthioninium Chloride Proveblue

Marseille, 11 March, 2011 - Provepharm, a start-up specialized in the development of pharmaceutical applications, announces today that, following a one-year centralized review procedure, the European Medicines Agency's Committee for Medicinal Products for Human Use (CMPH) issued a favorable assessment of its methylthioninium chloride Proveblue on 17 February. As a result, the company's Marketing Authorization Application (MAA) should be approved shortly, opening the way for Provepharm to commercialize the product in the 27 countries of the European Union and the three attached countries (Norway, Iceland and Liechtenstein). The product belongs to the category of antidotes.

The French Health Safety Agency Afssaps already granted a Compassionate Use Authorization ("ATU de cohorte" in French) for methylthioninium chloride Proveblue on 22 November 2010, which enabled Provepharm to make the product available to French hospitals.

Methylthioninium chloride (or methylene blue) has always been used extensively in diagnostic and therapeutic applications. Up to now, however, it generally contained high levels of heavy metals that were toxic for patients. Provepharm has developed a new process that has considerably reduced the amounts of organic and inorganic impurities (heavy metals) in the compound. This process was considered innovative by the European authorities, enabling Provepharm to submit an MAA under the EMA's centralized review procedure. The patents filed by Provence Technologies, Provepharm's parent company which developed Proveblue™, protect this innovation up to 2027.

"This first marketing authorization gives Provepharm very substantial commercial potential, with annual revenues forecast to reach 30 to 40 million euros within five years," said Provepharm's chairman, Michel Féraud. "We are actively looking for distributors in the different markets covered by the MAA, and we also hope to make the product available in other markets, starting with the United States and Japan. Talks are underway to select partners in these two regions."

Proveblue™ is the first compound developed by Provepharm to have passed every stage of development and regulatory approval. This active principle is compliant with the monograph of the European Pharmacopoeia and prevailing pharmaceutical demands. The company is also planning to contact the United States Pharmacopoeia to suggest that it updates the monograph for methylene blue in the United States.

In view of these international developments, Provepharm's management team will be present at DCAT Week (the Annual Congress of the Drug, Chemical and Associated Technologies Association) in New York on 14-15 March.

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About Provepharm

Provepharm is a subsidiary of the Provence Technologies Group that is specialized in the development and commercialization of pharmaceutical drug products derived from active pharmaceutical ingredients (APIs) synthesized and patented by its parent company. Provepharm's expertise is assured by a management team with extensive experience in the international pharmaceutical industry.

Anticipating the pharmaceutical industry's needs, Provepharm started by adopting a strategy of repositioning and rehabilitating known compounds in new indications. This development strategy was designed to cater for the growing demand for APIs that comply with current quality demands.

Provepharm supplies the pharmaceutical industry with pharmaceutical-grade methylene blue and has embarked on studies of its efficacy in indications under development, such as malaria, as well as offering the compound for research into neurodegenerative diseases.

Provepharm is based in Marseille and employs 10 people. The company has raised funding of around 6 million euros to date from its founders, business angels and venture capital companies. Provepharm is one of 2,000 firms that have received the OSEO Excellence designation of the French Innovation Promotion Agency OSEO.

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