Provepharm receives FDA approval for marketing of ProvayBlue™ (methylene blue) Injection

ProvayBlue™ is the first approved methylene blue injection in the United States

Marseille, France, May 11, 2016 – Provepharm SAS, a French company specializing in the development of pharmaceutical products, today announces that the US Food & Drug Administration (FDA) has approved the New Drug Application (NDA) for ProvayBlue™ (methylene blue) Injection. ProvayBlue™ was approved under FDA's accelerated approval regulations.

In June 2013, the FDA granted Provepharm Orphan Drug Designation for the approved use of Methylene Blue.

The Proveblue® active substance is cGMP and Ph. Eur. – compliant Methylene Blue, developed by Provepharm through its patented technology. Provepharm is working with the USP to update the USP monographs.

Provepharm's Methylene Blue injection has previously been approved by the European Medicines Agency (EMA), by the Pharmaceuticals and Medical Device Agency (PMDA) in Japan and in Australia by the Therapeutic Goods Administration (TGA) for the same indication.

Michel Féraud, CEO, said: "Provepharm, together with its partners, is very proud of this recognition by the FDA. We will soon make this approved important medicine available to US patients."

About Provepharm

Provepharm is a company specializing in the development and commercialization of innovative healthcare products from designed and patented active pharmaceutical ingredients (APIs). Anticipating the pharmaceutical industry's needs, Provepharm adopted a strategy of repositioning and rehabilitating known compounds in new indications. This strategy was designed to cater to the growing demand for APIs that must comply with current quality demands. Provepharm is present in 20 countries across the world.

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