

European approval for SCENESSE[®], an extended-release pharmaceutical product developed and manufactured by Evonik for Clinuvel

SCENESSE[®], a new drug developed by the Australian company Clinuvel, used for treating erythropoietic protoporphyria (EPP) – a rare photosensitivity disorder, has now been granted regulatory approval from the European Medicines Agency (EMA). The medication, which is effective for up to two months, uses a drug release system that was developed by Evonik in Birmingham, Alabama (USA). Evonik will also manufacture SCENESSE[®] on behalf of Clinuvel from its state-of-the-art facilities.

EPP is a debilitating genetic disorder associated with an absolute intolerance to light. EPP patients must avoid light in order to prevent second-degree burns. The active agent in SCENESSE[®] is afamelanotide, which acts as an antioxidant and photoprotectant. This substance protects the skin from bright visible light and from UV radiation, allowing EPP patients to lead relatively normal lives.

Evonik supported Clinuvel from the original concept to SCENESSE[®] approval, developing the controlled release system for afamelanotide and preparing the product for clinical trials. The formulation of this extended-release medication uses a biodegradable, rod-shaped implant based on poly(lactide-co-glycolide) (PLG), a biocompatible, biodegradable polymer from the RESOMER[®] product line of Evonik. RESOMER[®] can be used in drug-delivery formulations and medical devices.

“SCENESSE[®], a small implant roughly the size of a grain of rice relieves patients' symptoms for up to two months” says Dr. Jean-Luc Herbeaux, the head of Evonik’s Health Care Business Line. “This is an excellent example of what can be achieved by combining competencies via partnering.” Clinuvel CEO Dr. Philippe Wolgen expands on this thought, saying, “Evonik is a leader in the industry when it comes to technology and has shown itself to be exceptionally committed to taking the technology from the prototype stage to clinical studies, and now to market launch.”

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Clinuvel is now working on giving European patients access to SCENESSE®. Evonik is preparing to manufacture the drug product for market launch in the coming months and will continue to produce implants for further clinical trials in other regions for Clinuvel.

Evonik's Health Care Business Line provides a large array of products and services for the pharmaceutical industry, including API and API intermediates manufacturing, excipient products and drug product development and production services. Evonik has exceptional expertise in the field of formulating and developing complex, injectable drug products like SCENESSE®. The Evonik site in Birmingham (Alabama, USA) is EMA-certified and serves as a competence center for parenteral drug delivery systems and for commercial production of finished pharmaceutical products. The focus includes extended-release parenterals, including microparticles, implants, liposomes, and nanomedicines.

Company information

Evonik, the creative industrial group from Germany, is one of the world leaders in specialty chemicals. Profitable growth and a sustained increase in the value of the company form the heart of Evonik's corporate strategy. Its activities focus on the key megatrends health, nutrition, resource efficiency and globalization. Evonik benefits specifically from its innovative prowess and integrated technology platforms.

Evonik is active in over 100 countries around the world. In fiscal 2014 more than 33,000 employees generated sales of around €12.9 billion and an operating profit (adjusted EBITDA) of about €1.9 billion.

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