



FDA approves ivabradine for patients with chronic heart failure

First oral drug for chronic heart failure to be approved by the FDA in nearly a decade

Suresnes, France – April 16 2015 – Servier today announced that Amgen, the holder of US commercial rights to ivabradine has yesterday obtained from the Food and Drug Administration (FDA) the marketing authorisation for the product under the brand name CORLANOR® in the treatment of chronic heart failure (CHF).

This is the first new chronic heart failure US approval in nearly a decade.

CHF, a condition affecting nearly 5.7 million Americans constitutes both a major medical and economic burden.

In July 2013, Amgen obtained the U.S. commercial rights for Servier's ivabradine. Under the terms of the agreement, Servier also obtained the European marketing rights for Amgen's omecamtiv mecarbil, a cardiac myosin activator currently undergoing Phase 2 trial in heart failure.

"The FDA approval of ivabradine marks an important step in the worldwide recognition of this molecule coming from the Servier research to address cardiovascular diseases and heart failure which are still major public health issues", declared Emmanuel Canet, Servier Senior Executive Vice-President of Research and Development.

"The U.S. registration of ivabradine has been obtained on the basis of trials conducted by Servier, in particular the SHIFT study in heart failure patients. SHIFT was carried out in 37 countries, acknowledging the capability of Servier's development teams to work throughout the world in accordance with the highest pharmaceutical industry standards", pointed out Isabelle Tupinon-Mathieu, Director of Servier's Cardiovascular and Metabolism Innovation Centre, Vice-President of Research and Development.

Pascal Touchon, Servier Senior Executive Vice-President of Scientific Cooperation and Business Development, stressed: "we're particularly proud that our partner Amgen will be marketing a Servier product, ivabradine, already registered by our company in over 104 countries, and in so doing help American patients to benefit from this molecule coming from the French research", and then went on to conclude: "this success is a clear reward of two years of an exemplary partnership with Amgen in which the notions of complementarity and joint value creation for the benefit of patients have always been at the core of both of our companies' considerations".

About ivabradine

Ivabradine is an innovative agent that selectively and specifically inhibits the sinoatrial node I_f current. Ivabradine exclusively reduces heart rate while preserving myocardial contractility.

In 2012, Ivabradine was approved by the European Commission for the treatment of chronic heart failure NYHA II to IV class with systolic dysfunction, in patients in sinus rhythm and whose heart rate is ≥ 75 bpm, in combination with standard therapy including beta-blocker therapy or when beta-blocker therapy is contraindicated or not tolerated. The decision to authorise the indication for ivabradine in heart failure was consequent of data from the SHIFT trial, a large morbi-mortality study in chronic heart failure involving more than 6500 patients which demonstrated ivabradine's proven benefits in cardiovascular prevention in heart failure.

Ivabradine is also indicated for the symptomatic treatment of chronic stable angina pectoris in coronary artery disease adults with normal sinus rhythm and heart rate ≥ 70 bpm, in adults unable to tolerate or with a contra-indication to the use of beta-blockers or in combination with beta-blockers in patients inadequately controlled with an optimal beta-blocker.

Ivabradine is marketed globally under the brand names Procoralan[®], Coralan[®], Coraxan[®], Corlentor[®] and Corlanor[®].

About Servier

Servier is an independent French research-based pharmaceutical company. Its development is driven by the pursuit of innovation in the therapeutic areas of cardiovascular, metabolic, central nervous system, psychiatric, bone, muscle and joint diseases, as well as cancer.

In 2014, the company recorded a turnover of 4 billion euros.

92% of Servier medicines are prescribed outside of France.

28% of turnover from Servier drugs was reinvested in Research and Development in 2014.

With a strong international presence in 146 countries, Servier employs more than 21 400 people worldwide.

More information is available at: www.servier.com

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