FDA Issues Complete Response Letter for RLX030 for Acute Heart Failure

Friday 16 May, 2014

Novartis announced today that the US Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding the Biologics License Application (BLA) for RLX030 (serelaxin) for the treatment of acute heart failure (AHF), stating that further evidence on the efficacy of RLX030 is required for a US license to be granted.

"We continue to believe RLX030 has the potential to be an important treatment for AHF and have been encouraged by feedback from FDA advisory committee members noting the data are intriguing," said Tim Wright, Global Head of Development, Novartis Pharmaceuticals. "In accordance with the FDA's advice we will continue to expedite our clinical trial program to build the supporting body of evidence."

The RLX030 submission to the FDA included phase II and III efficacy and safety data from the clinical development program, including the pivotal phase III RELAX-AHF study. Novartis is continuing to expand the data supporting the efficacy of RLX030 in acute heart failure with an extensive global clinical program, including the RELAX-AHF-2 trial which will enroll over 6,300 patients.

About RLX030
RLX030, a relaxin receptor agonist[1], is a recombinant form of a naturally occurring hormone (human relaxin 2) present in both men and women which rises in women during pregnancy to help the body cope with the additional cardiovascular demands[2],[3]. RLX030 has multiple effects including relaxing the blood vessels and reducing fluid buildup. Some evidence also suggests it can reduce damage to heart and vital organs, which may be of particular importance when considering the cascade of damage that occurs during an AHF episode[4],[5],[6].

Novartis' commitment in heart failure
Heart failure is a debilitating and potentially life-threatening condition where the heart cannot pump enough blood around the body. This, in most cases, happens because the heart muscle responsible for the pumping action weakens over time or becomes too stiff. Heart failure is a significant and growing public health concern affecting over 20 million people worldwide[6],[7] and costing the world economy $45 billionannually[8],[9],[10],[11].
Novartis is committed to research in heart failure with a portfolio including RLX030 for acute heart failure and LCZ696 for chronic heart failure.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as "progressing," "intends," "when available," "continue," "potential," "will," "expedite," "continuing," "suggests," "can," "may," "commitment," "growing," "committed," or similar terms, or by express or implied discussions regarding potential marketing approvals for RLX030 or LCZ696, or regarding potential future revenues from RLX030 and LCZ696. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that RLX030 or LCZ696 will be submitted or approved for sale in any market, or at any particular time. Nor can there be any guarantee that RLX030 or LCZ696 will be commercially successful in the future. In particular, management's expectations regarding RLX030 and LCZ696 could be affected by, among other things, the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected manufacturing issues, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis
Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these

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needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2013, the Group achieved net sales of USD 57.9 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 135,000 full-time-equivalent associates and sell products in more than 150 countries around the world. For more information, please visit http://www.novartis.com.
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