Novartis announces new data on the effects of investigational RLX030 on kidney blood flow in chronic heart failure patients

Sep 23, 2013

- *Study result signals potential kidney benefit with RLX030;[1] future studies will further explore this impact*

- *Kidney dysfunction affects approximately 30 percent of US heart failure patients and is associated with worse prognosis of these patients[2]*

- *Data presented at a late-breaking session at the 17th annual Heart Failure Society of America (HFSA) Scientific Meeting in Orlando, Fla.*

East Hanover, September 23, 2013 – Novartis today announced new data from a study in chronic heart failure patients assessing the effects of RLX030 (serelaxin) on renal hemodynamics, which included co-primary end points of renal plasma flow (RPF: amount of blood reaching the kidneys) and glomerular filtration rate (GFR: how fast blood is being filtered through the kidneys).[1] Results demonstrated there was a statistically significant improvement in RPF in patients taking RLX030 (n=39) compared to placebo (n=48), and there was no statistically significant difference in GFR change. Results also showed RLX030 infusion was well tolerated.[1]

The kidneys filter blood and remove excess fluid and waste.[3] Heart failure, a condition where the heart cannot pump enough blood to the body,[4] may decrease RPF. Decreased RPF can initiate a cascade of damage and ultimately lead to reduced kidney function.[5] Certain standard of care treatments for heart failure (eg, diuretics) can also contribute to the worsening of kidney function in some patients, making it challenging for physicians to optimally treat this condition at present.[5]

“Approximately 30 percent of heart failure patients also suffer from kidney dysfunction, an indicator for adverse outcomes,” said Javed Butler, MD, Professor of Medicine and Director, Heart Failure Research at Emory University. “This study is of particular interest because it showed a positive impact on the kidneys. Further studies are needed to establish the relationship of the renal hemodynamic effects seen in this study of stable patients with chronic heart failure to those in patients with acute heart failure.”

RLX030 is currently under review by the US Food and Drug Administration (FDA) for acute heart failure.

Study details[1]

This was a randomized, double-blind, exploratory study, designed to assess the effects of RLX030 on renal hemodynamics. Patients with chronic heart failure and mild to moderate renal dysfunction received RLX030 or a placebo infused intravenously for 24-hours. The study had two co-primary end points, assessing the effects of RLX030 compared to placebo on renal plasma flow (RPF) in patients and on glomerular filtration rate (GFR), over 8–24 hours after start of infusion.

The results showed RPF increased from baseline over 8–24 hours by 29% in the RLX030 group and 14% in the placebo group. Compared with placebo, RLX030 increased RPF over 8–24 hours by 13% (p=0.0386). There was no statistically significant treatment difference for the co-primary endpoint of GFR change from baseline over 8–24 hours.

Observed as one of the secondary end points in this trial, RLX030 resulted in a 16% relative reduction in filtration fraction (a measure of how hard the kidneys are working) over 8–24 hours, compared with placebo. Filtration fraction is the ratio of GFR to RPF and is a measure of renal work, which is elevated in heart failure.

RLX030 was well tolerated by the patients treated in this study, with slightly fewer patients reporting adverse events (n=8; 20.5%) compared with the placebo group (n=12; 25.0%). The most common AE seen in previous clinical trials (hypotension/blood pressure decrease) occurred in 2 RLX030 patients versus 1 patient in the placebo group.

About RLX030

RLX030 is a recombinant form of a naturally occurring hormone (human relaxin-2), present in both men and women, although its levels rise in pregnant women to help the body cope with the additional cardiovascular demands during pregnancy.[6]

About heart failure

Heart failure is a debilitating and potentially life-threatening condition where the heart cannot pump enough blood around the body.[4] An estimated 5.1 million people suffer from heart failure in the US.[7] The condition is often fatal when patients have one or repeated acute heart failure (AHF) episodes.[8,9] As an AHF episode approaches, patients become severely breathless and incapacitated and may rapidly gain weight due to fluid build-up in the lungs and around the body.[9]

Patients experiencing an AHF episode usually need to be rushed to the emergency room for urgent treatment.

In fact, AHF is the most common cause of hospitalization in patients over 65 years.[10]

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as “investigational,” “potential,” “under review,” “potentially,” or similar expressions, or by express or implied discussions regarding potential marketing approvals for RLX030 or regarding potential future revenues from RLX030. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that RLX030 will be approved for sale in any market, or at any particular time. Nor can there be any guarantee that RLX030 will achieve any particular levels of revenue in the future. In particular, management’s expectations regarding such products could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; the company’s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; unexpected manufacturing issues; the impact that the foregoing factors could have on the values attributed to the Novartis Group's assets and liabilities as recorded in the Group's consolidated balance sheet, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. 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 Pharmaceuticals Corporation researches, develops, manufactures and markets innovative medicines aimed at improving patients’ lives. We offer a broad range of medicines for cancer, cardiovascular disease, endocrine disease, inflammatory disease, infectious disease, neurological disease, organ transplantation, psychiatric disease, respiratory disease and skin conditions. The company's mission is to improve people's lives by pioneering novel healthcare solutions.

Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG, which 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 needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2012, the Group achieved net sales of USD 56.7 billion, while R&D throughout the Group amounted to approximately USD 9.3 billion (USD 9.1 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 131,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis.

# # #

Novartis Media Relations

Julie Masow

Novartis Media Relations

+1 212 830 2465 (direct)

+1 862 579 8456 (mobile)

julie.masow@novartis.com

Tina Tuttle

Novartis Pharmaceuticals Corporation

+1 862 778 1625 (direct)

+1 862 222 6092 (mobile)

tina.tuttle@novartis.com

e-mail: us.mediarelations@novartis.com

For Novartis multimedia content, please visit www.thenewsmarket.com/Novartis
For questions about the site or required registration, please contact: journalisthelp@thenewsmarket.com.

References

1. Voors AA, Meyer S, Stepinska J, et al. HFSA 2013 Study A2202 Renal Hemodynamics Abstract [abstract]. Data presented at: HFSA; Orlando, Fla. September 2013.
2. Metra M, Cotter G, Gheorghiade M, Dei Cas L, Voors AA. The Role of the Kidney in Heart Failure. *Eur Heart J.*2012;33(17):2135-2142.
3. How Your Kidneys Work. National Kidney Foundation. 2013. Available at:

http://www.kidney.org/kidneydisease/howkidneyswrk.cfm. Accessed August 23, 2013.

1. McMurray JJV, Adamopoulos S, Anker SD, et al. The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association (HFA) of the ESC. *Eur Heart J.* 2012;33:1787-1847.
2. Schrier RW. Role of Diminished Renal Function in Cardiovascular Mortality. *J Am Coll Cardiol*.

2006;47:1–8.
3. Teichman S, Unemori E, Teerlink J, et al. Relaxin: Review of Biology and Potential Role in Treating Heart Failure. *Curr Heart Fail Rep*. 2010;7:75-82.
4. Go AS, et al. Heart Disease and Stroke Statistics -- 2013 Update: A Report From the American Heart Association. *Circulation*. 2013;127:e6-e245.
5. Mosterd A, Hoes A. Clinical epidemiology of heart failure. *Heart*. 2007;93:1137-1146.
6. Warning Signs of Heart Failure. American Heart Association. http://www.heart.org/HEARTORG/Conditions/HeartFailure/Warning-SignsforH…- Heart-Failure_UCM_002045_Article.jsp. Accessed October 17, 2012.
7. Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013; 2013;128:000–000.

Source URL: *https://prod1.novartis.com/us-en/news/media-releases/novartis-announces-new-data-effects-investigational-rlx030-kidney-blood-flow-chronic-heart-failure-patients*

List of links present in page

1. https://prod1.novartis.com/us-en/us-en/news/media-releases/novartis-announces-new-data-effects-investigational-rlx030-kidney-blood-flow-chronic-heart-failure-patients
2. http://www.novartis.com/
3. http://twitter.com/novartis
4. mailto:julie.masow@novartis.com
5. mailto:us.mediarelations@novartis.com
6. mailto:tina.tuttle@novartis.com
7. http://www.thenewsmarket.com/Novartis
8. mailto:journalisthelp@thenewsmarket.com
9. http://www.kidney.org/kidneydisease/howkidneyswrk.cfm
10. http://www.heart.org/HEARTORG/Conditions/HeartFailure/Warning-SignsforHeartFailure/Warning-Signsfor