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Cardioentis' Ularitide Receives FDA Fast Track Designation for the Treatment of Acute Decompensated Heart Failure

TRUE-AHF Phase III Top-Line Results Anticipated in Spring 2016

U.S. NDA and European MAA Submissions Planned for Second Half of 2016

ZUG, Switzerland – December 11, 2015 – Cardioentis AG, a privately held biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track status to Ularitide, an investigational therapy for the treatment of acute decompensated heart failure (ADHF). The FDA's Fast Track process is intended to facilitate the development and expedite the review of drugs for the treatment of serious conditions addressing an unmet medical need. Cardioentis anticipates top-line results from the TRUE-AHF Phase III trial in Spring 2016 and expects to file a U.S. New Drug Application (NDA) and European Marketing Authorization Application (MAA) in the second half of 2016.

The treatment of ADHF has remained the same for decades, with poor short term and long term prognoses for patients that are significantly worse than for many types of cancer^[1]. "When patients with ADHF are admitted to the hospital, we have an opportunity and responsibility to not only alleviate their symptoms but to stabilize their clinical course," said Milton Packer, MD, principal investigator of the TRUE-AHF study. "For many decades, the focus has been on symptoms, but now we are developing ways of achieving and maintaining clinical stability, primarily by reducing the risk of worsening during the patient's hospital stay."

"We are pleased that the FDA continues to acknowledge the current high unmet need for patients with ADHF by granting Fast Track status for Ularitide," said Johannes Holzmeister, M.D., CEO of Cardioentis. "We look forward to working closely with the FDA on an expedited review process for Ularitide, as we are eager to provide a potential new treatment option for patients suffering from ADHF."

Ularitide is a natriuretic peptide in Phase III development for the treatment of ADHF. The trial has fully enrolled 2,157 patients in over 200 centers across the U.S., Europe, Canada and Latin America. TRUE-AHF is a randomized, double-blind, placebo-controlled event driven trial with two co-primary endpoints. The first is a composite endpoint for ADHF, which assesses a patient's symptoms and persistent or worsening heart failure within the first 48 hours after initiation of treatment. The second co-primary endpoint is cardiovascular mortality.



About ADHF

Heart failure occurs when the heart loses its ability to pump blood efficiently through the body and vital organs.^[2] It is a growing problem worldwide, affecting more than 26 million people worldwide^{[3],[4]}. In 2011, there were nearly 3 million hospital admissions with heart failure as the primary diagnosis in countries across the globe^[5]. It is a life-threatening condition, which requires immediate medical attention. Signs and symptoms of ADHF include extreme fatigue and shortness of breath, worsening kidney function, severe swelling, sudden weight gain and a distended jugular vein along the side of the neck. The American Heart Association estimated the total cost of this chronic disease approached \$39.2 billion in 2010^[6].

About the U.S. FDA's Fast Track Designation

Fast Track is designed to facilitate the development, and expedite the review, of drugs to treat serious conditions and address an unmet medical need. Once a drug receives *Fast Track* designation, early and frequent communication between the FDA and a drug company is encouraged throughout the entire drug development and review process. The frequency of communication can help resolve questions and issues quickly, often leading to earlier drug approval and patient access to important new therapies. Fast Track designated products are eligible for accelerated approval and priority review, if relevant criteria are met, and rolling FDA review of marketing applications.

About Ularitide

Ularitide is in Phase III development as an intravenous (IV) infusion treatment for ADHF limited by United States law to investigational use only. Ularitide is the chemically synthesized form of urodilatin - a human, natriuretic peptide that is produced in the kidneys and induces excretion of sodium into the urine (natriuresis) and increased urine production (diuresis) to regulate fluid balance and sodium haemostasis. Ularitide induces natriuresis and diuresis by binding to specific natriuretic peptide receptors (NPR-A, NPR-B and other natriuretic peptide receptors), thereby increasing intracellular cyclic guanosine monophosphate (cGMP) helping to relax smooth muscle tissues, leading to vasodilation and increased blood flow^[7].

About Cardioentis Ltd.

Cardioentis is a private biopharmaceutical company headquartered in Zug, Switzerland. The company is committed to bringing novel therapies to the treatment of heart failure and related cardiovascular diseases. Cardioentis' disease-based technology platform integrates expertise in protein biology to identify novel targets and rationally design small molecule compounds and peptides for markets with unmet medical needs. For more information, visit www.cardioentis.com.

¹ Eur Heart J Supplements 2002; 4 (Suppl D):D50-D58
- http://eurheartjsupp.oxfordjournals.org/content/4/suppl_D/D50.full.pdf

- ² ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012. ESC Guidelines. European Heart Journal doi:10/1093/eurheartj/ehs104
- ³ Fang J, Mensah GA, Croft JB, Keenan NL. Heart failure-related hospitalization in the U.S.,1979 to 2004. J Am Coll Cardiol 2008;52(6):428-34.
- ⁴ McMurray JJ, Petrie MC, Murdoch DR, Davie AP. Clinical epidemiology of heart failure: public and private health burden. Eur Heart J 1998; 19 Suppl P:P9.
[<http://www.uptodate.com/contents/epidemiology-and-causes-of-heart-failure/abstract/8>].
- ⁵ Organisation for Economic Co-operation and Development. Health care utilisation – Hospital discharges by diagnostic categories – All causes (<http://stats.oecd.org/>).
- ⁶ Lloyd-Jones D, Adams RJ, Brown TM, Carnethon M, Dai S, De Simone G, et al. Heart disease and stroke statistics – 2010 update: a report from the American Heart Association. Circulation 2010;121:e46-215
- ⁷ Anker SD, Ponikowski P, Mitrovic V, Peacock WF, Filippatos G. Ularitide for the treatment of acute decompensated heart failure: from preclinical to clinical studies. Eur Heart J. 2015 Mar 21;36(12):715-23. doi: 10.1093/eurheartj/ehu484. Epub 2015 Feb 10. Review. PubMed PMID: 25670819.

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