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Announcement no. 2, 2010

Serodus AS licenses compound from Roche for potential treatment of heart failure

Serodus AS (Serodus) today announced that it has entered into a license agreement with Roche (SIX: RO, ROG; OTCQX: RHHBY) for a selective serotonin-4 (5-HT₄) antagonist for the potential treatment of heart failure (RO1160367).

Serodus, a Norwegian biopharmaceutical company dedicated to the development of innovative compounds for cardiovascular diseases, has in-licensed RO1160367, a drug candidate ready to enter a clinical Phase II Proof-of-Concept study in heart failure.

Eva Steiness, M.D., Chief Executive Officer of Serodus, said, "We are excited about this opportunity to work with the excellent Roche compound. This agreement will enable Serodus to move its heart failure programme directly into the clinic without waiting for our own preclinical development."

Dan Zabrowski, Ph.D., Global Head of Roche Partnering, commented, "Finding partners such as Serodus who bring their own scientific insights to the development of Roche compounds is an important part of our partnering strategy. Through out-licensing deals like this, the high quality work carried out by Roche scientists can be continued, potentially providing significant benefits to patients."

Under the Agreement, Serodus will receive the full preclinical and clinical documentation for RO1160367. In return, Roche will receive an upfront payment as well as be entitled to receive development, regulatory and commercial milestone payments. Roche is also eligible to receive royalties on sales of products commercialized under the license. Serodus has been granted the exclusive development, manufacturing and worldwide marketing and sale rights with the rights to sub-license. In certain cases, Roche has a right to negotiate to regain the product rights.

The disease

Heart failure is the pathophysiological state in which the heart is unable to pump blood at a rate commensurate with what is required for normal body function. To compensate for this condition, the kidneys retain water and patients may experience shortness of breath (dyspnoea). In most patients, symptoms develop gradually and the patient may not register the physical limitations until it become obvious that their symptoms are abnormal. The condition limits the patients' physical capability. Heart failure is a very serious disease with a high burden to society and mortality comparable with the most serious cancers.

5-HT₄ antagonists in heart failure

Researchers at the University of Oslo (Prof. Levy and co-workers) discovered the presence of 5-HT₄ receptors on muscle cells in failing cardiac ventricles and that a failing cardiac ventricle expresses 5-HT₄ receptors as a response to the serious condition.

The effect of 5-HT₄ antagonists in heart failure has been demonstrated in rat and man

and therefore, remains an important area for research and development of suitable treatments.

Serodus will utilize its proprietary know-how to optimize and develop the compound under the name SER101 to establish clinical Proof-of-Concept for the indication heart failure, addressing a market worth more than USD 5 billion annually.

About Serodus

Serodus is a biopharmaceutical company headquartered in Oslo, Norway, dedicated to the development of compounds for the treatment of patients with cardiovascular diseases.

Serodus was founded based on a discovery from the University of Oslo identifying a hormonal regulatory system, which is activated in patients with heart failure. Based on this invention, it is expected that treatment with a 5-HT₄ receptor antagonist will benefit patients with chronic congestive heart failure and possibly patients with atrial fibrillation.

Serodus has acquired the rights to Zealand Pharma's ORL-1 agonist ZP120 developed under the Serodus' name, SER100. Serodus intends to develop the compound for the treatment of patients with isolated systolic hypertension.

After entering into the agreement with Roche, Serodus' pipeline consists of two clinical advanced programs to be advanced into clinical Phase II trials and one compound in preclinical development.

For further information: www.serodus.com

For enquiries please contact:

Serodus AS:

Eva Steiness

eva.steiness@serodus.com

+45 22 26 56 87

Product pipeline

Product candidate	Indication	Status	Clinical endpoints of clinical studies	Market potential
SER100	Isolated Systolic Hypertension (ISH)	Entering clinical Phase II Proof-of-Concept study	Reduction of systolic blood pressure by more than 10 mmHg and only minor effect on diastolic pressure	The lifetime risk of hypertension for individuals of 55 years of age is approximately 90%.
SER101	Heart Failure (HF)	Entering clinical Phase II Proof-of-Concept study	Improvement of the pump function of the heart	It is estimated that about 30 million patients are suffering from heart failure in the western world.
SER102	Post operative Atrial Fibrillation (AF)	Pre-clinic tox	Normalisation of heart rate	The risk of AF is 30 % after coronary by-pass surgery and 30 % after lung cancer surgery.