

Zealand provides an update on activities relating to danegaptide for the protection of cardiac tissue against reperfusion injuries

- ***New collaboration with the University of Copenhagen to further elucidate the tissue protective profile and full therapeutic potential of danegaptide***
- ***The project selected by the Danish Innovation Fund to receive a DKK 1 million grant***
- ***Enrolment on track in Zealand's ongoing Phase II study to evaluate the efficacy of danegaptide in the protection of cardiac tissue after a heart attack***

Copenhagen, 24 June 2014 – Zealand Pharma A/S (“Zealand”) (NASDAQ OMX Copenhagen: ZEAL) informs that it has initiated a collaboration with the University of Copenhagen, with the objective of fully elucidating the cell protective properties and the therapeutic potential of danegaptide. The collaboration, in the form of a two-year industrial post doctoral project, has been selected by the Danish Innovation Fund (InnovationsFonden) to receive a DKK 1 million grant, complementary with its goal of generating new knowledge with attractive growth potential.

Danegaptide is a novel therapeutic peptide, invented by Zealand, which has shown promising anti-arrhythmic and cell protective properties. In preclinical studies, danegaptide has been shown to protect against cardiac reperfusion injuries, caused by the return of blood flow to tissue which, due to a blood clot, has been deprived of oxygen.

To evaluate the protective effect of danegaptide in patients after an acute myocardial infarction (AMI), Zealand collaborates with a leading cardiac center in Denmark in a clinical Phase II Proof-of-Concept study, planned to enroll up to 600 patients. The study is advancing as planned with more than 170 patients now enrolled and treated, and results are expected in H2 2015.

Commenting on the post doctoral project and the prospects for danegaptide, **Torsten Hoffmann, Chief Scientific Officer at Zealand**, said: *“Danegaptide has shown promising potential as a first-in-class treatment approach to save cardiac tissue in patients with a heart attack, an area of major unmet medical need. Our clinical Phase II Proof-of-Concept study is advancing well and according to plan, and we are looking forward to the results in H2 2015. The tissue protective qualities of danegaptide, however, reach further, so in collaboration with the University of Copenhagen we now aim to reveal the full therapeutic potential for this innovative Zealand-peptide. We are very pleased that our project has been recognized and selected for grant support from the prestigious Danish Innovation Fund.”*



Based on the previous promising results for danegaptide, Zealand together with the University of Copenhagen will now intensify their work in order to demonstrate the mechanisms which make it possible for danegaptide to protect heart tissue against reperfusion injury, and examine whether the peptide also has cell protective effects in other tissue types.

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About danegaptide

Danegaptide is a therapeutic peptide invented by Zealand, exerting effect via activation of gap junction communication channels between cells, and demonstrating both anti-arrhythmic and cell protective properties.

In a pre-clinical model of acute myocardial infarction (AMI), i.e. an acute blood clot in the heart, danegaptide has shown dose-dependent significant reductions in infarct size after reperfusion. In another relevant translational model of reperfusion injury associated with an AMI, danegaptide significantly reduced infarct size compared to immediate full reperfusion¹. Results from an extensive Phase I program, including three (3) individual studies with a total of 153 subjects, showed that danegaptide was safe and well tolerated.

Reference

¹ Journal of the American College of Cardiology: Volume 61, Issue 10, Supplement, Page E67, 12 March 2013

About Ischemic Reperfusion Injury

In case of an acute myocardial infarction (AMI), or a heart attack, a blood clot blocks the blood flow to important parts of the heart for a longer period of time (ST segment elevation myocardial infarction, STEMI). The standard treatment of AMI today is different types of interventions aimed at enabling the return of blood flow to the ischemic myocardium, thereby limiting the size of the infarct. Percutaneous coronary intervention (PCI), also called balloon dilatation, is the most common. In 2020, the incidence for STEMI is predicted to be 756.700 in US, EU and Japan combined, and approximately 80% of STEMI patients undergo PCI procedure.

Interventional treatment is the most effective method to restore blood flow or re-perfuse the heart, thereby reducing the infarct size and improving the outcome for patients with a STEMI. The process of myocardial reperfusion however, can paradoxically itself induce further cardiac tissue damage, a phenomenon known as myocardial reperfusion injury.



To date there are no marketed pharmacological treatments for the prevention of reperfusion injury. Both mechanical pre- and post-conditioning (series of repetitive interruptions of the coronary blood flow during the PCI procedure) seem to protect cardiomyocytes during reperfusion. Reducing infarct size by 15% corresponds to a reduction in six month absolute mortality of 1% making this a meaningful marker for long term outcomes for patients.

About the Innovation Fund (InnovationsFonden)

InnovationsFonden was established on 1 April 2014 and will be offering grants for activities within strategic research, technology and innovation. The budget of InnovationsFonden is 210 €m in 2014. In addition the companies and universities will also provide funding for participating in projects.

The establishment of InnovationsFonden is the biggest reform of the Danish research and innovation system in the past two decades with a significant simplification of the research and innovation system, which now more focused on demand. InnovationsFonden will focus its efforts on combining research, technological development and innovation and be responsible for the future societal partnerships, where companies, universities and public authorities will work together on challenges facing society today.

About the Innovation Fund industrial postdoc project

An industrial postdoc project is a collaboration between a company and a public research institution to address a specific challenge within research and development.

The expectations for the industrial postdoc project:

- To give the industrial postdoc's career a unique competence boost by combining research skills with experiences of the business world.
- To give the company the opportunity to address specific research and development challenges and to strengthen the relationship to existing and new business partners in the university environment.
- To strengthen the relationship between public research and the business community, while creating a breeding ground for new research.

About Zealand

Zealand Pharma A/S ("Zealand") (NASDAQ OMX Copenhagen: ZEAL) is a biotechnology company based in Copenhagen, Denmark. Zealand has leading expertise in the discovery, design and development of novel peptide medicines and a mature portfolio of therapeutic products, which are all based on internal inventions. The company's focus lies in the field of cardio-metabolic diseases, diabetes and obesity in particular, and its lead product is lixisenatide, a once-daily prandial GLP-1 agonist for the treatment of Type 2 diabetes, marketed as Lyxumia® under a license agreement with Sanofi. Lyxumia® is approved in several countries globally, including Europe and Japan. In the US, submission of an NDA is expected in 2015, after completion of a cardiovascular outcome study, ELIXA. A once-daily single injection combination of Lyxumia® and Lantus® (LixiLan) is in Phase III development by Sanofi with planned first regulatory filing as early as at the end of 2015.



Zealand has a partnering strategy for the development and commercialization of its products and in addition to the license agreement with Sanofi in Type 2 diabetes, the company has partnerships with Boehringer Ingelheim in diabetes/obesity, Lilly in diabetes and obesity, Helsinn Healthcare in chemotherapy induced diarrhea and AbbVie in acute kidney injury.

For further information: www.zealandpharma.com

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