Dezima Pharma extends clinical development program for its CETP Inhibitor TA-8995

Phase 2b TULIP study readout in August 2014, new Lipoprotein(a) study approved

Naarden, The Netherlands, 8 July 2014 – Dezima Pharma ('Dezima'), the biotechnology company developing innovative drugs in the field of dyslipidemia, today announced the approval of a phase 1 pilot study in subjects with isolated, elevated Lipoprotein(a) (Lp(a)), for which additional funding has been secured.

The aim of this new study is to investigate the Lp(a) lowering effects of TA-8995 (DEZ-001), a best-in-class CETP inhibitor, in 36 asymptomatic subjects with isolated, elevated Lp(a) levels. Lp(a) is an independent major risk factor for cardiovascular disease and aortic stenosis. In previous phase 1 studies in healthy volunteers with normal baseline Lp(a) levels, TA-8995 has shown a potent effect on Lp(a) plasma levels.

Dezima Pharma is currently in the process of completing a phase 3 enabling program for TA-8995. "A key milestone will be reached in August when the readout of the phase 2b TULIP study in 364 patients with mild dyslipidemia is planned", stated Rob de Ree, CEO of Dezima Pharma.

"The start of this new Lp(a) study is another milestone event for Dezima Pharma" said Rob de Ree. "There are currently no approved or effective drug treatments available for patients with elevated Lp(a) levels. These patients are at continuous risk of cardiovascular events from an early age. TA-8995 has the potential to be a breakthrough drug for these patients".

John Kastelein, CSO and co-founder of Dezima added: "The potent Lp(a) reductions achieved in the phase 1 study by TA-8995 will hopefully translate into clinically relevant lowering of this very atherogenic lipoprotein in this study".

36 male and female subjects with isolated, increased Lp(a) levels will be selected from the Copenhagen General Population Study database and will be randomised to one of two different dosages of TA-8995 or placebo and treated for 12 weeks. The Lp(a) pilot study will be conducted at the Herlev Hospital in Denmark. Prof. Børge Nordestgaard is the principal investigator of the study.

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Notes to editors:

About Dezima Pharma B.V.
Dezima Pharma was founded in 2012 by Prof. John Kastelein, Professor of Medicine at the Department of Vascular Medicine at the Academic Medical Center of the University of Amsterdam, The Netherlands, and financed by Forbion Capital Partners, BioGeneration Ventures and New Science Ventures, to develop novel products to treat dyslipidemic patients suffering from cardiovascular disease (CVD). The company's lead product TA-8995 has been in-licenced from Mitsubishi Tanabe Pharma Corporation and is a potentially best-in-class CETP inhibitor. The company has an outstanding Scientific Advisory Board including world-leading experts in the dyslipidemia space such as Dr Philip Barter, Professor at The Heart Research Institute, Sydney, Australia, and Dr Bryan Brewer, Senior Research Consultant of Lipoprotein and Atherosclerosis Research at the Medstar Research Institute, Washington DC, USA.

About dyslipidemia and CETP inhibitors
Dyslipidemia is a generally asymptomatic disease in which serum lipid levels deviate from the normal level. It is considered to be a modifiable risk factor for cardiovascular disease due the direct relation with atherosclerosis. The market for dyslipidemic drugs, including statins, fish oils and fibrates, topped $25Bn in 2010. Though current treatment

is relatively effective a high unmet need remains: about 60% of treated patients have a considerable chance of experiencing a cardiovascular event, which comes with significant morbidity and mortality.

The Cholesteryl Ester Transfer Protein (CETP) facilitates the transfer of cholesterol from HDL to other lipoproteins including LDL, in exchange for triglycerides. The CETP mediated transfer of cholesterol into LDL particles results into maturation of those LDL particles to more atherogenic LDL particles, which contribute to macrophage foam cell, and eventually plaque formation. Large Mendelian Randomization studies, epidemiological as well as preclinical studies have provided evidence for the notion that CETP activity is inversely related to cardiovascular mortality and reduced activity of CETP by pharmaceutical means or by naturally occurring mutations in the CETP gene results in increased HDL and decreased LDL levels. This provides a rationale for inhibition of CETP activity as a therapeutic intervention in dyslipidemic conditions characterized by either low HDL or high LDL cholesterol.

Lipoprotein(a) (also called Lp(a)) is a lipoprotein subclass. Genetic studies and numerous epidemiologic studies have identified elevated Lp(a) levels as a risk factor for myocardial infarction, aortic stenosis, coronary heart disease and stroke. Elevated Lp(a) levels predict risk of early atherosclerosis or stenosis independently of other cardiac risk factors, including LDL. Lp(a) concentrations are mainly genetic determined but may be affected by disease states, for example kidney failure. It is only slightly affected by diet, exercise, and other environmental factors. Most commonly prescribed lipid-reducing drugs have little or no effect on Lp(a) concentration.

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