



Dezima Pharma Announces Complete Enrolment of CETP Inhibitor TA-8995 Study in Subjects With Isolated, Elevated Lipoprotein(a) Levels

Readout of the study is planned for the first quarter 2015

Naarden, The Netherlands, 13 November 2014 – Dezima Pharma ('Dezima'), the biotechnology company developing innovative drugs in the field of dyslipidemia, today announced the complete enrolment of a study with TA-8995 in asymptomatic subjects with isolated, severely elevated Lipoprotein(a) (Lp(a)), which was initiated in September of this year.

The aim of this study, that enrolled 42 male and female subjects from the Copenhagen General Population Study database, is to investigate the Lp(a) lowering effects of TA-8995 (DEZ-001), a best-in-class CETP inhibitor. The subjects have been randomised to one of two different doses of TA-8995 or placebo and will be treated for 12 weeks. The Lp(a) pilot study is being conducted at the Herlev Hospital, Copenhagen University Hospital in Denmark.

Prof. Børge Nordestgaard, principal investigator of the study, commented: "This will be a very important study because at present, we cannot offer these patients any specific therapy and I am looking forward to finding out the effects of TA-8995 on Lp(a) levels in this population".

Lp(a) is an independent major risk factor for cardiovascular disease and aortic valve stenosis. In previous phase 1 studies in healthy volunteers with normal baseline Lp(a) levels, as well as in the phase 2b TULIP study, TA-8995 has shown a potent effect on Lp(a) plasma levels.

"After the positive results in the Phase 2b TULIP trial with TA-8995 in general dyslipidemia we also want to explore its potential for this different patient population" said Rob de Ree, CEO at Dezima.

John Kastelein, CSO and co-founder of Dezima added: "Now that Lp(a) levels are proven to be causal in the pathway to cardiovascular disease, we desperately need a pharmacological therapy to lower them. TA-8995 might be such therapy. Therefore, we are very happy that Prof. Nordestgaard has so expeditiously enrolled all patients in this exciting 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-licensed 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 plasma 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 valve 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 genetically 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.

For more information, please contact:

Dezima Pharma:

Rob de Ree
rderee@dezimapharma.com
+31 35 699 3000

For media enquiries on behalf of Dezima Pharma:

Instinctif Partners
Melanie Toyne Sewell / Dr Robert Mayer
dezima@instinctif.com
+44 20 7457 2029 / +49 89 3090 5189 13