



Dezima Pharma's CETP Inhibitor, TA-8995, Phase 2b (TULIP) Study Results Published in *The Lancet*

TA-8995 shows blockbuster potential with strong LDL-C reducing and unparalleled cholesterol efflux increasing properties

Naarden, The Netherlands, 03 June 2015 – Dezima Pharma ('Dezima'), the biotechnology company developing innovative drugs in the field of dyslipidemia, today announced the publication of the phase 2b TULIP study results with its CETP inhibitor, TA-8995, in the *Lancet*.

The peer-reviewed article is entitled "*Cholesterol ester transfer protein inhibition by TA-8995 in patients with mild dyslipidaemia (TULIP): a randomised, double-blind, placebo-controlled phase 2 trial*". Please follow this link to Dezima Pharma's article in [The Lancet](#).

The TULIP ("TA-8995: its **U**se in patients with mild dys**LIP**idaemia") study was conducted in specialized cardiovascular centres across Denmark and the Netherlands. A total of 364 individuals with dyslipidaemia were randomised into nine cohorts: placebo, TA-8995 as monotherapy at different doses, or in combination with different statins. The study investigated the effects of TA-8995 on a wide range of established cardiovascular disease (CVD) biomarkers over a three month dosing period.

The results showed potent effects on the primary endpoint, which was a composite of change from baseline in LDL-C and HDL-C. 5 mg of TA-8995 reduced LDL-C by 45% and increased HDL-C by 161%. 10 mg of TA-8995 in combination with statin therapy reduced LDL-C by an additional 48%. With this combination therapy nearly all patients achieved the most stringent LDL-C target of <1.8 mmol/L. In addition, TA-8995 boosted cholesterol efflux significantly. Finally, TA-8995 was safe and well tolerated without any drug accumulation as has been reported with other CETP inhibitors.

Philip Barter, Professor at the University of New South Wales, Sydney and member of the scientific advisory board of Dezima, explained: "Cholesterol efflux represents the capacity of plasma to remove toxic cholesterol from the plaque in the coronary arteries. It has recently been established that cholesterol efflux is a strong and inverse, independent risk factor for cardiovascular events. At the 5 mg dose, TA-8995 increases this capacity by over 40%, when compared to placebo. This is an unparalleled finding for any oral medication to date. Adding to the potent LDL-C reduction, this is expected to have a large, additional effect on the relative risk reduction for cardiovascular events in the phase 3 program of TA-8995."

"This study clearly shows that TA-8995 is a best-in-class CETP inhibitor with an unrivalled combined efficacy and safety profile," added Dezima's CEO Rob de Ree. "Besides its strong differentiation within the CETP inhibitor class, we believe TA-8995 to be well positioned vis-à-vis PCSK9 antibodies in treating dyslipidemia from a perspective of efficacy, price and delivery. Besides requiring frequent injections, PCSK9 antibodies will likely be expensive and have not shown any beneficial effect on cholesterol efflux."

The Company anticipates starting a phase 3 cardiovascular outcomes trial in the first half of 2016.

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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 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.

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