

type of report	Current report
number	61/2013
company	PHARMENA

Completion of formal assessment of application to Health Canada for granting permission for phase II clinical trials of 1-MNA anti-atherosclerotic medicinal product

With reference to the Company's Strategy for 2012-2015 (published in current report no. 16/2012 of 13th April 2012) and current report no. 51/2013 of 16th July 2013 (Filing to Health Canada for granting permission to phase II clinical trials of anti-atherosclerosis medicinal product 1-MNA), the Management Board of Pharmena informs that on 19th August 2013, the subsidiary company Cortria Corporation (USA) received notification that Health Canada (an authority supervising clinical trials in Canada) completed the formal assessment of application for granting permission to conducting phase II clinical trials ("Proof of Concept") of an innovative anti-atherosclerotic medicinal product based on 1-MNA active substance (working name of the product – TRIA-662). All information and materials included in the application are complete and will be subjected to further substantive evaluation in order to be given permission from Health Canada for phase II clinical trials.

It is planned, that phase II clinical trials ("Proof of Concept") will be randomised, multi-centred, placebo controlled, with total participation of at least 64 subjects (two control groups: 1-MNA, placebo, ratio: 3:1). Key inclusion criteria for subjects' inclusion in the trial shall be: TG > 200 mg/dl (2.26 mmol/l) and < 700 mg/dl (7.91 mmol/l) levels as well as HDL-C < 40 mg/dl (1.0 mmol/L) level in men and < 50 mg/dl (1.3 mmol/L) level in women. The actual clinical trial will be preceded by a 6-week period, when 200 subjects will be subjected to controlled diet. Randomly selected subjects who fulfil the inclusion criteria will participate in the actual clinical trial, in which 1-MNA medicinal product will be administered to them. Medicinal product will be administered 3 times a day, with a meal, for the period of 14 weeks. Key parameters of lipid profile will be controlled (i.e. TG, HDL, LDL and TC levels), inflammation (CRP, IL6) and parameters related to the safety of the medicinal product (i.e. glucose, ALT, ASP, electrocardiogram). Upon completion of the trial a report containing trial results will be issued.

The aim of the trial is to establish the effective dose of the medicinal product and to confirm the lack of side effects in humans in higher doses. Planned time scope for the trial is 12 months from the date of obtaining permission from Health Canada market regulator. The supervisory institution will be Montreal Heart Institute, and participation of ca. 15 clinics in the trial is planned.

Montreal Heart Institute is a leading research centre in Canada, specialising in cardiology, and one of the largest institutes of this type in the world. It is a world renown Institute, that has introduced many innovatory solutions nationally and world-wide. For more information see www.icm-mhi.org.

Phase II clinical trials ("Proof of Concept") are planned to be financed from funds raised through the issue of series D shares. In the following current reports the Company will inform on progress of research and trials of the 1-MNA innovative anti-atherosclerotic medicinal product.

The information is made public due to the fact that conducting phase II clinical trial is necessary for commercialisation of 1-MNA anti-atherosclerotic medicinal product project, while potential revenues on the medicinal product commercialisation may have very significant impact on financial results and market valuation of the Issuer.

Legal basis: Alternative Trading System Rules – Exhibit 3 "Current and Periodical Information in the Alternative Trading System on the NewConnect Market", Article 3 (1).

Representatives of the company:

- Konrad Palka – President of the Board
- Marzena Wiczorkowska – Vice President of the Board