

type of report	Current report
number	54/2014
company	Pharmena Spółka Akcyjna

#### **Toxicity tests within the project of 1-MNA dietary supplement successfully completed**

With reference to the Company's Strategy for 2012-2015 (published in current report no. 16/2012 of 13<sup>th</sup> April 2012) and the communication on the progress in toxicity tests within the project of 1-MNA dietary supplement (published in current report no. 50/2014 of 21<sup>st</sup> October 2014), the Management Board of PHARMENA S.A. informs that on 30<sup>th</sup> October 2014, the Company PHARMENA received a full report from subchronic (90 days) toxicity test on animal models. The test was ordered in March 2014 in order to supplement the application for authorisation of 1-MNA as new food ingredient (dietary supplement), pursuant to Art. 4 of Regulation (EC) No. 258/97.

The analysis of the toxicity tests results demonstrated very good tolerance as well as high safety of use of the tested substance, i.e. 1-MNA. The tests showed no adverse effects depending on the tested substance. The assessment covered clinical observations, physical activity, body mass, food intake, ophthalmological and haematological assessment, clinical chemistry, evaluation of blood clotting parameters, evaluation of internal organ masses, macroscopic and microscopic analysis of internal organs, and bone density analysis (DXA densitometry). The study included 124 animals in total. The value of NOAEL (No Observable Adverse Effect Level) ratio has been indicated – it is 1000 mg/kg of the animal's (rat's) body mass. This value is the highest tested dose of 1-MNA substance and simultaneously constitutes the highest recommended dose of the substance (according to OECD recommendation no 408) administered within the 90-day toxicity test. It should be highlighted that the indicated NOAEL value for 1-MNA corresponds to ca. 9600 mg/day for humans, which is almost 40 times higher a dose when compared to the planned dose of 1-MNA (250 mg) in dietary supplement (based on the 1-MNA substance). The results of the tests are compliant with the Company's expectations.

The Issuer will immediately present the test results to Advisory Committee on Novel Foods and Processes (ACNFP), which conducts assessment concerning the authorisation of 1-MNA as a new food ingredient (dietary supplement) in cooperation with Food Standards Agency (FSA), pursuant to Art. 4 of Regulation (EC) No. 258/97 of the European Parliament and of the Council of 27<sup>th</sup> January 1997. In a separate current report, the Company shall inform about the submission of the test results to ACNFP committee.

The procedure stipulated in the provisions of Art. 4 of Regulation (EC) no. 258/97 of the European Parliament and of the Council of 27<sup>th</sup> January 1997, concerns foods and food ingredients that have no record of safe consumption in the Community, which means they were not used in foods before 15<sup>th</sup> May 1997 in any EU Member State. The goal of subjecting 1-MNA to this procedure is to prove, by the use of available for PHARMENA S.A. research and scientific publications, the safety of the ingredient's use within the proposed area. Within this procedure, the entity responsible for placing on the Community market submits appropriate application to EU Member State, where the new foodstuff is to be first placed on the market. An additional scientific assessment at European level may appear necessary. In such case, it will be performed by European Food Safety Authority. Following full assessment, the European Commission grants permission for placing the new foodstuff on the market.

Successful authorisation will open EU markets for the dietary supplement.

The 1-MNA dietary supplement will be an innovative product with a capacity to influence the risk biomarkers of cardiovascular diseases and to stimulate the endogenous (natural) production of prostacyclin. Low levels of prostacyclin in human organism increase the risk of atherosclerosis. Studies have shown that the concentration of endogenous 1-MNA in human organism decreases with age. 1-MNA dietary supplement can complement 1-MNA deficiency in the organism and therefore stimulate the production of prostacyclin which reduces the risk of atherosclerosis development.

The information is made public due to the fact that introduction of innovative dietary supplement containing 1-MNA on the market may have a significant influence on the Company's revenue in the next few years.

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
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