

type of report	Current report
number	55/2014
company	Pharmena Spółka Akcyjna

#### **Supplement the application for authorisation of 1-MNA as new food ingredient**

With reference to the Company's Strategy for 2012-2015 (published in current report no. 16/2012 of 13<sup>th</sup> April 2012), the communication on assessment of the application for authorisation of 1-MNA as new food ingredient (published in current report no. 80/2013 of 5<sup>th</sup> December 2013), and the communication on the successful completion of toxicity tests (published in current report no. 54/2014 of 31<sup>st</sup> October 2014), the Management Board of PHARMENA S.A. informs that on 6<sup>th</sup> November 2014, the Company PHARMENA submitted to Food Standard Agency and Advisory Committee on Novel Foods and Processes (ACNFP) the test results from subchronic (90 days) toxicity test on animal models, in order to supplement the application for authorisation of 1-MNA as new food ingredient, 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 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 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