| | |
|---|---|
| type of report | **Current report** |
| number | 80/2013 |
| company | PHARMENA |

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

With reference to the Company's Strategy for 20012-2015 (published in current report no. 16/2012 of 13th April 2012) and the communication on the progress in the project of 1-MNA dietary supplement (published in current report 79/2013 of 15th November 2013), the Management Board informs that on 4th December 2013, it has received information from Food Standard Agency, that the application for authorisation of 1-MNA as new food ingredient by regulation no. 258/97 was assessed during the meeting of Advisory Committee on Novel Foods and Processes (ACNFP), on 20th November 2013. The Committee addressed the answers to additional questions submitted by the Company. The Committee asked the Company to submit additional information on the influence of 1-MNA supplementation on the niacin metabolism. The Committee had no further reservations to the remaining answers. Apart from that, basing on the opinion of the subgroup of toxicologists, the ACNFP Committee asked the Company to submit additional results of sub-chronic toxicity study (90-day) on animal models.

The Company undertakes to commission the performance of the above-mentioned study without any delay. The Issuer assumes that within the period of next 6 months it will have chosen the researcher, conducted the sub-chronic toxicity study and submitted its results to ACNFP Committee. The Issuer makes it clear, that the application for authorisation of 1-MNA as new food ingredient was supplemented with the results of toxicity study conducted during the period of 28 days. Having acquainted with the study results, the ACNFP Committee asked for additional results of toxicity study conducted during a longer time period (90 days).

Further assessment of the application for authorisation of 1-MNA as new food ingredient by regulation no. 258/97 will be carried out after the Issuer has submitted the above-mentioned additional study results.

The procedure stipulated in the provisions of Art. 4 of Regulation (EC) no. 258/97 of the European Parliament and of the Council of 27th 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 15th 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 diatery 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 Wieczorkowska – Vice President of the Board