Does European Commission approval of VAZKEPA grant regulatory exclusivity to Amarin for the label indication?

As announced on March 30, 2021, following a review and approval recommendation by the European Medicines Agency (EMA), the European Commission (EC) granted marketing authorization for icosapent ethyl in the European Union (EU) for cardiovascular risk reduction under the brand name of VAZKEPA. The EC decision letter conveys that the Committee for Medicinal Products for Human Use considers icosapent ethyl as a new active substance, which qualified icosapent ethyl for centralized review, with the recent approval entitling icosapent ethyl to regulatory exclusivity.

The current regulatory data protection ("RDP") rules in the EU[1] provide for the following protection ("**8+2 – rule**"):

- An **8-year period of data exclusivity (DE)** starting with initial marketing authorisation (**MA**) granted by the EC during which a medicinal product may not be used as a reference medicinal product for the purposes of an abridged application procedure and/or the data contained in the pre-clinical and clinical file of that product cannot be relied on by other applicants or the authorities in a subsequent application to ascertain the safety and efficacy of other products, and

- An additional **2-year period of market protection (MP)** during which medicinal products authorized under such an abridged procedure may not be placed on the market.

This 10-year RDP period can be prolonged by one additional year of MP to a total period of 11 years (so-called "**8+2+1 rule**") under the condition that during the first 8-year period after the initial MA grant, a new therapeutic indication is authorised for this medicinal product which is held to bring a significant clinical benefit in comparison with existing therapies.

The number of patients with very high triglyceride levels in Europe is generally considered to be insufficient to justify the investment and risk of conducting a large, long-term outcomes study, even if such a trial could be reasonably designed. For more information, please see this FAQ.

VAZKEPA is a registered trademark of Amarin Pharmaceuticals Ireland Limited in Europe and other countries and regions and is pending registration in the United States.

Dated: April 16, 2021

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1 Article 14(11) of Regulation 726/2004 for medicinal products being approved ***centrally*** by the European Commission, based on a scientific assessment by the European Medicines Agency (**EMA**) and Article 10(1) of Directive 2001/83/EC for medicinal products being approved ***nationally***.