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OPKO's Citicoline Products Approved for Commercialization in Spain

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE:OPK) announced that its Barcelona, Spain subsidiary, Pharmadiet, S.L.U., received regulatory approval from Spain's health authority (Agencia Española de Medicamentos y Productos Sanitarios) for commercialization of its oral and injectable formulations of citicoline. Final marketing authorization is expected within 60 to 90 days.

Sales of the other citicoline product presently available in Spain, Somazina®, exceeded \$80 million in 2012. Citicoline also enjoys strong sales throughout Latin America, including those countries where OPKO maintains a growing presence.

"OPKO plans to commercialize its oral and injectable citicoline products in Europe, Latin America, and other markets as well," said Phillip Frost, M.D., OPKO's Chairman and Chief Executive Officer.

About Citicoline

Citicoline products are indicated for the treatment of memory disorders and behavior related to stroke, head injury, chronic disease, as well as degenerative brain disorders. Citicoline enhances the level of phosphatidylcholine in the brain.

About OPKO Health, Inc.

We are a multi-national biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large and rapidly growing medical markets by leveraging our discovery, development and commercialization expertise and our novel and proprietary technologies.

This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding expected financial performance, the market for and expected sales of citicoline products, our ability to commercialize citicoline products in Spain, Europe, Latin America and other markets, and expectations regarding timing for final marketing authorization for our citicoline products, as well as other non-historical statements about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described in our filings with the Securities and Exchange Commission, as well as the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments. In addition, forward-looking statements may also be adversely affected by general market

factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this press release speak only as of the date the statements were made, and we do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.

OPKO Health, Inc.

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Source: OPKO Health, Inc.