Amneal Enters into Exclusive European Licensing Agreement with Zambon Biotech for IPX203

February 27, 2024

BRIDGEWATER, N.J. and Cadempino, Switzerland -- Amneal Pharmaceuticals, Inc. (NASDAQ: AMRX) ("Amneal" or the "Company") today announced that it has entered into an exclusive licensing agreement with Zambon Biotech SA, part of the Zambon group ("Zambon"), for IPX203 in the European Union, United Kingdom, and Switzerland.

IPX203 is a novel, oral formulation of carbidopa/levodopa (CD/LD) extended-release capsules for the treatment of Parkinson's disease (PD) that is under review with the U.S. Food and Drug Administration. Zambon will seek regulatory approval and commercialize IPX203 in Europe. Financial terms of the agreement were not disclosed.

Zambon is a privately held multinational chemical-pharmaceutical company founded in Italy in 1906. The company continues to be managed by the family of the original founder. Zambon has extensive presence in the European neurology space, having launched and commercialized XADAGO® (safinamide), which is used as add on to LD to treat fluctuating PD patients. IPX203 is expected to complement their existing portfolio and PD focus in Europe, where XADAGO® is a registered trademark of Zambon SpA.

"We believe IPX203 can improve the lives of the more than 10 million people worldwide living with Parkinson's disease. It has been a strategic goal of Amneal to ensure that not only U.S. patients, but also Parkinson's patients worldwide have access to our products. Zambon, a family-owned business with whom we share a long-term vision and commitment toward patient communities, is the right partner to extend the reach of IPX203 to Europe," said Chirag and Chintu Patel, Co-Chief Executive Officers at Amneal.

"Zambon Biotech's mission is to build a long-term pipeline of innovative medicines that make patients' lives better. Given our group's capabilities in commercialization and our existing footprint in neurology, particularly Parkinson's, we are pleased to partner with Amneal to bring IPX203 to Parkinson's patients in Europe," said Frank Weber, Chief Executive Officer at Zambon Biotech.

Today's announcement of a licensing agreement with a European partner is part of Amneal's broader strategy to bring IPX203 to Parkinson's patients around the world. Earlier this year, Amneal also signed a license agreement with Knight Therapeutics Inc. granting exclusive rights to seek regulatory approval and commercialize IPX203 in Canada and Latin America.

About IPX203
IPX203 is a novel, oral formulation of CD/LD extended-release capsules designed for the treatment of Parkinson's disease. IPX203 contains immediate-release granules and extended-release coated beads. The IR granules consist of CD and LD, with a disintegrant polymer to allow for rapid dissolution. The ER beads consist of LD, coated with a sustained release polymer to allow for slow release of the drug a mucoadhesive polymer to keep the granules adhered to the area of absorption longer, and an enteric coating to prevent the granules from disintegrating prematurely in the stomach. This formulation is distinct from RYTARY® (carbidopa/levodopa) extended-release capsules, Amneal's extended-release CD/LD treatment for PD approved by the U.S. FDA in 2015.

About Parkinson's Disease

Parkinson's disease has become the fastest growing neurological disorder worldwide, with approximately 1 million patients diagnosed in the U.S. and over 10 million patients globally[1,2,3] It is a progressive disorder of the central nervous system (CNS) that affects dopamine-producing neurons in the brain that affect movement.

PD is characterized by slowness of movement, stiffness, resting tremor and impaired balance.[4] While PD is not considered a fatal disease, it is associated with significant morbidity and disability.[5] The average age at diagnosis for patients with PD is 60; as people live longer, the number of patients living with PD is predicted to grow significantly over the coming decades.[1,6]

About Amneal
Amneal Pharmaceuticals, Inc. (NASDAQ: AMRX), headquartered in Bridgewater, NJ, is a fully integrated global pharmaceuticals company. We make healthy possible through the development, manufacturing, and distribution of a diverse portfolio of over 270 pharmaceutical products, primarily within the United States. In its Generics segment, the Company is expanding across a broad range of complex product categories and therapeutic areas, including injectables and biosimilars. In its Specialty segment, Amneal has a growing portfolio of branded pharmaceuticals focused primarily on central nervous system and endocrine disorders, with a pipeline focused on unmet needs. Through its AvKARE segment, the Company is a distributor of pharmaceuticals and other products for the U.S. federal government, retail, and institutional markets. For more information, please visit www.amneal.com.

About Zambon Biotech SA
Zambon Biotech SA is a specialized biotech company that aims to build a scientifically robust and commercially viable portfolio of innovative patient-oriented drugs through the scouting, acquisition, licensing and development of new molecules. Zambon Biotech is part of Zambon, a modern multinational chemical-pharmaceutical company established in 1906 in Vicenza, whose history is founded on the values of an Italian family committed to innovating cure and care to improve patients' lives. Zambon employs 2,798 people worldwide, is present in 23 countries in Europe, America and Asia, and has production facilities in Italy, Switzerland, China, Brazil and in France with its APIs and CDMO site. Thanks to its innovative, quality products commercialized in 87 countries, the group reported a revenue of 900 million euros in 2023. Alongside the three historical therapeutic areas - diseases of the respiratory system, urinary tract infections and pain treatment – Zambon pharma business is focused on developing treatments for neurodegenerative diseases such as Parkinson's or rare diseases such as cystic fibrosis, BOS, to which is linked the major 2019 acquisition of Breath Therapeutics, and NCFB. For further information on Zambon please visit www.zambon.com

Cautionary Statement on Forward-Looking Statements
Certain statements contained herein, regarding matters that are not historical facts, may be forward-looking statements (as defined in the U.S. Private Securities Litigation Reform Act of 1995). Such forward-looking statements include statements regarding management's intentions, plans, beliefs, expectations, financial results, or forecasts for the future, including among other things: discussions of future operations, including international expansion; expected or estimated operating results and financial performance; the Company's growth prospects and opportunities as well as its strategy for growth; product development and launches; the successful commercialization and market acceptance of new products, and other non-historical statements. Words such as "plans," "expects," "will," "anticipates," "estimates," and similar words, or the negatives thereof, are intended to identify estimates and forward-looking statements.

The reader is cautioned not to rely on these forward-looking statements. These forward-looking statements are based on current expectations of future events, including with respect to future market conditions, company performance and financial results, operational investments,

business prospects, new strategies and growth initiatives, the competitive environment, and other events. If the underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of the Company.

Such risks and uncertainties include, but are not limited to: our ability to successfully develop, license, acquire and commercialize new products on a timely basis; the competition we face in the pharmaceutical industry from brand and generic drug product companies, and the impact of that competition on our ability to set prices; our ability to obtain exclusive marketing rights for our products; our ability to manage our growth through acquisitions and otherwise; our revenues are derived from the sales of a limited number of products, a substantial portion of which are through a limited number of customers; the continuing trend of consolidation of certain customer groups; our dependence on third-party suppliers and distributors for raw materials for our products and certain finished goods; our substantial amount of indebtedness and our ability to generate sufficient cash to service our indebtedness in the future, and the impact of interest rate fluctuations on such indebtedness; our ability to secure satisfactory terms when negotiating a refinancing or other new indebtedness; our dependence on third-party agreements for a portion of our product offerings; legal, regulatory and legislative efforts by our brand competitors to deter competition from our generic alternatives; risks related to federal regulation of arrangements between manufacturers of branded and generic products; our reliance on certain licenses to proprietary technologies from time to time; the significant amount of resources we expend on research and development; the risk of product liability and other claims against us by consumers and other third parties; risks related to changes in the regulatory environment, including U.S. federal and state laws related to healthcare fraud abuse and health information privacy and security and changes in such laws; changes to Food and Drug Administration product approval requirements; the impact of healthcare reform and changes in coverage and reimbursement levels by governmental authorities and other third-party payers; our potential expansion into additional international markets subjecting us to increased regulatory, economic, social and political uncertainties, including recent events affecting the financial services industry; our ability to identify, make and integrate acquisitions or investments in complementary businesses and products on advantageous terms; the impact of global economic, political or other catastrophic events; our ability to attract, hire and retain highly skilled personnel; our obligations under a tax receivable agreement may be significant; and the high concentration of ownership of our Class A Common Stock and the fact that we are controlled by the Amneal Group. The forward-looking statements contained herein are also subject generally to other risks and uncertainties that are described from time to time in the Company's filings with the Securities and Exchange Commission, including under Item 1A, "Risk Factors" in the Company's most recent Annual Report on Form 10-K and in its subsequent reports on Forms 10-Q and 8-K. Investors are cautioned not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. Forward-looking statements included herein speak only as of the date hereof and we undertake no obligation to revise or update such statements to reflect the occurrence of events or circumstances after the date hereof.

References:

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