

## NEWS RELEASE

# Amneal Adds Two Denosumab Biosimilars to U.S. Pipeline, Expanding Oncology Portfolio

10/12/2023

- Biosimilar candidates referencing Prolia® and XGEVA®
- Builds on first year success of Amneal's initial three biosimilar launches
- Expands existing biosimilar partnership with mAbxience

BRIDGEWATER, N.J.--(BUSINESS WIRE)-- Amneal Pharmaceuticals, Inc. (NYSE: AMRX) ("Amneal" or the "Company") today announced the addition of two denosumab biosimilars referencing both Prolia® and XGEVA® to its biosimilar pipeline.

Denosumab is a monoclonal antibody drug that inhibits bone reabsorption. It is indicated for two major categories of therapy: bone metastasis from various forms of cancer and prevention of bone pain and fractures, including osteoporosis-related injuries.

The two denosumab products are being developed by mAbxience, a global biotech company with over a decade of experience in the development, manufacture, and commercialization of biopharmaceuticals. Under the terms of the agreement, mAbxience will fully develop the biosimilar molecule and manufacture it in its state-of-the-art, Good Manufacturing Practice (GMP)-approved facilities, while Amneal will guide the product through regulatory approval and have exclusive commercialization rights in the United States. Amneal and mAbxience also currently partner on ALYMSYS®, a bevacizumab biosimilar.

"Our goal is to be a top five player in the U.S. biosimilar space, similar to our leadership position in U.S. retail

generics. Biosimilars represent the next wave of affordable medicines and these new product opportunities are aligned with our strategy to provide high quality, essential therapies," said Harsher Singh, Senior Vice President, Amneal Biosciences. "Our first three commercial U.S. biosimilars are doing very well as our excellent commercial team drives uptake in these competitive categories. We are pleased to partner again with mAbxience on these next two biosimilar candidates, which deepens our pipeline and expands our presence in oncology."

"We are thrilled to strengthen our partnership with Amneal through this second agreement, marking a significant step forward in our shared mission to enhance global health. This collaboration will bring two world-class biosimilars for the treatment of bone diseases and oncology to patients across the U.S., reinforcing our commitment to ensuring worldwide access to high-quality, life-enhancing treatments. Together with Amneal, we continue to make strides in offering affordable and accessible healthcare solutions, contributing positively to public health and solidifying our presence in the global biosimilar space," said Emmanuelle Lepine, Chief Executive Officer, mAbxience.

According to IQVIA®, U.S. annual sales for Prolia® and XGEVA® for the 12 months ended August 2023 were approximately \$4.4 billion.

The financial terms of the transaction were not disclosed, and any incremental expenses associated with these products are contemplated within Amneal's guidance.

## About Amneal

Amneal Pharmaceuticals, Inc. (NYSE: 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 approximately 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](http://www.amneal.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.

## Investors

Anthony DiMeo

Head of Investor Relations

**[anthony.dimeo@amneal.com](mailto:anthony.dimeo@amneal.com)**

Source: Amneal Pharmaceuticals, Inc.