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Amneal Announces BLA Submission of Biosimilar Candidate to XOLAIR® (omalizumab)

September 26, 2025

Potential first-wave entry into the \$4+ billion U.S. market and an important new growth driver for Amneal

BRIDGEWATER, N.J., Sept. 26, 2025 (GLOBE NEWSWIRE) -- Amneal Pharmaceuticals, Inc. (Nasdaq: AMRX) ("Amneal" or the "Company") today announced the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for a proposed biosimilar to XOLAIR® (omalizumab), developed by Kashiv BioSciences, LLC. XOLAIR® is a registered trademark of Novartis AG.

Omalizumab, a humanized monoclonal antibody that targets free IgE, is indicated for the treatment of moderate to severe persistent asthma (6 years and older patients), chronic rhinosinusitis with nasal polyps (CRSwNP) (18 years and older patients), food allergies (>1 year and older patients), and chronic spontaneous urticaria (12 years and older patients).



Omalizumab has a black boxed warning of anaphylaxis, presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been

reported to occur after administration of the first dose and beyond one year during regularly administered treatment. The drug should be initiated and administered in a healthcare setting (hospital or clinic setting) and patients should be closely observed for an appropriate period of time after administration, and if occurs, anaphylaxis should be managed. It is contraindicated in patients with severe hypersensitivity reaction to the drug or any ingredient contained in the product.

“The earlier-than-expected BLA submission for this important therapeutic is excellent news for Amneal, as this product represents a significant potential growth catalyst in the coming years,” said Andy Boyer, Executive Vice President and Chief Commercial Officer, Affordable Medicines at Amneal Pharmaceuticals. “We are excited about the opportunity to be part of the first wave of omalizumab biosimilars in this large and attractive market. Alongside our three marketed biosimilars, we expect another five biosimilar launches from 2026 to 2027, including our biosimilar to XOLAIR, positioning biosimilars as a key growth driver for Amneal.”

“Kashiv continues to execute strongly on our expanding biosimilar portfolio, which already includes RELEUKO® (filgrastim-ayow) and FYLNETRA® (pegfilgrastim-pbbk). This BLA submission represents an important milestone in making our omalizumab biosimilar available to patients,” said Dr. Sandeep Athalye, Chief Executive Officer at Kashiv BioSciences. “Kashiv is proud to be one of the U.S.-based companies having manufacturing as well as marketing authorizations for multiple biosimilars, reflecting our commitment to cost-effective, high-quality medicines through strong partnerships.”

According to IQVIA®, U.S. annual sales for XOLAIR® totaled approximately \$4.1 billion for the 12 months ending July 2025.

As a result of the earlier BLA filing, Amneal expects to incur a \$22.5 million R&D milestone charge in the third quarter of 2025, rather than the fourth quarter as previously expected. This cost was included in the company’s financial guidance. Amneal holds exclusive U.S. commercialization rights for the product, pending regulatory approval.

Note: XOLAIR® is a registered trademark of Novartis AG.

About Amneal

Amneal Pharmaceuticals, Inc. (Nasdaq: AMRX), headquartered in Bridgewater, NJ, is a global biopharmaceutical company. We make healthy possible through the development, manufacturing, and distribution of a diverse portfolio of over 280 pharmaceuticals, primarily within the United States. In its Affordable Medicines 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. 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 and follow us on LinkedIn.

About Kashiv BioSciences

Kashiv BioSciences, LLC is a vertically integrated biopharmaceutical company with numerous commercial and advanced clinical-stage assets. Kashiv BioSciences, LLC in the USA, and its subsidiaries in India (together “Kashiv BioSciences”) operate together with robust infrastructure and highly skilled teams that provide global R&D, clinical, manufacturing, regulatory, and IP capabilities. We believe our people, partners, and shared purpose fuel our work to advance patient care and access to important medicines.

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; expected or estimated operating results and financial performance; and statements regarding our positioning, including our ability to drive sustainable long-term growth, 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 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. 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.

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Source: Amneal Pharmaceuticals LLC

Amneal

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