ANI Pharmaceuticals Announces the FDA Approval and Launch of Naproxen Delayed-Release Tablets, USP

July 2, 2024

PRINCETON, N.J., July 02, 2024 (GLOBE NEWSWIRE) -- ANI Pharmaceuticals, Inc. (ANI or the Company) (Nasdaq: ANIP) today announced that it received U.S. Food and Drug Administration (FDA) approval for the Abbreviated New Drug Application (ANDA) and launched Naproxen Delayed-Release Tablets, USP. ANI's Naproxen Delayed-Release Tablets is the generic version of the reference listed drug (RLD) EC-Naprosyn ®.

"We are pleased to announce the first cycle FDA approval and commercialization of Naproxen Delayed-Release Tablets. ANI remains committed to driving growth through superior new product launch execution, in keeping with our purpose of 'Serving Patients, Improving Lives,'" stated Nikhil Lalwani, President and Chief Executive Officer of ANI.

U.S. annual sales for Naproxen Delayed-Release Tablets total approximately $36.7 million, based on April 2024 moving annual total (MAT) IQVIA data.

About ANI Pharmaceuticals, Inc.

ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) is a diversified biopharmaceutical company serving patients in need by developing, manufacturing, and marketing high-quality branded and generic prescription pharmaceutical products, including for diseases with high unmet medical need. The Company is focused on delivering sustainable growth by scaling up its Rare Disease business through its lead asset Purified Cortrophin® Gel, strengthening its Generics business with enhanced research and development capabilities, delivering innovation in Established Brands, and leveraging its U.S. based manufacturing footprint. For more information, visit www.anipharmaceuticals.com.

Forward-Looking Statements

To the extent any statements made in this release deal with information that is not historical, these are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, those relating to the commercialization and potential sales of the product and any additional product launches from the Company's generic pipeline, other statements that are not historical in nature, particularly those that utilize terminology such as "anticipates," "will," "expects," "plans," "potential," "future," "believes," "intends," "continue," other words of similar meaning, derivations of such words and the use of future dates.

Uncertainties and risks may cause the Company's actual results to be materially different than those expressed in or implied by such forward-looking statements. Uncertainties and risks include, but are not limited to: acquisitions and other investments could disrupt our business and harm our financial position and operating results; the limited number of suppliers for our active pharmaceutical ingredients could result in lengthy delays in production if we need to change suppliers; the risk that the Company may face with respect to importing raw materials and other ingredients and supplies necessary for manufacture of its products from both domestic and overseas sources due to supply chain disruptions or any other reason; delays or failure in obtaining and maintaining product approval from the U.S. Food and Drug Administration ("FDA") of the products we sell; changes in policy, guidelines or actions taken by the FDA and other regulatory agencies, including drug recalls; the ability of the Company's manufacturing partners to meet our product demands and timelines; acceptance of our products at levels that will allow us to achieve profitability; the level of competition we face and the legal, regulatory and/or legislative strategies employed by our competitors to prevent or delay competition from generic alternatives to branded products; the impact of legislative or regulatory reform on the pricing for pharmaceuticals products; issues with product quality, manufacturing or supply, or patient safety issues; our ability to protect our intellectual property rights; our ability to retain the services of our key executives and other personnel; general business and economic conditions, including the ongoing impact of and uncertainties regarding the COVID-19 pandemic and inflationary pressures, as well as geopolitical conditions, including but not limited to the conflict between Russia and Ukraine, the conflict between Israel and Gaza, or conflicts relating to attacks on cargo ships in the Red Sea.

More detailed information on these and additional factors that could affect the Company's actual results are described in the Company's filings with the Securities and Exchange Commission ("SEC"), including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as other filings with the SEC. All forward-looking statements in this news release speak only as of the date of this news release and are based on the Company's current beliefs, assumptions, and expectations. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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