ANI Pharmaceuticals Launches Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution

September 13, 2024

PRINCETON, N.J., Sept. 13, 2024 (GLOBE NEWSWIRE) -- ANI Pharmaceuticals, Inc. (ANI or the Company) (Nasdaq: ANIP) today announced the launch of Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution, 6.25 mg/15 mg per 5 mL.

"The launch of Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution just prior to the onset of cough and cold season is especially timely. With our 14th new product launch this year, we continue to drive strong growth in our Generics business," stated Nikhil Lalwani, President and Chief Executive Officer of ANI.

U.S. annual sales for Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution total approximately $42.6 million, based on July 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: our ability to continue to achieve commercial success with Cortrophin Gel, our first rare disease pharmaceutical product, including expanding the market and gaining market share, our business, financial condition, and results of operations will be negatively impacted; the ability of our approved products, including Cortrophin Gel, to achieve commercialization at levels of market acceptance that will continue to allow us to achieve profitability; our ability to complete or achieve any, or all of the intended benefits of acquisitions and investments, including the acquisition of Alimera, in a timely manner or at all; the risks that our acquisitions and investments, including the acquisition of Alimera, could disrupt our business and harm our financial position and operating results; delays in production, increased costs and potential loss of revenues if we need to change suppliers due to the limited number of suppliers for our raw materials, active pharmaceutical ingredients, excipients and other materials; our reliance on single source third-party contract manufacturing supply for certain of our key products, including Cortrophin Gel, and post-consummation of the acquisition of Alimera, for Alimera's products; delays or failure in obtaining and maintaining approvals by the FDA of the products we sell; changes in policy or actions that may be taken by the FDA, United States Drug Enforcement Administration, and other regulatory agencies, including among other things, drug recalls, regulatory approvals, facility inspections and potential enforcement actions; our ability to develop, license or acquire, and commercialize new products; 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; our ability to protect our intellectual property rights; the impact of legislative or regulatory reform on the pricing for pharmaceutical products; the impact of any litigation to which we are, or may become, a party; our ability, and that of our suppliers, development partners, and manufacturing partners, to comply with laws, regulations and standards that govern or affect the pharmaceutical and biotechnology industries; our ability to maintain the services of our key executives and other personnel; and general business and economic conditions, such as inflationary pressures, geopolitical conditions including, but not limited to, the conflict between Russia and the Ukraine, the conflict between Israel and Gaza, conflicts related to the attacks on cargo ships in the Red Sea, and the effects and duration of outbreaks of public health emergencies, and other risks and uncertainties that are described in ANI's Annual Report on Form 10-K, quarterly reports on Form 10-Q, and other periodic reports filed with the Securities and Exchange Commission.

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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