ANI Pharmaceuticals Announces the Launch of Pentoxifylline Extended-Release Tablets, USP

January 23, 2024

BAUDETTE, Minn., Jan. 23, 2024 (GLOBE NEWSWIRE) -- ANI Pharmaceuticals, Inc. (ANI or the Company) (Nasdaq: ANIP) today announced the launch of Pentoxifylline Extended-Release (ER) Tablets, USP 400mg.

ANI's Pentoxifylline ER Tablets are the generic version of the Reference Listed Drug (RLD) Trental ®. The current annual U.S. market for Pentoxifylline ER Tablets is approximately $19.7 million, according to latest estimates from IQVIA/IMS Health, a leading healthcare data and analytics provider.

"We are pleased to continue the momentum in our generics business with another launch into a limited competition market. ANI remains committed to driving growth through superior new product launch execution, operational excellence, cost-competitiveness, and supply reliability. With a patient-first mindset, our goal is to ensure that patients in need, and the providers who care for them, have access to our high-quality therapeutics," stated Nikhil Lalwani, President and Chief Executive Officer of ANI.

About ANI

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. Our team is focused on delivering sustainable growth by scaling up our Rare Disease business through the successful launch of our lead asset, Purified Cortrophin® Gel, strengthening our generics business with enhanced research and development capability, innovation in established brands and leveraging our North American manufacturing capabilities. For more information, please visit our website 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, the risk that the Company may face with respect to importing raw materials and other ingredients and supplies necessary for manufacture of our products; delays or failure in obtaining and maintaining product approval from the U.S. Food and Drug Administration ("FDA"); changes in policy or actions taken by the FDA and other regulatory agencies, including drug recalls; the ability of our 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; 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 the conflict between Russia and Ukraine.

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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