ANI Pharmaceuticals Announces the FDA Approval and Imminent Launch of Fludrocortisone Acetate Tablets USP

June 1, 2022

BAUDETTE, Minn.--(BUSINESS WIRE)-- ANI Pharmaceuticals, Inc. (“ANI” or the “Company”) (Nasdaq: ANIP) today announced that the Company received U.S. Food and Drug Administration (“FDA”) approval for the Abbreviated New Drug Application (ANDA) for Fludrocortisone Acetate Tablets USP, 0.1 mg.

ANI’s Fludrocortisone Acetate Tablets are the generic version of the Reference Listed Drug (RLD) Florinef ®. The current annual U.S. market for Fludrocortisone Acetate Tablets, 0.1 mg is approximately $24.2 million, according to IQVIA/IMS Health, a leading healthcare data and analytics provider.

"The commercialization of Fludrocortisone Acetate Tablets, the third generic to this RLD, continues to highlight the strength of our research and development engine and our commitment to rapidly bringing limited market competition generic products to our patients in need and to our customers,” stated Nikhil Lalwani, President and Chief Executive Officer of ANI.

About ANI

ANI Pharmaceuticals, Inc. is a diversified bio-pharmaceutical 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 building a successful Purified Cortrophin® Gel franchise, strengthening our generics business with enhanced 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; competition from other products; acquisitions; contract manufacturing arrangements; delays or failure in obtaining product approval from the U.S. Food and Drug Administration; general business and economic conditions; market trends; products development; regulatory and other approvals and marketing.

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.

Investor Relations:
Lisa M. Wilson, In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com

Media:
Angela Salerno-Robin
dna Communications
T: 212-445-8219
E: ASalerno-Robin@dna-comms.com

Source: ANI Pharmaceuticals, Inc.