ANI Pharmaceuticals Announces Refiling of Cortrophin sNDA with FDA

July 6, 2021

BAUDETTE, Minn.--(BUSINESS WIRE)-- ANI Pharmaceuticals, Inc. (“ANI” or the “Company”) (Nasdaq: ANIP) today announced that the Company has re-filed its supplemental new drug application (“sNDA”) for Cortrophin ® Gel with the U.S. Food and Drug Administration (“FDA”).

“We are delighted to have re-filed our sNDA for Cortrophin Gel in the last week of June. ANI has carefully reviewed every communication from the FDA with our internal subject matter experts and enlisted additional expert advice from industry consultants to make every effort to address all of the FDA’s comments. Cortrophin Gel is an important product for ANI, and we look forward to bringing the product to market for patients who can benefit, if approved. I sincerely appreciate the efforts and dedication of the ANI team and our partners to support the re-filing,” stated Nikhil Lalwani, Chief Executive Officer of ANI Pharmaceuticals.

About ANI

ANI Pharmaceuticals, Inc. is an integrated specialty pharmaceutical company focused on delivering value to our customers by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals. We focus on niche and high barrier to entry opportunities including controlled substances, oncology products (anti-cancers), hormones and steroids, and complex formulations. For more information, please visit our website www.anipharmaceuticals.com.

Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as “believe,” “expect,” “may,” “plan,” “potential,” “will,” and similar expressions, and are based on ANI’s current beliefs and expectations. These forward-looking statements include statements regarding the refiling of the sNDA for Cortrophin, the clinical development of Cortrophin, and the potential benefit of Cortrophin to patients if approved by the FDA. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the development of pharmaceutical products, ANI’s reliance on third parties over which it may not always have full control, costs and regulatory requirements relating to contract manufacturing arrangements, delays or failure in obtaining product approvals from the FDA, increased competition and strategies employed by competitors, uncertainties regarding the COVID-19 pandemic, market trends for our products, regulatory environment and changes, regulatory and other approvals relating to product development and manufacturing, 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 U.S. Securities and Exchange Commission. Any forward-looking statements speak only as of the date of this press release and are based on information available to ANI as of the date of this release, and except as required by law ANI assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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