ANI Receives Refusal to File Letter from FDA for Cortrophin® Gel

April 28, 2020

BAUDETTE, Minnesota (April 29, 2020) - ANI Pharmaceuticals, Inc. (“ANI”) (Nasdaq: ANIP) today announced that it received a Refusal to File (RTF) letter from the U.S. Food and Drug Administration (FDA) regarding its supplemental new drug application (sNDA) for Cortrophin® Gel. Upon its preliminary review, the FDA determined that certain portions of the Chemistry, Manufacturing and Controls section in the sNDA were not sufficiently complete to permit a substantive review. ANI will seek immediate guidance, which potentially includes requesting a Type A meeting with the FDA, to clarify and respond to the issues identified in the RTF letter.

Arthur S. Przybyl, ANI’s President and CEO commented, “We remain highly confident in our Cortrophin Gel filing and are fully committed to working with the FDA as quickly as possible to address their letter. We believe that the majority of items mentioned have already been addressed in our original March 23rd sNDA filing and that the remaining items can be reasonably addressed. We look forward to clarifying certain aspects of the filing with the agency.”

About Cortrophin® Gel

Purified Cortrophin® Gel (Repository Corticotropin Injection USP) (80 U/ml) has 54 indications on its previously approved label, including but not limited to acute exacerbations of multiple sclerosis, rheumatoid arthritis, systemic lupus erythematous and ulcerative colitis. For more information, including the complete list of indications and usages, please see the Full Prescribing Information. An sNDA for Cortrophin® Gel was filed with the FDA on March 23, 2020. The current annual market for Cortrophin® Gel is approximately $950 million and has only one competitor.

About ANI

ANI Pharmaceuticals, Inc. (the “Company” or “ANI”) is an integrated specialty pharmaceutical company developing, manufacturing, and marketing branded and generic prescription pharmaceuticals. The Company's targeted areas of product development currently include narcotics, oncolytics (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. 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, statements about ANI’s planned response to the RTF letter, and 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; increased competition; 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, including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as its proxy statement. 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.

For more information about ANI, please contact:
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