ANI Pharmaceuticals Provides Update on Recent Regulatory Filing

June 1, 2020

Baudette, Minnesota (June 1, 2020) – ANI Pharmaceuticals, Inc. (“ANI”) (NASDAQ: ANIP) announced today that it continues to make progress toward addressing items identified in the Refusal to File letter received from the FDA relating to its Cortrophin ® Gel sNDA filing.

“The most efficient path forward is to concentrate efforts on the preparation of the resubmission of the sNDA,” commented ANI Pharmaceuticals Interim CEO Patrick Walsh. “As such, we decided to forego a request for a Type-A meeting with the FDA and respond to all observations as part of the comprehensive resubmission of the sNDA. To further support our efforts, we have retained a prominent regulatory consulting firm to support the company’s re-filing plan, including a comprehensive review of the entire application before re-submission.”

The Company plans on refiling its sNDA for Cortrophin® Gel with the FDA upon completion of the review process.

About ANI

ANI Pharmaceuticals, Inc. (the “Company” or “ANI”) is an integrated specialty pharmaceutical company developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals. The Company's targeted areas of product development currently include controlled substances, oncolytics (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. For more information, please visit the Company’s 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 the company’s beliefs regarding its review and observations relating to its initial Cortophin® Gel sNDA filing, the company’s beliefs concerning its ability to satisfactorily respond to the matters raised in the FDA’s Refusal to File Letter in a re-submission of the filing, the company’s beliefs concerning the information and activities required to resubmit to the FDA the Cortophin® Gel sNDA filing, the timing of resubmission of the company’s sNDA to the FDA and the timing and outcome of the FDA’s review of any resubmitted sNDA relating to the Cortophin® Gel product.

These statements are only predictions and involve known and unknown risks, uncertainties and other factors, which may cause ANI’s actual results to be materially different from these forward-looking statements. There can be no assurances that the results of the additional review and refiling plan will be successful, that the company will be able to successfully develop the additional information that may be required for resubmission of the sNDA, or concerning the timing of completion of development of any additional information for resubmission of the sNDA. In addition, there can be no assurance that the FDA will conclude that any sNDA that the company resubmits will satisfactorily respond to the matters raised in the FDA’s Refusal To File letter, or concerning the timing of any resubmission by ANI of the sNDA, that the FDA will approve our sNDA relating to our Cortophin® Gel product or concerning the timing of any future action by the FDA on our sNDA, regarding the commercialization options that the company will pursue if our sNDA is approved, or that the product will be able to compete successfully in the market if approved and launched.

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 risks described above or that the Company may face with respect to importing raw materials; increased competition; acquisitions; contract manufacturing arrangements; delays or failure in obtaining product approvals from the U.S. Food and Drug Administration; general business and economic conditions; market trends; regulatory environment; 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. 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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