ANI Pharmaceuticals Announces the Filing of a Prior Approval Supplement for Purified Cortrophin® Gel 80 U/mL

March 24, 2020

BAUDETTE, Minnesota (March 24, 2020)- ANI Pharmaceuticals, Inc. (“ANI”) (Nasdaq: ANIP), an emerging leader in the specialty pharmaceutical industry, today announced that it has submitted a prior approval supplement (PAS) to the Endocrinology Division at the FDA for re-commercialization of Purified Cortrophin® Gel (Repository Corticotropin Injection USP) (80 U/mL). The current annual market for Cortrophin® Gel is approximately $950 million and has only one competitor. Cortrophin® Gel was originally approved by the FDA in 1954 and last used in patients in the 1980s. Cortrophin® Gel has over 54 indications on its previously approved label, including but not limited to acute exacerbations of multiple sclerosis, rheumatoid arthritis, systemic lupus erythematosus and ulcerative colitis.

ANI acquired the NDA for Cortrophin® Gel from Merck in January of 2016 and has spent over four years and over $100 million to re-establish and validate the commercial corticotropin active pharmaceutical ingredient (API) and Cortrophin® Gel drug product manufacturing processes. This effort has included rebuilding a U.S. based supply chain that includes pig pituitaries, replicating and improving the manufacturing process for corticotropin API and drug product, and implementing modernized process controls, analytical methods and process characterization to ensure compliance with current FDA standards.

As part of the PAS, ANI has submitted a comprehensive characterization package which demonstrates an unparalleled understanding of both the API and Cortrophin® Gel. The drug has been proven to meet both historical release specifications, as well as modernized release specifications, to ensure compliance with current FDA process validation, method validation and Quality by Design approaches outlined in ICH Guidelines Q8/Q9/Q10. “We are very pleased to have submitted this PAS on schedule and in hopes of bringing Cortrophin® Gel back to the market for both patients and physicians,” said Dr. Mark Ginski, Vice President of Corticotropin Development for ANI.

ANI’s Cortrophin® Gel re-commercialization effort represents a unique opportunity to re-introduce much needed competition, patient and physician choice and substantial drug cost savings into a U.S. corticotropin market currently monopolized by Mallinckrodt’s H.P. Acthar® Gel. At one point in the mid to late 20th century, there were over a half-dozen approved and active corticotropin NDAs; however, all other NDAs, except for ANI’s Cortrophin® Gel and Cortrophin® Zinc, have been withdrawn and are no longer marketed. In addition, a number of potential competitors who were developing synthetic corticotropin products have since ceased development.

Arthur S. Przybyl, ANI’s President and CEO commented, “Cortrophin® Gel represents the last real hope for potential competition for H.P Acthar® Gel. ANI’s effort to re-commercialize Cortrophin® Gel has led to a high-quality product that is the result of a robust modernization plan with unparalleled process characterization and in-process controls. In the past, these two products competed with each other and were largely viewed as interchangeable.”

ANI has publicly committed to offering Cortrophin® Gel at a substantial discount when compared to the current price for H.P Acthar® Gel. ANI’s objective is to introduce direct competition into this $950 million monopoly and reduce drug costs for the U.S. Government, specifically Medicare and Medicaid, which is responsible for approximately 60% of corticotropin spend.

“Today’s submission marks a significant milestone for our company,” said Mr. Przybyl. “I am incredibly proud of what our Cortrophin® Gel team has accomplished over the past 4 years. This drug is truly a transformational opportunity for ANI.”

The FDA has a four-month PDUFA requirement to respond to ANI’s application and determine whether the Cortrophin® Gel PAS submission is complete and acceptable for approval.

About Purified Repository Cortrophin® Gel Injection

Purified Cortrophin® Gel has 54 indications on its previously approved label. For more information, including the complete list of indications and usages, please see the Full Prescribing Information.

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 price increases, the Company’s future operations, products, financial position, operating results and prospects, the Company’s pipeline or potential markets therefor, 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.

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