



## **ANI Pharmaceuticals Announces FDA Acceptance of Purified Cortrophin® Gel Supplemental New Drug Application for Multiple Indications Including Multiple Sclerosis, Rheumatoid Arthritis, and Nephrotic Syndrome**

August 31, 2021

-- Prescription Drug User Fee Act ("PDUFA") target action date is October 29, 2021 --

BAUDETTE, Minn.--(BUSINESS WIRE)-- ANI Pharmaceuticals, Inc. ("ANI" or the "Company") (Nasdaq:ANIP) today announced that the Company's supplemental New Drug Application ("sNDA") for Purified Cortrophin® Gel ("Cortrophin Gel") has been accepted by the U.S. Food and Drug Administration ("FDA") for review.

"FDA's acceptance of our sNDA for Cortrophin Gel marks a significant milestone for ANI. With a PDUFA target action date of October 29, 2021, we are one step closer to bringing a much-needed product to patients and healthcare providers. We look forward to further productive engagement with the FDA, and in parallel, we are focused on preparations for the launch of Cortrophin Gel," stated Nikhil Lalwani, Chief Executive Officer of ANI Pharmaceuticals.

Chris Mutz, Chief Commercial Officer and Head of Rare Disease of ANI Pharmaceuticals, stated, "The availability of a second corticotropin – or ACTH-based – treatment is meaningful for patients struggling with the devastating consequences of chronic auto-immune disorders, including multiple sclerosis, rheumatoid arthritis, and nephrotic syndrome."

### **About Purified Cortrophin Gel**

Purified Cortrophin Gel (Repository Corticotropin Injection USP) is a purified adrenocorticotrophic hormone (ACTH) previously approved in the U.S. for multiple indications including multiple sclerosis (MS), rheumatoid arthritis (RA), and nephrotic syndrome (NS).

### **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. 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](http://www.anipharmaceuticals.com).

### **Forward-Looking Statements**

To the extent any statements made in this release relate to information that is not historical, these are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by words 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. These forward-looking statements include statements regarding the timing of approval of our sNDA for Cortrophin Gel, the clinical development of Cortrophin Gel, and the potential benefit of Cortrophin Gel to patients and size of the market opportunity to the Company if approved by the FDA. Risks and uncertainties that may cause the Company's actual results to be materially different than those expressed in or implied by such forward-looking statements include, but are not limited to, 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 related 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 Exchanges Commission.

Any 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. Except as required by law, 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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