



Tricida Receives Complete Response Letter from the FDA for its New Drug Application for Veverimer for the Treatment of Metabolic Acidosis and Slowing of Kidney Disease Progression in Patients with Metabolic Acidosis Associated with CKD

August 24, 2020

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 24, 2020-- Tricida, Inc. (Nasdaq: TCDA), a pharmaceutical company focused on the development and commercialization of its drug candidate, veverimer (TRC101), a non-absorbed, orally-administered polymer designed to treat metabolic acidosis in patients with chronic kidney disease (CKD), announced today that it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for its New Drug Application (NDA) for veverimer on August 21, 2020. The NDA was reviewed under the Accelerated Approval Program.

According to the CRL, the FDA is seeking additional data beyond the TRCA-301 and TRCA-301E trials regarding the magnitude and durability of the treatment effect of veverimer on the surrogate marker of serum bicarbonate and the applicability of the treatment effect to the U.S. population. FDA also expressed concern as to whether the demonstrated effect size would be reasonably likely to predict clinical benefit. There were no safety, clinical pharmacology/biopharmaceutics, CMC or non-clinical issues identified in the CRL.

The CRL provided multiple options for resolving the identified deficiencies. In order to obtain approval for veverimer the company may or may not have to conduct an additional clinical trial. The FDA indicated it is willing to meet with Tricida to discuss options for obtaining approval, including under the Accelerated Approval Program.

"We have collaborated with the FDA on the Accelerated Approval Program for veverimer and while we are disappointed to receive this CRL, we are pleased that the FDA has provided helpful, specific comments and indicated their willingness to continue to work with us to pursue approval of veverimer," said Gerrit Klaerner, Ph.D., Tricida's Chief Executive Officer and President. "We remain confident in the fundamentals of, and unmet medical need for, veverimer and we continue to conduct our confirmatory trial, VALOR-CKD."

Tricida plans to request a Type A meeting with the FDA in the coming weeks. A Type A meeting is usually scheduled within 30 days of the meeting request. Following the Type A meeting, anticipated early in the fourth quarter, Tricida plans to provide an update on next steps and estimated timing of a potential resubmission of the NDA.

Tricida notes that cash, cash equivalents and investments were \$437 million at the end of the second quarter of 2020. Based on the current operating plan, the company believes that it is well positioned financially to fund its operations into early 2022.

About Tricida

Tricida, Inc. is a pharmaceutical company focused on the development and commercialization of its drug candidate, veverimer (TRC101), a non-absorbed, orally-administered polymer designed to treat metabolic acidosis in patients with CKD. Tricida is currently conducting its confirmatory postmarketing trial, VALOR-CKD, of veverimer. The Tricida NDA for veverimer was submitted to the FDA for review through the Accelerated Approval Program in August 2019. A CRL was received from the FDA in August 2020. There are no FDA-approved treatments for chronic metabolic acidosis, a condition commonly caused by CKD that is believed to accelerate the progression of kidney deterioration. It is estimated to pose a health risk to approximately three million patients with CKD in the United States.

For more information about Tricida, please visit www.Tricida.com.

Cautionary Note on Forward-Looking Statements

This press release includes forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934 ("Exchange Act"). Forward-looking statements relate to expectations concerning matters that are not historical facts. Words such as "projects," "believes," "anticipates," "plans," "expects," "intends," "may," "will," "could," "should," "would," and similar words and expressions are intended to identify forward-looking statements. Any statements contained herein which do not describe historical facts, including the Company's expectations with regard to its interactions and communications with the FDA and its plans and expectations as to the pathway to approval of veverimer by the FDA are forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements. Such risks and uncertainties include, without limitation, whether the Company will be able to address the deficiencies identified by FDA, whether additional trials will be necessary, the availability of the Accelerated Approval Program, the receipt and timing of regulatory approval for veverimer, the Company's ability to market and sell veverimer, if approved, the Company's ability to manufacture veverimer, and risks associated with the Company's business prospects, financial results and business operations. These and other factors that may affect the Company's future business prospects, results and operations are identified and described in more detail in the Company's filings with the Securities and Exchange Commission (the "SEC"), including the Company's most recent Annual Report filed on Form 10-K and the subsequently filed Quarterly Report(s) on Form 10-Q. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this filing. Except as required by applicable law, the Company does not intend to update any of the forward-looking statements to conform these statements to actual results, later events or circumstances or to reflect the occurrence of unanticipated events.

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