Tricida Provides Regulatory Update on Veverimer

July 15, 2020

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jul. 15, 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 on July 14, 2020, the Company received a notification from the U.S. Food and Drug Administration (FDA) stating that, as part of its ongoing review of the Company's New Drug Application (NDA), the FDA has identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time. The FDA stated that the notification does not reflect a final decision on the information under review.

The notification does not specify the deficiencies identified by the FDA. The Company plans to work with the FDA to identify and seek to resolve the deficiencies. The Company has no current plans to modify or suspend its ongoing confirmatory postmarketing trial, VALOR-CKD. However, at this time the Company is unable to evaluate whether it will be able to address the FDA's concerns.

"We are surprised and disappointed by this news," said Gerrit Klaerner, Ph.D., Tricida's Chief Executive Officer and President. "We continue to believe in the potential of veverimer to be disease modifying and our goal is to work with FDA to identify and resolve the issues in order to bring veverimer to patients."

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. Metabolic acidosis is 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. Tricida is currently conducting its confirmatory postmarketing trial, VALOR-CKD, of veverimer. The Tricida NDA for veverimer has been accepted for review by the FDA through the Accelerated Approval Program. The FDA has assigned a PDUFA goal date of August 22, 2020.

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

Cautionary Note on Forward-Looking Statements

This current report on Form 8-K contains "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, statements regarding the potential receipt and timing of the FDA's approval of the NDA, the Company's expectations with regard to its interactions and communications with the FDA, plans, and expectations as to the PDUFA date 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, any deficiencies the FDA may identify with respect to veverimer and whether the Company will be able to address the issues that may relate to those deficiencies, the receipt 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 our business prospects, financial results and business operations. These and other factors that may affect our future business prospects, results and operations are identified and described in more detail in our filings with the Securities and Exchange Commission (the "SEC"), including the Company's most recent Annual Report filed on Form 10-K and our 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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Jackie Cossmon
Tricida, Inc.
Senior Vice President of Investor Relations and Communications
IR@Tricida.com

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