Tricida Provides Update on FDA Interactions

October 29, 2020

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Oct. 29, 2020-- Tricida, Inc. (Nasdaq: TCDA), a pharmaceutical company focused on the development and commercialization of its investigational 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 held an End-of-Review conference as a Type A meeting with the Division of Cardiology and Nephrology of the U.S. Food and Drug Administration (FDA) on October 20, 2020. This meeting followed a Complete Response Letter (CRL) that was received by the company on August 21, 2020 for the veverimer NDA that was under review by the FDA through the Accelerated Approval Program.

In Tricida's meeting package before the Type A meeting, the company included a proposal to conduct an interim analysis of serum bicarbonate data from VALOR-CKD in ~500 patients treated for 12 months for purposes of confirming the treatment effect of veverimer observed in the TRCA-301/301E trials and its applicability to the U.S. population and practice of medicine. If accepted by the FDA, Tricida believed this proposal would allow resubmission of the NDA for veverimer within a matter of months. Based on feedback during the Type A meeting, Tricida now believes the FDA will also require evidence of veverimer's effect on CKD progression from a near-term interim analysis of the VALOR-CKD trial for approval under the Accelerated Approval Program and that the FDA is unlikely to rely solely on serum bicarbonate data for determination of efficacy. The company's ongoing VALOR-CKD trial was designed to be a confirmatory trial to demonstrate the effect of veverimer on slowing CKD progression following accelerated approval. Based on the primary endpoint and patient population in VALOR-CKD, Tricida does not believe it can provide information on CKD progression from a near-term interim analysis of the VALOR-CKD trial without compromising the integrity of the ongoing trial.

The company believes any requirement for early interim CKD progression data in addition to surrogate data at the time of accelerated approval is inconsistent with the intent of the Subpart H regulation. Indeed, prior to the End-of-Review Type A meeting, over nearly four years, Tricida's discussions with the FDA focused on development of veverimer based solely on the use of serum bicarbonate as the surrogate endpoint to enable accelerated approval, with CKD progression data to be provided only at the completion of the VALOR-CKD trial. Tricida has developed a deep understanding of the surrogate endpoint of an increase in serum bicarbonate and how it reasonably likely translates to clinical benefit. The company continues to believe that its current development program for veverimer is an appropriate candidate for accelerated approval based on (1) the seriousness of end-stage renal disease (ESRD), (2) the high unmet need for an approved therapy, and (3) data supporting the link between metabolic acidosis and progression of CKD, including data describing the pathophysiology of metabolic acidosis, published data from multiple interventional trials and observational cohort analyses, and the availability of two validated models that consistently describe the relationship between serum bicarbonate and the renal outcome that is being measured in VALOR-CKD.

"We are surprised by the feedback received from the FDA during the Type A meeting," said Gerrit Klaerner, Ph.D., Tricida's Chief Executive Officer and President. "The introduction of a requirement for data on the effect of veverimer on renal disease progression to support initial accelerated approval clearly represents a major setback in the timeline for the development of veverimer. We remain dedicated to bringing veverimer to patients with CKD and metabolic acidosis who currently have no FDA-approved therapy for their disease."

Tricida plans to wait for formal meeting minutes from the FDA related to the End-of-Review Type A meeting prior to determining how to proceed with obtaining regulatory approval for veverimer. The company expects to receive the formal minutes within 30 days from the meeting.

Organizational Update and Financial Position

Tricida is re-organizing the company to extend its financial runway in order to maximize the options for bringing veverimer to patients. The company is significantly reducing its headcount from 152 to 59 people and will discuss its commitments with vendors and contract service providers to potentially provide additional financial flexibility. This reduction in headcount will reduce Tricida's annual operating costs by approximately $25 million.

Cash and cash equivalents as of September 30, 2020 were approximately $375 million. Tricida currently has $75 million principal amount of debt with Hercules which is scheduled to be amortized from April 2021 to April 2023 and has $200 million in outstanding principal amount of 3.5% Convertible Senior Notes which mature in May 2027.

Tricida Conference Call Information

Tricida will host a conference call and webcast at 8:00 am Eastern Time today to discuss the preliminary feedback from its FDA interactions and future plans. The webcast, including slides, or conference call may be accessed as follows:

Tricida Conference Call

Thursday, October 29, 2020

8:00 am Eastern Time

Webcast: IR.Tricida.com

Dial-in: **(877) 377-5478**

International: (629) 228-0740

Conference ID: 9786643

A replay of the webcast will be available on Tricida's website approximately two hours following the completion of the call and will be available for up to 90 days following the presentation.

About Tricida

Tricida, Inc. is a pharmaceutical company focused on the development and commercialization of its investigational drug candidate, veverimer (TRC101), a non-absorbed, orally-administered polymer designed to treat metabolic acidosis in patients with CKD. 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 of 1933 and Section 21E of the Securities Exchange Act of 1934. 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, its plans and expectations as to the pathway to approval of veverimer by the FDA and the design of its ongoing clinical trials, and expectations regarding financial runway 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, the timing of the FDA's approval of veverimer, if at all; the potential availability of the Accelerated Approval Program and the approvability of veverimer under that program; the Company's plans and expectations with regard to its interactions with the FDA, including the potential resubmission of an NDA for veverimer; the Company's plans and expectations for VALOR-CKD and future clinical and product development milestones; the Company's financial projections and cost estimates; 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 press release. 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20201029005440/en/

Jackie Cossmon, IRC
Tricida, Inc.
Senior Vice President of Investor Relations and Communications
IR@Tricida.com

Source: Tricida, Inc.