Tricida Announces Updates on Veverimer Development Program, Regulatory Status and New Patent Extending Protection through 2038

December 8, 2020

SOUTH SAN FRANCISCO, Calif., Dec. 08, 2020 (GLOBE NEWSWIRE) -- 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 key updates on veverimer's development program, regulatory status and patent protection.

Veverimer Development Update

Tricida has revised the protocol for its VALOR-CKD outcome trial. The VALOR-CKD trial evaluates the effect of treating metabolic acidosis with veverimer on the clinical endpoint of slowing of CKD progression. The trial protocol previously had an adaptive design and included an unblinded interim analysis for sample size re-estimation. The revised protocol has a group sequential design, no interim analysis for sample size adjustment, and unblinded interim analyses for early stopping for efficacy after 150 primary endpoint events (anticipated in the second half of 2021) and 250 primary endpoint events (anticipated in mid-2022) have accrued. A primary endpoint event is defined as renal death, end-stage renal disease (ESRD) or ≥ 40% reduction in estimated glomerular filtration rate (eGFR) (DD40). The interim analyses will be conducted by an independent unblinded Interim Analysis Committee, and the trial will remain blinded unless it is stopped early for efficacy. If this trial is successful, Tricida intends for it to serve as the confirmatory trial for accelerated approval or form the basis for traditional approval of veverimer.

As of December 7, 2020, the VALOR-CKD trial has randomized 1,277 of 1,600 subjects with an average treatment duration of approximately one year and has accrued 50 of the 511 required subjects with positively adjudicated primary endpoint events. In response to feedback from the U.S. Food and Drug Administration (FDA) at the End-of-Review Type A Meeting, recruitment has been closed in all regions except for the United States, Canada and Western Europe. Recruitment completion is projected to occur by the end of 2022.

Veverimer Regulatory Status Update

A Formal Dispute Resolution Request (FDRR) has been submitted to the FDA to seek clarity on the path forward for resubmitting our New Drug Application (NDA) through the Accelerated Approval Program. The FDRR requests that the Office of New Drugs (OND) find that the magnitude of serum bicarbonate change seen in the TRCA-301 and TRCA-301E trials is reasonably likely to predict clinical benefit in the treatment of metabolic acidosis associated with CKD and that it can therefore serve as the basis for accelerated approval. If accepted for consideration, a decision on the FDRR is expected in the first quarter of 2021. The timing and next steps for a resubmission of the NDA for veverimer will be dependent upon the OND's decision.

"We believe that we are studying the right patient population and the right CKD progression endpoint in VALOR-CKD. Hence, we believe that an adaptive design is no longer necessary and have locked in the sample size at 1,600 subjects and built in two opportunities for stopping early for efficacy over the next 18 to 24 months, in the event that the effect of veverimer on slowing CKD progression is greater than currently modeled," said Gerrit Klaerner, Ph.D., Tricida's Chief Executive Officer and President. "And while we are disappointed that we could not come to a resolution with the Division of Cardiology and Nephrology on the resubmission of our NDA during our Type A meeting, we believe that the focused, single issue FDRR currently represents the best approach to bring veverimer to patients through accelerated approval."

Financial Guidance

Tricida currently has the financial resources to fund our operations into at least mid-2022, prior to modifying any of its material agreements. Cash, cash equivalents and investments as of September 30, 2020 were approximately $376 million. Tricida currently has $75 million principal amount of debt with Hercules which has a final maturity of April 2023 and has $200 million in outstanding principal amount of 3.5% Convertible Senior Notes which mature in May 2027.

Veverimer Patent Protection Update

Tricida has recently received notice of allowance for a new Orange Book eligible patent which, upon issuance, will extend veverimer's patent coverage in the United States to 2038. Tricida also holds six previously issued Orange Book eligible patents that provide patent protection until 2034 and several pending patent applications. Tricida also holds multiple patents in Europe and other key international markets that provide patent protection for veverimer to at least 2034.

Tricida Conference Call Information

Tricida will host a conference call and webcast at 4:30 pm Eastern Time today to discuss the veverimer updates. The webcast, including slides, or conference call may be accessed as follows:

Tricida Conference Call
Tuesday, December 8, 2020
4:30 pm Eastern Time

Webcast:	IR.Tricida.com
Dial-in:	**(877) 377-5478**
International:	(629) 228-0740

Conference ID: **2669339**

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 trial, VALOR-CKD, and its 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, whether the FDA will accept the Company's FDRR; 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.

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

TRICIDA

Source: Tricida, Inc.