Tricida Provides Update on Timing of Top-Line Data for the VALOR-CKD Trial Based on Conflict in Ukraine

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SOUTH SAN FRANCISCO, Calif., March 02, 2022 (GLOBE NEWSWIRE) -- Tricida, Inc. (Nasdaq: TCDA), a pharmaceutical company focused on the development and commercialization of its investigational drug candidate, veverimer, a non-absorbed, orally-administered polymer designed to slow chronic kidney disease (CKD) progression in patients with metabolic acidosis and CKD, announced today an update on the anticipated date for top-line data from the VALOR-CKD trial based on the ongoing events in Ukraine. Approximately fifteen percent (15%) of the patients randomized in VALOR-CKD are from Ukraine. Given the uncertainty around future participation of Ukrainian subjects in the trial and the potential challenges to collecting and monitoring data from Ukrainian sites, top-line data from the VALOR-CKD trial is now anticipated early in the fourth quarter of 2022, versus Tricida's previous guidance of the third quarter of 2022. The revised guidance is based on Tricida's evaluation of the current situation in Ukraine which is dynamic. Its estimates may change as events in Ukraine evolve. Tricida believes it will need this incremental time to deal with anticipated disruptions and/or delays in data collection. Tricida does not expect the utility of the data already collected from Ukrainian subjects to be affected. Based upon the latest review of its forecast, Tricida believes that its financial resources will extend for approximately six months following the anticipated announcement of top-line results from the VALOR-CKD trial.

As of March 1, 2022, the VALOR-CKD trial had accrued 197 subjects with positively adjudicated primary endpoint events, defined as renal death, end-stage renal disease (ESRD), or greater than or equal to a 40% decline in estimated glomerular filtration rate (eGFR), with an average treatment duration of approximately 23 months.

"We are deeply concerned for the people of Ukraine, including the VALOR-CKD patients, investigators, site staff and our CRO colleagues who we have worked with for many years. We are horrified by what they and all of the Ukrainian people are having to endure defending their homeland against a brutal Russian invasion," said Gerrit Klaerner, Ph.D., Tricida's Chief Executive Officer and President. "We believe that an incremental delay of the administrative stop is prudent to obtain interpretable data from the VALOR-CKD trial with approximately the same number of events and six-months cash runway as outlined in our prior communications."

About Tricida

Tricida, Inc. is a pharmaceutical company focused on the development and commercialization of its investigational drug candidate, veverimer, a non-absorbed, orally-administered polymer designed to slow CKD progression in patients with metabolic acidosis and CKD. Tricida is currently conducting a renal outcomes clinical trial, VALOR-CKD, to determine if veverimer slows CKD progression in patients with metabolic acidosis associated with CKD. Metabolic acidosis is a condition commonly caused by CKD that is believed to accelerate the progression of kidney deterioration. There are currently no therapies approved by the FDA to slow progression of kidney disease through the treatment of chronic metabolic acidosis in patients with CKD. 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 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. These forward-looking statements include, but are not limited to, statements regarding the Company's plans and expectations for the VALOR-CKD trial, including early termination of the trial, and the rate of accrual of primary endpoint events, and its expectations regarding the potential timing of the announcement of top-line date from the VALOR-CKD trial and its financial runway. These forward-looking statements 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, developments in Ukraine and the region, the Company's plans and expectations for its VALOR-CKD trial, including the estimated number of subjects with primary endpoints in the final analysis and the estimated timing for receipt of top-line data from that trial, 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.

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