# Tricida Announces Publication of Positive Long-Term Phase 3 Clinical Trial Results of Veverimer (TRC101) in The Lancet

June 25, 2019

*TRCA-301E trial is the first, long-term, randomized, multicenter, blinded, placebo-controlled trial to evaluate the treatment of metabolic acidosis in patients with CKD*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 25, 2019-- 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 that *The Lancet* published online detailed results from its long-term, Phase 3, multicenter, parallel, randomized, blinded, placebo-controlled trial, TRCA-301E, in 196 patients with CKD and metabolic acidosis. Full results of the trial are available in *The Lancet*:

A multicentre, randomised, blinded, placebo-controlled, 40-week extension study to assess the long-term safety and efficacy of veverimer for the treatment of metabolic acidosis in chronic kidney disease

"This new data highlights the value of treating metabolic acidosis in patients with CKD," said Donald E. Wesson, M.D., M.B.A., Professor of Medicine at Texas A&M Health Science Center College of Medicine in Dallas, TX, lead investigator of the study and primary author of *The Lancet* paper. "As patients advance to later stages of CKD, metabolic acidosis may further complicate their disease, resulting in muscle wasting, bone loss and further progression of CKD. The importance of metabolic acidosis as both a serious complication of CKD and an underlying cause of CKD progression has been under-recognized, and it has been markedly under-treated."

"The publication of our veverimer clinical trial data from both our 12-week TRCA-301 trial and now our TRCA-301E 40-week extension trial in two separate publications in *The Lancet*, one of the most prestigious general medical journals in the world, clearly advances the understanding of metabolic acidosis and speaks to the importance of these results," said Gerrit Klaerner, Ph.D., CEO and President of Tricida, and a coauthor of *The Lancet* paper. "I would like to personally thank the authors, our clinical trial investigators, and the patients who participated in the study for their contributions to this important work."

Tricida provided a summary of the topline trial data from the TRCA-301E clinical trial in a March 28, 2019 press release.

In addition to Dr. Wesson, study authors included: Vandana Mathur, M.D. (MathurConsulting); Navdeep Tangri, M.D., Ph.D.(University of Manitoba), Yuri Stasiv, Ph.D. (Tricida), Dawn Parsell, Ph.D.(Tricida); Elizabeth Li, M.S.(PharmaStat LLC); Gerrit Klaerner, Ph.D.(Tricida) and David A. Bushinsky, M.D.(University of Rochester School of Medicine).

**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 chronic kidney disease (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 has successfully completed all of the clinical trials that it planned to complete prior to submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA). Tricida plans to submit an NDA in the second half of 2019, seeking approval of veverimer through the FDA's Accelerated Approval Program.

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

**Cautionary Note on Forward-Looking Statements**

This press release includes forward-looking statements, including for example, statements about our ability to submit an NDA for veverimer under the FDA's Accelerated Approval Program. Forward -looking statements involve known and unknown risks, uncertainties, assumptions and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks and uncertainties include, among others, timing and results of clinical trials and other studies; that many drug candidates that have completed Phase 3 trials do not become approved drugs on a timely or cost effective basis or at all; there can be no assurance that the FDA would approve an NDA under the Accelerated Approval Program, or at all, and even if approval for a drug is obtained, there can be no assurance that it will be adopted in the market or accepted as a benefit to patients and healthcare providers; possible safety and efficacy concerns; and that we completely rely on third-party suppliers to manufacture our clinical drug supply. The forward-looking statements contained in this press release reflect Tricida's current views with respect to future events, and Tricida does not undertake and specifically disclaims any obligation to update any forward-looking statements.

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