Tricida Announces Hiring of Dawn Parsell as Senior Vice President of Clinical Development

August 1, 2018

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 1, 2018-- Tricida, Inc. (Nasdaq: TCDA) today announced the hiring of Dawn Parsell, Ph.D., as Senior Vice President of Clinical Development. Dr. Parsell will lead Tricida's clinical development of TRC101 as the company prepares to begin its VALOR-CKD confirmatory postmarketing trial and submit a New Drug Application (NDA) under the U.S. Food and Drug Administration's (FDA) Accelerated Approval Program.

"Dawn's extensive experience in all phases of clinical development and regulatory affairs make her an ideal addition to Tricida's executive team," said Gerrit Klaerner, Ph.D., Tricida's CEO, president and board member. "As a consultant to Tricida since 2014, Dawn has been instrumental in the preclinical and clinical development of, and regulatory strategy for, TRC101. Dawn's focused efforts on TRC101 clinical development will be invaluable to ensuring our goal of providing a first-in-class treatment to patients with CKD who suffer from metabolic acidosis. We are very pleased to have Dawn join the Tricida team."

Dr. Parsell has over 24 years of biotechnology and pharmaceutical industry experience, where she has been involved in the successful development and approval of nine FDA-approved drugs. She has served as an independent regulatory consultant to the industry since 2001, providing strategic and tactical clinical and regulatory support to her clients, including assisting in the design and implementation of Tricida's TRC101 development program. From 1994 to 2001, Dr. Parsell worked at Connetics Corporation in discovery, clinical development and regulatory affairs positions, most recently as Director of Regulatory Affairs. Dr. Parsell received a B.S. in Biochemistry and Genetics/Cell Biology with Distinction from the University of Minnesota, a Ph.D. in Biology from the Massachusetts Institute of Technology and completed a post-doctoral research fellowship at the Howard Hughes Medical Institute at The University of Chicago.

"I share Tricida's passion to develop a drug that can potentially slow the progression of CKD," said Dr. Parsell. "The growing evidence that treating metabolic acidosis can make a difference in the lives of CKD patients drives the urgency to develop a drug like TRC101. I am eager to continue this important work and delighted to join the company at this important time."

About Tricida

Tricida, Inc. is a pharmaceutical company focused on the development and commercialization of its product candidate, 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. Tricida has successfully completed a pivotal Phase 3, double-blind, placebo-controlled trial of TRC101 in CKD patients with metabolic acidosis. The results of this Phase 3 trial along with results from a successful double-blind, randomized, placebo-controlled Phase 1/2 trial and an ongoing safety extension trial, TRCA-301E, are intended to serve as the basis for the submission of an NDA for TRC101 under the Accelerated Approval Program of the FDA.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements, including for example, the ability of our drug candidate to provide benefit to patients or to become a first-in-class drug for the treatment of metabolic acidosis and our ability to submit an NDA for TRC101 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, the cost, timing and results of clinical trials and other studies; that many drug candidates that have completed Phase 3 trials do not become approved drugs; 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; and that there will not be possible safety and efficacy concerns. 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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