Talphera Announces 50% Enrollment Milestone in Ongoing NEPHRO-CRRT Registrational Trial

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Enrolled 35 of the 70 patients in the ongoing NEPHRO-CRRT registrational study, supported by new target profile sites

Company to host a virtual investor and analyst event on March 23 at 11:00 am ET featuring nephrologists, Dr. Blaithin McMahon and Dr. Joao Teixeira

SAN MATEO, Calif., March 2, 2026 /PRNewswire/ -- Talphera, Inc. (Nasdaq: TLPH), ("Talphera"), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings, today announced 50% patient enrollment of the NEPHRO-CRRT clinical trial.

"Over the course of 2025, with agreement from the FDA, we implemented significant changes to the NEPHRO CRRT clinical trial, including a nearly 60% reduction in the total number of patients to be enrolled and revising other enrollment criteria. In addition, we reviewed and updated our target profile for clinical sites to focus on medical ICUs and having nephrologists as our principal investigators. These changes have yielded positive results in enrollment rates, allowing us to achieve our 50% enrollment milestone with more than 90% of the patients from our new sites," said Vince Angotti, CEO of Talphera. "We're looking forward to completing the study, and anticipate filing our PMA this year to potentially have the only FDA approved regional anticoagulant for CRRT. We continue to receive feedback from physicians— that they desperately need a better CRRT anticoagulant. In just a few weeks, we are excited to have two key experts share their deep experience with CRRT at our planned virtual investor and analyst day," continued Angotti.

Virtual Investor and Analyst Event Information and Biographies of Key Experts

Talphera will hold a conference call and webcast for investors and analysts at 11:00 am Eastern Time on March 23, 2026 with two key experts and principal investigators in the NEPHRO CRRT study. The guest physicians will discuss their experience with CRRT and the anticoagulants currently being used during CRRT today, and how they see nafamostat filling a role. They will also take questions from investors and analysts.

The webcast can be accessed here or by visiting the Investors section of the Company's website at www.talphera.com and clicking on the webcast link posted within Investors/News & Events/Upcoming Events section. The webcast will include a slide presentation, and a replay will be available on the Talphera website for 90 days following the event.

Dr. Blaithin McMahon (Medical University of South Carolina)

Dr. McMahon is an Associate Professor of Medicine at the Medical University of South Carolina. She did her medical residency and nephrology fellowship training at the Johns Hopkins Hospital, Baltimore, from 2011-2016. In July 2016, she joined the nephrology faculty at the Johns Hopkins Hospital prior to moving to MUSC in September 2018. Dr. McMahon's key research is in the field of Acute Injury Kidney. She has published over 50 papers in leading peer reviewed international nephrology medical journals and penned numerous editorials, commentaries, case reports, expert opinions, review papers, book chapters and has more than 1000 citations in this area of interest. She is the director of nephrology clinical trials at MUSC and is involved in several prospective national and international ICU studies ongoing in the area of Acute Kidney Injury and continuous kidney replacement therapy. Dr. McMahon is also the Director of CRRT at MUSC and is responsible for managing prescription protocols related to dialysis in the intensive care unit. She has been awarded multiple teaching awards at Johns Hopkins Hospital MUSC and University College Dublin.

Dr. Joao Teixeira (University of New Mexico)

Dr. Teixeira is an Associate Professor in Divisions of Nephrology and Pulmonary, Critical Care, and Sleep Medicine in the Department of Internal Medicine (DOIM) at the University of New Mexico (UNM). He staffs the inpatient nephrology consult service and medical intensive care unit (ICU) at UNM Hospital (UNMH), works as medical co-director of a local outpatient hemodialysis unit, and serves as the director of the acute dialysis and continuous kidney replacement therapy (CRRT) programs at UNMH. He was previously the Training Program Director of UNM's Nephrology Fellowship and has served as Core Faculty in the Critical Care Medicine Fellowship and the Internal Medicine Residency.

As a critical care nephrologist, his scholarly interests lie in all areas of overlap between the two fields, centering on the realm of acute kidney injury (AKI). He developed a critical care research program focused on diagnostics and therapeutics for AKI, CRRT, septic shock, vasopressor therapy, extracorporeal membrane oxygenation (ECMO), hepatorenal syndrome (HRS), COVID-19, and acute respiratory distress syndrome (ARDS). As site principal investigator or an investigator, he has enrolled approximately 300 critically ill or hospitalized patients into more than a dozen investigator-initiated or industry-sponsored clinical trials. He has coauthored over 100 peer-reviewed publications, book chapters, and conference abstracts; he is on the editorial boards of three journals and has served as an ad hoc reviewer for several dozen other journals. He has served as invited faculty at over a dozen national and international conferences, including the National Kidney Foundation Spring Clinical Meeting, American Society of Nephrology Kidney Week, and European Society of Intensive Care Medicine.

About the NEPHRO CRRT Study

The NEPHRO CRRT Study is designed as a prospective, double-blinded trial to be conducted at up to 14 U.S. hospital intensive care units. The study will enroll and evaluate 70 adult patients undergoing renal replacement therapy, who cannot tolerate heparin or are at risk of bleeding. The primary endpoint of the study is the mean post-filter activated clotting time on Niyad versus placebo over the first 24 hours. Key secondary endpoints include the mean post-filter activated clotting time over 72 hours, filter lifespan, number of filter changes over 72 hours, number of transfusions over 72 hours and dialysis efficacy (based on urea concentration) over the first 24 hours.

About Niyad and Nafamostat

Nafamostat is a broad spectrum, synthetic serine protease inhibitor with anticoagulant, anti-inflammatory and potential anti-viral activities. Niyad™ is a lyophilized formulation of nafamostat and is currently being studied under an IDE, as an anticoagulant for the extracorporeal circuit, and has received Breakthrough Device Designation Status from the FDA. Talphera's registrational study of Niyad™ is named the NEPHRO CRRT (Nafamostat Efficacy in Phase 3 Registrational Continuous Renal Replacement Therapy) study. An ICD-10 procedural code, XY0YX37, has been issued for the

extracorporeal introduction of nafamostat. The ICD-10 code is a specific/billable code that can be used to indicate a procedure. LTX-608 is a proprietary nafamostat formulation for direct IV infusion that may be investigated and developed for the treatment of acute respiratory distress syndrome (ARDS), disseminated intravascular coagulation (DIC), acute pancreatitis or anti-viral treatment, amongst other potential targets.

About Talphera, Inc.

Talphera, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings. Talphera's lead product candidate, Niyad™ is a lyophilized formulation of nafamostat and is currently being studied under an investigational device exemption (IDE) as an anticoagulant for the extracorporeal circuit and has received Breakthrough Device Designation status from the U.S. Food and Drug Administration (FDA).

This release is intended for investors only. For additional information about Talphera, please visit www.talphera.com

Forward-looking statements

This press release contains forward-looking statements based upon Talphera's current expectations and assumptions. These and any other forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking terminology such as "believe," "expect," "anticipate," "may," "if," "intends," "plans," "potential," "projected," "will," or the negative of these words or other comparable terminology, and include: looking forward to completing the NEHPRO CRRT study and the Company's target filing of the PMA this year to potentially have the only FDA approved regional anticoagulant for CRRT. Talphera's discussion of its strategy, plans and intentions also include forward-looking statements, which are predictions, projections and other statements about future events that are based on current expectations and assumptions. These forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those projected, anticipated or implied by such statements, including: (i) risks relating to Talphera's product development activities, including that clinical studies may not be fully enrolled or completed and/or confirm any safety, efficacy or other potential developmental product characteristics described or assumed in this press release; (ii) Talphera's developmental product candidates may not be beneficial to patients or healthcare providers or be successfully commercialized; (iii) risks relating to Talphera's ability to obtain regulatory approvals for its developmental product candidates; (iv) risks related to the ability of Talphera and its business partners to implement development plans, commercial launch plans, forecasts and other business expectations; and (v) risks related to Talphera's liquidity and its ability to maintain capital resources sufficient to conduct its clinical studies. Although it is not possible to predict or identify all such risks and uncertainties, they may include, but are not limited to, those described under the caption "Risk Factors" and elsewhere in Talphera's annual, quarterly and current reports (i.e., Form 10-K, Form 10-Q and Form 8-K) as filed or furnished with the SEC and any subsequent public filings. You are cautioned not to place undue reliance on any such forward-looking statements, which speak only as of the date such statements were first made. To the degree financial information is included in this press release, it is in summary form only and must be considered in the context of the full details provided in Talphera's most recent annual, quarterly or current report as filed or furnished with the SEC. Talphera's SEC reports are available at www.talphera.com under the "Investors" tab. Except to the extent required by law, Talphera undertakes no obligation to publicly release the result of any revisions to these forward-looking statements to reflect new information, events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events.

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