Talphera Announces Two Abstracts Accepted for Presentation at AKI & CRRT 2026

Mar 25, 2026

SAN MATEO, Calif., March 25, 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 the acceptance of two abstracts for presentation at the 31st Annual International Conference on Advances in Critical Care Nephrology: AKI & CRRT 2026 to be held March 29-April 2, 2026 in San Diego.

Poster Presentation 1
Title: A Randomized, Placebo-Controlled, Multi-Center Study Of The Safety And Efficacy Of Niyad In Patients Undergoing Continuous Renal Replacement Therapy (CRRT) Who Cannot Tolerate Heparin Or Are At A Higher Risk of Bleeding
Presenter: Kayla Adler
Date and time: Sunday, March 29, 5:30 – 7:30 PM
Session title: Clinical Research in AKI 2

The poster will highlight the key components of the NEPHRO-CRRT study design, currently enrolling patients in the registrational study. There is an unmet medical need for safe, effective, and simple-to-use regional anticoagulants for use during CRRT. Nafamostat has desirable properties and extensive user experience as a regional anticoagulant for over three decades outside of the US. The NEPHRO-CRRT is an ongoing registrational study to evaluate the safety and efficacy of nafamostat for its potential approval in the US to address this unmet need.

Poster Presentation 2
Title: In Vivo Assessment Of Nafamostat, A Novel Regional Anticoagulant In a Porcine Model AKI And CKRT
Presenter: Kayla Adler
Date and time: Monday, March 30, 6:00 – 8:00 PM
Session title: Clinical Research in AKI 3

This study characterized the pharmacokinetics of nafamostat and its effect on post-filter and systemic Activated Clotting Time (ACT) across different membrane types in a porcine model of AKI receiving CRRT. When administered pre-filter, over 95 percent of nafamostat was removed by the hemofilter, resulting in the median systemic exposures of less than 5 percent of the pre-filter exposure. There was a minimal effect on the systemic ACT when the post-filter ACT was less than 275 seconds. The NEPHRO CRRT registrational study of nafamostat is targeting a post-filter ACT of 175 to 225 seconds, which is expected to provide sufficient extracorporeal anticoagulation while minimally affecting systemic ACT. In conclusion, nafamostat has unique PK and PD properties, making it a suitable candidate for further evaluation as a regional anticoagulant in CRRT.

"While we are currently enrolling patients in our NEPHRO-CRRT registrational study, based on use in Japan and South Korea for over three decades, we continue to believe nafamostat will be an effective regional anticoagulant for use during continuous renal replacement therapy (CRRT), and we're excited to share the poster presentations at AKI & CRRT 2026," stated Dr. Shakil Aslam, Chief Medical Officer of Talphera. "The current anticoagulants being used for CRRT are not ideal and have many disadvantages. If approved, nafamostat would become the first regional anticoagulant approved by the FDA for use during CRRT," continued Dr. Aslam.

About the NEPHRO CRRT Study

The NEPHRO CRRT Study, which has received central IRB approval, 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 for bleeding. The primary endpoint of the study is mean post-filter activated clotting time using 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 (**N**afamostat **E**fficacy in **Ph**ase 3 **R**egistrational **C**ontinuous **R**enal **R**eplacement **T**herapy) 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 as an 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. 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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