Talphera Announces First Patient Enrolled in the Registrational Trial Evaluating Nafamostat for Anticoagulation of the Extracorporeal Circuit

Aug 19, 2024

The safety and effectiveness of nafamostat is being assessed in the NEPHRO CRRT registrational trial in 166 patients at up to 14 clinical sites

Primary endpoint in the NEPHRO CRRT study is measured over the first 24 hours, with patients completing the study after 72 hours

Dr. Stuart Goldstein, a world-renowned nephrologist, is the first physician to enroll a patient in the NEPHRO CRRT study

SAN MATEO, Calif., Aug. 19, 2024 /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 first patient has been enrolled in the NEPHRO CRRT study.

The NEPHRO CRRT registrational study will enroll 166 patients undergoing continuous renal replacement therapy (CRRT) at up to 14 clinical sites across the United States. The primary endpoint of the study is the mean post-filter activated clotting time for circuits infused with nafamostat versus placebo over the first 24 hours.

"We are excited to be able to offer participation in this nafamostat study to our patients requiring CRRT," stated Stuart Goldstein, M.D., Professor of Pediatrics and Director of the Center for Acute Care Nephrology at Cincinnati Children's Hospital Medical Center. "Nafamostat, if approved following this trial, will be a valuable addition to our anticoagulant options for many patients."

"We are pleased the first patient was enrolled in the study last week. Nafamostat has the potential to address disadvantages of the currently available U.S. products used for anticoagulation of the extracorporeal circuit. Enrolling the first patient in the NEPHRO study is the first of what we believe will be several important milestones for Talphera," stated Dr. Shakil Aslam, Chief Development Officer at Talphera. "Nafamostat has been used, and is a standard of care, in Japan and South Korea for over 30 years and we're excited about the prospects of making nafamostat available to healthcare providers in the United States, if approved," continued Dr. Aslam.

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.

About the NEPHRO CRRT Study

The NEPHRO 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 166 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 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.

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," "finalize," "may," "if," "intends," "plans," "potential," "projected," "will," or the negative of these words or other comparable terminology, and include: Talphera's expectation that the NEPHRO study will enroll and complete efficiently, the potential of nafamostat to address unmet needs in anticoagulation of the extracorporeal circuit, and the potential advantage of having Breakthrough Device Designation and potential FDA approval of the nafamostat product candidate. 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 confirm any safety, efficacy or other 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.

View original content to download multimedia:https://www.prnewswire.com/news-releases/talphera-announces-first-patient-enrolled-in-the-registrational-trial-evaluating-nafamostat-for-anticoagulation-of-the-extracorporeal-circuit-302224599.html

SOURCE Talphera, Inc.

Investor Contacts: Talphera, Raffi Asadorian, CFO, 650-216-3500, investors@talphera.com; LifeSci Advisors, Kevin Gardner, 617-283-2856, kgardner@lifesciadvisors.com; Chris Calabrese, 917-680-5608, ccalabrese@lifesciadvisors.com