Chinook Therapeutics Announces Initiation of Phase 1 Healthy Volunteer Trial of CHK-336, a First-in-Class LDHA Inhibitor to Treat Hyperoxalurias

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SEATTLE, April 12, 2022 (GLOBE NEWSWIRE) -- Chinook Therapeutics, Inc. (NASDAQ: KDNY), a biopharmaceutical company focused on the discovery, development and commercialization of precision medicines for kidney diseases, today announced that dosing has been initiated in a phase 1 clinical trial evaluating CHK-336 in adult healthy volunteers. CHK-336 is an oral small molecule lactate dehydrogenase A (LDHA) inhibitor with liver-targeted tissue distribution being developed for the treatment of patients with primary hyperoxaluria (PH) and secondary hyperoxaluria due to increased endogenous oxalate production.

“The initiation of the phase 1 clinical trial of CHK-336 is an important milestone for Chinook as it is our first internally discovered program, and has a differentiated profile as an oral small molecule with potential to be a first-in-class therapy for patients with multiple types of hyperoxalurias,” said Andrew King, D.V.M., Ph.D., chief scientific officer of Chinook. “CHK-336 exemplifies Chinook’s commitment to discovering and developing novel precision medicines for rare, severe chronic kidney diseases with defined genetic and molecular drivers.”

The phase 1, single-center, randomized, placebo-controlled double-blind single and multiple ascending dose clinical trial is designed to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of CHK-336 in up to 104 healthy volunteers.

Preclinically, CHK-336 potently inhibits LDHA, the final enzymatic step in oxalate synthesis, and exhibits a liver-targeted tissue distribution profile characterized by high concentrations in the liver, the key pharmacodynamic site of action to block oxalate production, accompanied by low extra-hepatic exposures. Human pharmacokinetic and dose predictions based on non-clinical data suggest CHK-336 has the potential to produce sustained inhibition of hepatic LDHA with low systemic exposure following a low, once-daily oral dose in humans. Preclinical studies have demonstrated that CHK-336 produced significant reductions in urinary oxalate excretion in PH type 1 (PH1) and PH type 2 (PH2) mouse models into the range observed in wild-type mice.

About Hyperoxalurias
Hyperoxalurias, including PH, are diseases caused by excess oxalate. Symptoms of PH include recurrent kidney stones, severe pain, hematuria and urinary tract infections, and when left untreated, can result in kidney failure requiring dialysis or dual kidney/liver transplantation. In patients with hyperoxalurias, excess oxalate combines with calcium to form calcium oxalate crystals that deposit in the kidney, resulting in the formation of painful kidney stones and driving progressive kidney damage over time. PH, 1-3 are ultra-rare diseases caused by genetic mutations that result in excess oxalate production, and in its most severe forms, can lead to end-stage kidney disease at a young age.

LDHA catalyzes the final step in the production of oxalate from glyoxalate in the liver, therefore LDHA inhibition has the potential to treat all forms of PH as well as other disorders arising from excess oxalate production. An oral, small molecule, liver-targeted LDHA inhibitor has the potential to block excess oxalate synthesis by rapidly distributing to the site of oxalate production, while minimizing systemic exposures and potential for off-target activity, to facilitate a favorable tolerability profile required in this chronic disease.

About Chinook Therapeutics, Inc.
Chinook Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing precision medicines for kidney diseases. Chinook’s product candidates are being investigated in rare, severe chronic kidney disorders with opportunities for well-defined clinical pathways. Chinook’s lead program is atrasentan, a phase 3 endothelin receptor antagonist for the treatment of IgA nephropathy and other proteinuric glomerular diseases. BION-1301, an anti-APRIL monoclonal antibody is being evaluated in a phase 1/2 trial for IgA nephropathy. CHK-336, an oral small molecule LDHA inhibitor for the treatment of hyperoxalurias, is being evaluated in a phase 1 healthy volunteer trial. In addition, Chinook is advancing research programs for other rare, severe chronic kidney diseases. Chinook is building its pipeline by leveraging insights in kidney single cell RNA sequencing, human-derived organoids and new translational models, to discover and develop therapeutics with differentiating mechanisms of action against key kidney disease pathways. To learn more, visit www.chinooktx.com.

Cautionary Note on Forward-Looking Statements
Certain of the statements made in this press release are forward looking, including those relating to Chinook’s business, future operations, advancement of its product candidates and product pipeline, clinical development of its product candidates, including expectations regarding the advancement of its products and the timing of initiation and results of clinical trials. In some cases, you can identify these statements by forward-looking words such as “may,” “will,” “continue,” “anticipate,” “intend,” “could,” “project,” “expect” or the negative or plural of these words or similar expressions. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, our ability to develop and commercialize our product candidates, including initiation of clinical trials of our existing product candidates or those developed as part of the Evotec collaboration, whether results of early clinical trials or preclinical studies will be indicative of the results of future trials, our ability to obtain and maintain regulatory approval of our product candidates, our ability to operate in a competitive industry and compete successfully against competitors that may be more advanced or have greater resources than we do, our ability to obtain and adequately protect intellectual property rights for our product candidates and the effects of COVID-19 on our clinical programs and business operations. Many of these risks are described in greater detail in our filings with the SEC. Any forward-looking statements in this press release speak only as of the date of this press release. Chinook assumes no obligation to update forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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