Chinook Therapeutics Announces First Patient Enrolled in Pivotal Phase 3 ALIGN Study of Atrasentan for Patients with IgA Nephropathy

March 16, 2021

Phase 2 AFFINITY Trial of Atrasentan for Patients with Glomerular Diseases Also on Track to Begin Enrollment in the First Half of 2021

VANCOUVER, British Columbia and SEATTLE, March 16, 2021 (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 the first patient with IgA nephropathy (IgAN) has been enrolled in the ALIGN Study, a pivotal phase 3 clinical trial evaluating the efficacy and safety of atrasentan, a potent and selective inhibitor of the endothelin A receptor.

“The initiation of the phase 3 ALIGN Study is an important milestone for Chinook as we advance our pipeline of programs for rare, severe chronic kidney diseases,” said Alan Glicklich, M.D., chief medical officer of Chinook. “Atrasentan has been studied in over 5,300 diabetic kidney disease patients in the phase 2 RADAR and phase 3 SONAR studies, demonstrating rapid, sustained proteinuria reductions of approximately 30 to 35 percent as well as improved eGFR. Importantly, treatment with atrasentan also resulted in a reduction in clinical outcomes of development of end-stage kidney disease and doubling of serum creatinine. We look forward to exploring the proteinuria-lowering, anti-inflammatory and anti-fibrotic effects of atrasentan in patients with IgA nephropathy, a serious progressive disease for which there are no approved therapies.”

“I am pleased to see Chinook kick off the well-designed phase 3 ALIGN Study of atrasentan in IgA nephropathy. Given the strong correlation between endothelin system activation and disease progression, and the drug’s demonstrated impact on proteinuria in patients with diabetic nephropathy, I believe atrasentan will be a beneficial therapeutic treatment option for patients with IgA nephropathy,” said Jonathan Barratt, Ph.D., F.R.C.P, the Mayer professor of renal medicine at University of Leicester, honorary consultant nephrologist at Leicester General Hospital and co-chair of the ALIGN Study steering committee.

About the ALIGN Study
The ALIGN Study (see www.clinicaltrials.gov, identifier NCT04573478) is a global, randomized, multicenter, double-blind, placebo-controlled phase 3 clinical trial comparing the efficacy and safety of atrasentan versus placebo in patients with IgAN at risk of progressive loss of kidney function. Approximately 320 patients with biopsy-proven IgAN will be randomized to receive 0.75 mg atrasentan or placebo as a once-daily oral pill for approximately 2.5 years. Patients will continue receiving a maximally tolerated and stable dose of a RAS inhibitor as standard of care. The study will also include a cohort of patients that are unable to tolerate RAS inhibitor therapy.

The primary efficacy endpoint of the ALIGN Study is to evaluate the effect of atrasentan versus placebo on proteinuria as measured by urine protein to creatinine ratio (UPCR) from baseline to 24 weeks. Secondary and exploratory objectives include evaluating the change in kidney function over time as measured by eGFR, safety and tolerability, as well as quality of life. Chinook expects to report top-line data from the 24-week primary endpoint efficacy analysis in 2023.

About IgA Nephropathy (IgAN)
Immunoglobulin A nephropathy (IgAN) is the most common primary glomerular disease globally and a leading cause of chronic kidney disease (CKD), with up to 45 percent of IgAN patients progressing to end-stage renal disease (ESRD), requiring dialysis or kidney transplantation. There are currently no approved therapies for IgAN and only limited treatment options for high-risk patients. IgAN is characterized by the deposition of IgA-containing immune complexes in the glomeruli of the kidney, which initiates an inflammatory response that results in protein and blood leaking into the urine, called proteinuria and hematuria, respectively. Proteinuria levels are the strongest predictor of kidney function loss and clinical outcomes in IgAN patients, and lowering proteinuria is associated with important clinical benefit. Blockade of the endothelin A receptor by atrasentan has potential to reduce proteinuria as well as kidney inflammation and fibrosis to preserve kidney function in IgAN.

About Chinook Therapeutics, Inc.
Chinook Therapeutics, Inc. is a clinical-stage biotechnology 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, an investigational phase 3 endothelin receptor antagonist for the treatment of IgA nephropathy and other primary glomerular diseases. BION-1301, an investigational anti-APRIL monoclonal antibody is being evaluated in a phase 1b trial for IgA nephropathy. In addition, Chinook is advancing CHK-336, an investigational oral small molecule LDHA inhibitor for the treatment of primary hyperoxaluria, as well as research programs for other rare, severe chronic kidney diseases, including polycystic kidney disease. 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 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, 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.

Contact:
Noopur Liffick
Vice President, Investor Relations & Corporate Communications
investors@chinooktx.com
media@chinooktx.com

Source: Chinook Therapeutics, Inc.