Chinook Therapeutics Receives Orphan Drug Designation from European Commission for Atrasentan for Treatment of Primary IgA Nephropathy

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- ***Enrollment ongoing in atrasentan pivotal phase 3 ALIGN study in IgAN and phase 2 AFFINITY study in proteinuric glomerular diseases***

- ***Chinook expects to present data from the IgAN patient cohort of the phase 2 AFFINITY study in the first half of 2022, with data from one or more additional cohorts expected in the second half of 2022***

SEATTLE, Dec. 14, 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 the European Commission has granted orphan drug designation for atrasentan for the treatment of primary IgA nephropathy (IgAN). The decision follows a positive opinion from the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA).

Orphan drug designation is granted to medicines that are intended to treat, prevent or diagnose a life-threatening or chronically debilitating rare disease with a prevalence in the European Union (EU) of fewer than five in 10,000 and with either no currently approved method of diagnosis, prevention or treatment or with significant benefit to those affected by the disease. Orphan designation in the EU provides sponsors with incentives including protocol assistance, 10 years of market exclusivity and reductions in regulatory fees.

“We are pleased the European Commission has granted Chinook orphan drug designation in the EU for atrasentan for IgA nephropathy, a rare, severe chronic kidney disease for which there are no approved therapies,” said Alan Glicklich, M.D., chief medical officer of Chinook Therapeutics. “Orphan drug designation in the EU represents an important regulatory milestone that has the potential to expedite the global clinical development of atrasentan, a potent and selective ET_A antagonist. We are highly encouraged and look forward to continue exploring atrasentan’s proteinuria-lowering, anti-inflammatory and anti-fibrotic effects in patients with IgAN in the ongoing pivotal phase 3 ALIGN study.”

About Atrasentan
Atrasentan is a selective and potent inhibitor of the endothelin A receptor (ET_A) that has the potential to provide benefit in multiple chronic kidney diseases by reducing proteinuria and having direct anti-inflammatory and anti-fibrotic effects to preserve kidney function. IgAN was identified as the lead indication for evaluation of atrasentan due to the role of ET_A activation in driving proteinuria, mesangial cell activation, kidney inflammation and fibrosis, the hallmarks of IgAN disease progression. The pivotal phase 3 ALIGN trial of atrasentan is currently enrolling patients with IgAN and the phase 2 AFFINITY trial of atrasentan is currently enrolling patients with proteinuric glomerular diseases.

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 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. In addition, Chinook is advancing CHK-336, an oral small molecule LDHA inhibitor for the treatment of primary hyperoxaluria, as well as 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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