Chinook Therapeutics Receives Orphan Drug Designation from European Commission for BION-1301 for Treatment of Primary IgA Nephropathy (IgAN)

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SEATTLE, July 05, 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 the European Commission has granted orphan drug designation for BION-1301 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 after approval and reductions in regulatory fees.

“We are pleased the European Commission has granted Chinook orphan drug designation in the EU for BION-1301 for IgA nephropathy, a serious, progressive disease for which there are limited treatment options,” said Eric Dobmeier, chief executive 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 BION-1301, an anti-APRIL monoclonal antibody with disease-modifying potential in IgAN. We are encouraged by the data generated to date demonstrating durable reductions in mechanistic biomarkers and corresponding proteinuria reductions and look forward to evaluating BION-1301 in a pivotal phase 3 study in 2023.”

About BION-1301
BION-1301 is a humanized IgG4 monoclonal antibody that blocks APRIL, a TNF-family cytokine believed to be implicated in IgAN and other indications, from binding to its receptors. Blockade of the APRIL pathway by BION-1301 is a potentially disease-modifying approach to treating IgAN by reducing circulating levels of galactose-deficient IgA1 (Gd-IgA1) to prevent the formation of pathogenic immune complexes. BION-1301 is currently being evaluated in a phase 1/2 clinical trial in patients with IgAN. Preliminary data from the first cohort of patients with IgAN demonstrated that BION-1301 has been well-tolerated to date, with no serious adverse events or treatment discontinuations due to adverse events. BION-1301 has demonstrated rapid and sustained reductions in mechanistic biomarkers in patients with IgAN, including free APRIL, IgA and Gd-IgA1 levels. BION-1301 has demonstrated approximately 50% proteinuria reductions in patients with IgAN after three to six months of treatment, with approximately 70% reductions observed in six patients at one year and in two patients at 1.5 years of treatment, providing initial proof-of-concept for BION-1301 in IgAN.

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 limited treatment options for patients. Steroids may potentially be considered in high-risk patients though toxicity risk must be carefully evaluated. 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.

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 results of clinical trials based on early results. 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, such as those described above for BION-1301, 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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