Chinook Therapeutics Presents BION-1301 Interim Phase 1/2 Data in Patients with IgA Nephropathy (IgAN) at the 58th ERA-EDTA Virtual Congress

June 8, 2021

- ***BION-1301 has been well-tolerated to date in patients with IgAN, with no serious adverse events (SAEs) or treatment discontinuations due to adverse events***
- ***Pharmacokinetics (PK) of BION-1301 observed in patients with IgAN are consistent with those previously reported in healthy volunteers and are sufficient to drive rapid and sustained reductions in free APRIL levels***
- ***BION-1301 has durably reduced Gd-IgA1, IgA, IgM, and to a lesser extent, IgG levels in patients with IgAN***
- ***BION-1301 has demonstrated a clinically meaningful mean reduction in 24-hour proteinuria (UPCR) in the first several patients enrolled in the study, providing initial proof-of-concept for BION-1301 in IgAN***
- ***Chinook to host investor conference call and webcast today at 4:00 pm EDT with Jonathan Barratt, Ph.D., the Mayer Professor of Renal Medicine at University of Leicester***

SEATTLE, June 08, 2021 (GLOBE NEWSWIRE) -- Chinook Therapeutics, Inc. (Nasdaq: KDNY), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of precision medicines for kidney diseases, today announced the presentation of data from the ongoing phase 1/2 study of BION-1301 in patients with IgAN. The findings were presented in an oral presentation at the 58th European Renal Association – European Dialysis and Transplant Association (ERA-EDTA) Virtual Congress.

“We are encouraged by the data we have generated to date for BION-1301 in patients with IgAN, including the clinically meaningful reductions in proteinuria observed, as well as safety, tolerability, PK and mechanistic biomarker responses,” said Alan Glicklich, M.D., chief medical officer of Chinook Therapeutics. “The data generated thus far have reaffirmed our belief that blocking and neutralizing APRIL in patients with IgAN plays a key role in depleting pathogenic Gd-IgA1 and reducing proteinuria, demonstrating strong rationale for BION-1301’s disease-modifying mechanism of action in IgAN.”

FC 040: Interim Results of Phase 1 and 2 Trials to Investigate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Clinical Activity of BION-1301 in Patients with IgA Nephropathy

BION-1301 is a novel anti-APRIL monoclonal antibody currently in phase 1/2 clinical development for IgAN. Blocking APRIL is a potential disease-modifying approach to treating IgAN by reducing circulating levels of galactose-deficient IgA1 (Gd-IgA1) to prevent the formation of immune complexes that deposit in the glomeruli of the kidney, causing injury.

Part 3 of the ongoing phase 1/2 multi-center trial (see www.clinicaltrials.gov, identifier NCT03945318) is evaluating the safety, tolerability, PK and pharmacodynamics (PD) of BION-1301 in patients with IgAN in an open-label setting. Patients in Cohort 1 receive an intravenous (IV) dose of 450 mg of BION-1301 every two weeks for up to 52 weeks. Patients in subsequent cohorts in Part 3 will be dosed subcutaneously.

Key highlights from the oral presentation include the following:

- BION-1301 has been well-tolerated to date in patients with IgAN, with no treatment-related adverse events, SAEs, infusion-related reactions or treatment discontinuations due to adverse events.
    - To date, no anti-drug antibodies (ADAs) have been observed in patients with IgAN.
- The PK plasma exposures of BION-1301 observed in patients with IgAN have been consistent with those previously reported in healthy volunteers and were sufficient to drive rapid, significant and sustained reductions in free APRIL concentrations, confirming effective APRIL neutralization by BION-1301.
- BION-1301 has durably reduced serum IgA and IgM levels, and to a lesser extent IgG levels, highly consistent with the kinetics and magnitude of immunoglobulin response previously reported in healthy volunteers.
- BION-1301 treatment has also resulted in significant and sustained reductions in Gd-IgA1, demonstrating depletion of the pathogenic IgA variant, and establishing the potential disease-modifying mechanism of BION-1301 in patients with IgAN by directly targeting Hit 1 in the multi-hit pathogenesis of IgAN.
- Ex vivo mesangial cell hyperproliferation, induced by IgA-containing plasma fractions isolated from patients treated with BION-1301, was attenuated, suggesting a reduction in circulating pathogenic IgA-containing immune complexes following BION-1301 treatment.

- BION-1301 demonstrated a clinically meaningful mean reduction in 24-hour UPCR in the first several patients with IgAN enrolled in the study. The UPCR reductions began after the first month of treatment and were evident by three months in patients with baseline UPCR levels ranging from 530 – 4551 mg/g.

Cohort 2 in Part 3 of the ongoing phase 1/2 study will soon begin enrolling patients with IgAN utilizing subcutaneous administration of BION-1301. To help inform future patient selection for clinical studies of BION-1301, biomarker analysis from IgAN patient serum in the NURTuRE CKD patient biobank is also ongoing, integrating patient characteristics, disease progression, kidney histopathology as well as transcriptomics and proteomic analysis.

Live Conference Call and Webcast
Chinook will host a live conference call and webcast today at 4:00 pm EDT to discuss the interim data from Part 3 of Chinook's ongoing phase 1/2 study of BION-1301 in patients with IgAN that was presented at the 58th ERA-EDTA Congress. Members of the Chinook executive team will be joined by Dr. Jonathan Barratt, the Mayer Professor of Renal Medicine at University of Leicester.

Conference Call and Webcast Details
To access the call, please dial (844) 309-0604 (domestic) or (574) 990-9932 (international) and provide the Conference ID 2591818 to the operator.

To access the live webcast, subsequent archived recording and slides that were developed to complement this and other company presentations, please visit the Investors section of Chinook's website. The archived webcast will remain available for replay on Chinook's website for 90 days.

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 1b 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 cash forecasts and 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, 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.

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

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