Chinook Therapeutics Presents Data from BION-1301 Phase 1/2 Trial in Patients with IgA Nephropathy (IgAN) and Atrasentan Program at the American Society of Nephrology (ASN) Kidney Week 2021

November 4, 2021

- ***BION-1301 was well-tolerated and demonstrated rapid and sustained reductions in mechanistic biomarkers in patients with IgAN, including free APRIL, IgA and Gd-IgA1 levels***
- ***BION-1301 demonstrated >50% proteinuria reduction in patients with IgAN after three to six months of treatment, with further reductions in two patients through one year of treatment***
- ***Additional data was presented on the atrasentan program, including translational research demonstrating ET_A activation is associated with clinical progression in IgAN***
- ***Chinook to host investor conference call and webcast today at 4:30 pm EDT with Jonathan Barratt, MChB, PhD, Mayer Professor of Renal Medicine at University of Leicester, and Laura Kooienga, MD, practicing nephrologist and Director of Research at Colorado Kidney Care***

SEATTLE, Nov. 04, 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 six ePoster presentations on the BION-1301 and atrasentan clinical programs at ASN Kidney Week 2021.

“Our BION-1301 and atrasentan presentations at this year’s ASN Kidney Week underscore our commitment to developing therapies for rare, severe chronic kidney diseases such as IgA nephropathy, a serious progressive disease for which there are no approved therapies,” said Alan Glicklich, M.D., chief medical officer of Chinook Therapeutics. “The data we presented on BION-1301 provides further validation of this potentially disease-modifying therapy for patients with IgA nephropathy, as it continues to demonstrate consistent mechanistic biomarker responses as well as clinically meaningful proteinuria reductions within three months of initiating treatment. We look forward to building upon this exciting data to determine the optimal subcutaneous dose of BION-1301 in the ongoing phase 1/2 study to take forward into later-stage trials.”

PO1632: Pharmacodynamic and Clinical Responses to BION-1301 in Patients with IgA Nephropathy: Initial Results of a Ph1/2 Trial
BION-1301 is a novel anti-APRIL monoclonal antibody currently in phase 1/2 clinical development for patients with IgAN. Blocking APRIL is a potentially disease-modifying approach to treating IgAN by reducing circulating levels of galactose-deficient IgA1 (Gd-IgA1).

Data was presented from Cohort 1 in Part 3 of the ongoing phase 1/2 multi-center trial (see www.clinicaltrials.gov, identifier NCT03945318) evaluating the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD) and initial clinical responses of open-label BION-1301 treatment in patients with IgAN. Patients in Cohort 1 received an intravenous (IV) dose of 450 mg of BION-1301 every two weeks. Based on a recent protocol amendment, patients in Cohort 1 are now transitioning to subcutaneous (SC) therapy after at least 24 weeks of IV therapy and will continue SC dosing at 600 mg every two weeks for up to a total treatment duration of 52 weeks. Cohort 2 in Part 3 of this study is also currently enrolling additional patients with IgAN for subcutaneous administration of BION-1301 at a dose of 600 mg every two weeks.

Key highlights from the poster presentation include the following:

- BION-1301 has been well-tolerated to date in patients with IgAN, with no treatment-related adverse events, serious adverse events, infusion-related reactions or treatment discontinuations due to adverse events.
    - To date, no anti-drug antibodies 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 and sustained reductions in free APRIL concentrations, confirming effective APRIL neutralization by BION-1301.
- BION-1301 durably reduced serum IgA and IgM levels, and to a lesser extent IgG levels, which remained above the study-defined threshold in all patients, providing a pharmacodynamic window to deplete IgA while minimizing impact on IgG.
- BION-1301 treatment resulted in sustained reductions in Gd-IgA1, demonstrating depletion of the pathogenic IgA variant, and establishing the potentially disease-modifying mechanism of BION-1301 in patients with IgAN by directly targeting Hit 1 in the multi-hit pathogenesis of IgAN.
- BION-1301 demonstrated a >50% geometric mean reduction in 24-hour urine protein creatinine ratio (UPCR) after three

(n=6) to six months (n=4) of treatment, with further reductions in two patients with IgAN through one year of treatment. Median baseline 24-hour urine protein excretion was 1.22 g/day, with a range of 0.74 – 6.47 g/day.

Data generated in Cohort 2 will help inform the subcutaneous dose and schedule that will be used in later-stage trials of BION-1301.

PO1633: Atrasentan Exhibits a Consistent, Predictable Pharmacokinetic Profile Among Healthy Asian Adults
Geographic differences in IgAN have been reported, with Asian populations having a higher incidence and potentially accelerated disease progression. Data from three separate, single-dose, randomized phase 1 studies of atrasentan demonstrated consistent and predictable safety, tolerability and linear dose-proportionality in healthy Chinese, Japanese and North American adults of non-Asian descent. Atrasentan had similar PK profiles (C_{max}, T_{max}, AUC) among the studied groups following administration of a single oral dose of either 0.75 mg or 1.25 mg. We believe these data, along with previously published results, support the safety and tolerability of atrasentan in Asian adults as well as the use of the 0.75 mg dose in the ongoing global phase 3 ALIGN study in IgAN and phase 2 AFFINITY study in proteinuric glomerular diseases.

PO1593: Precision Medicine Approach Identifies Patients with IgA nephropathy at Risk for Progression Using Endothelin Activation Signatures
An intra-renal transcriptional signature of endothelin (ET)-activation to stratify risk of progression in patients with IgAN from the European Renal cDNA Bank (ERCB) was identified. ET-activation scores strongly associated with clinical progression of IgAN, including increased proteinuria and decreased eGFR. Analysis of single-cell transcriptional profiles from kidney biopsies of patients with IgAN revealed strong activation of the ET-signature in mesangial cells, which are activated as the initiating intra-renal event to the deposition of IgA-immune complexes in IgAN. In a cellular model system, ET-1 induced transcriptional networks driving cell proliferation, inflammation and fibrosis in human mesangial cells, which were blocked by atrasentan. This translational research was conducted in collaboration with the laboratory of Matthias Kretzler, M.D., Professor of Nephrology and Professor of Computational Medicine & Bioinformatics at University of Michigan Medical School, and we believe supports the therapeutic potential of ET_A receptor blockade with atrasentan in patients with IgAN at high risk of progression.

Live Conference Call and Webcast
Chinook will host a live conference call and webcast today at 4:30 pm EDT to discuss the data from Cohort 1 of Part 3 of Chinook's ongoing phase 1/2 study of BION-1301 in patients with IgAN as well as the atrasentan posters that were presented at ASN Kidney Week 2021. Members of the Chinook executive team will be joined by Dr. Jonathan Barratt, the Mayer Professor of Renal Medicine at University of Leicester and Dr. Laura Kooienga, practicing nephrologist and Director of Research at Colorado Kidney Care.

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 1381696 to the operator.

To access the live webcast and subsequent archived recording of 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 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 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.

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