UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 19, 2022

Chinook Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-37345	**94-3348934**
(Commission File No.)	**(IRS Employer Identification No.)**

400 Fairview Avenue North, Suite 900
Seattle, WA
(Address of principal executive offices)

98109
(Zip Code)

Registrant's telephone number, including area code: (206) 485-7241

Not applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**KDNY**	**The Nasdaq Stock Market LLC (The Nasdaq Global Select Market)**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD.

On May 19, 2022, Chinook Therapeutics, Inc. ("Chinook") issued a press release announcing a presentation at the 59th European Renal Association 2022 ("ERA") in Paris, France describing an interim analysis of data from its BION-1301 Phase 1/2 Trial in patients with IgA Nephropathy ("IgAN") among other items (the "BION-1301 Press Release").

In addition, on May 20, 2022, Chinook issued a press release announcing a presentation at the ERA describing an interim analysis of data from its Atrasentan Phase 2 AFFINITY IgAN trial among other items (the "Atrasentan Press Release").

A copy of each of Chinook's BION-1301 Press Release and Atrasentan Press Release is filed as Exhibits 99.1 and 99.2, respectively, to this Current Report and is incorporated by reference.

The information furnished in this Item 7.01, including Exhibits 99.1 and 99.2, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On May 19, 2022 and May 20, 2022, Chinook presented additional data from its atrasentan and BION-1301 programs at ERA.

Chinook presented data from the IgAN patient cohort of the phase 2 AFFINITY basket trial for atrasentan, demonstrating highly consistent and clinically meaningful proteinuria reductions at weeks six, 12 and 24 of treatment in patients with IgAN already on a maximally tolerated and stable dose of a RAS inhibitor. Specifically, atrasentan demonstrated a 38.0% geometric mean reduction in 24-hour urine protein creatinine ratio ("UPCR") in 20 patients at six weeks of treatment, 49.9% geometric mean reduction in 24-hour UPCR in 18 patients at 12 weeks of treatment and 58.5% geometric mean reduction in 24-hour UPCR in 11 patients at 24 weeks of treatment. After 24 weeks of treatment, ten of the 11 patients (91%) who had completed this visit had greater than a 40% reduction in proteinuria. As of the April 22, 2022 data cutoff, atrasentan has been well-tolerated to date in patients with IgAN, with no treatment-related SAEs. Eighteen of 20 patients remained on treatment, with time on treatment ranging from six to 52 weeks. There were no meaningful changes in blood pressure or acute eGFR effects, suggesting proteinuria reductions were not primarily due to hemodynamic effects of atrasentan. There were no increases in BNP or mean bodyweight, suggesting minimal fluid retention.

Chinook also presented additional data from the phase 1/2 study of BION-1301 in IgAN further demonstrating its disease-modifying potential in IgAN by generating durable reductions in mechanistic biomarkers and corresponding impressive proteinuria reductions within three months of initiating treatment. BION-1301 treatment resulted in steady-state reductions in Gd-IgA1 in the range of 70-80%, demonstrating depletion of the pathogenic IgA variant, and establishing the potentially disease-modifying mechanism of BION-1301 by directly targeting the initial pathway in the pathogenesis of IgAN. Additionally, BION-1301 demonstrated a 48.8% geometric mean reduction in 24-hour UCPR in all eight patients at six months of treatment, a 70.9% geometric mean reduction in 24-hour UPCR in six patients at one year of treatment and a 69.1% geometric mean reduction in 24-hour UPCR in two patients at 1.5 years of treatment. As of the May 6, 2022 data cutoff, BION-1301 has been well well-tolerated, with no serious adverse events or treatment discontinuations due to adverse events. Additionally, all eight patients currently on trial have transitioned to subcutaneous, or SC, administration, with a mean SC treatment duration of 22 weeks (range of five to 28 weeks).

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press Release, dated May 18, 2022, titled "Chinook Therapeutics Presents Updated Data from BION-1301 Phase 1/2 Trial in Patients with IgA Nephropathy (IgAN) and from Atrasentan Preclinical Mechanism of Action Studies at the 59th European Renal Association (ERA) Congress."
99.2	Press Release, dated May 20, 2022, titled "Chinook Therapeutics Presents Data from Atrasentan Phase 2 AFFINITY IgA Nephropathy (IgAN) Patient Cohort and Evotec Collaboration at the 59th European Renal Association (ERA) Congress."
104	Cover Page Interactive File (the cover page tags are embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: May 20, 2022

Chinook Therapeutics, Inc.

By: /s/ Eric L. Dobmeier
Eric L. Dobmeier
President and Chief Executive Officer

Chinook Therapeutics Presents Updated Data from BION-1301 Phase 1/2 Trial in Patients with IgA Nephropathy (IgAN) and from Atrasentan Preclinical Mechanism of Action Studies at the 59th European Renal Association (ERA) Congress 2022

- ***All patients with IgAN in Cohort 1 have transitioned to subcutaneous (SC) dosing, and BION-1301 remains well-tolerated, with no serious adverse events (SAEs) and no treatment discontinuations due to adverse events (AEs)***
- ***BION-1301 continues to demonstrate 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 ~70% reductions observed in six patients at one year and in two patients at 1.5 years of treatment***
- ***Preclinical mechanistic data was presented, describing atrasentan's effect to block mesangial cell injury and the pathogenic transcriptional networks driving IgAN progression in a model system***
- ***Chinook to host investor conference call and webcast on Friday, May 20th at 4:15 pm EDT with Dr. Muh Geot Wong, associate professor of nephrology at Concord Repatriation General Hospital at University of Sydney and Dr. Jonathan Barratt, Mayer Professor of Renal Medicine at University of Leicester***

SEATTLE May 18, 2022 – Chinook Therapeutics, Inc. (Nasdaq: KDNY), a biopharmaceutical company focused on the discovery, development and commercialization of precision medicines for kidney diseases, today announced three mini-oral presentations on the BION-1301 and atrasentan clinical programs at the 59th ERA Congress 2022 being held virtually and live in Paris, France.

"The additional data we presented today at ERA from the ongoing phase 1/2 study of BION-1301 further demonstrates its disease-modifying potential in IgAN by generating durable reductions in mechanistic biomarkers and corresponding impressive proteinuria reductions within three months of initiating treatment," said Eric Dobmeier, president and chief executive officer of Chinook Therapeutics. "IgAN is a serious progressive disease for which there are limited treatment options, and the data from this trial will inform the design of a phase 3 trial of BION-1301 for patients with IgAN that we plan to initiate in 2023."

MO212 - Updated Interim Results of a Phase 1/2 Study to Investigate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Clinical Activity of BION-1301 in Patients with IgA Nephropathy

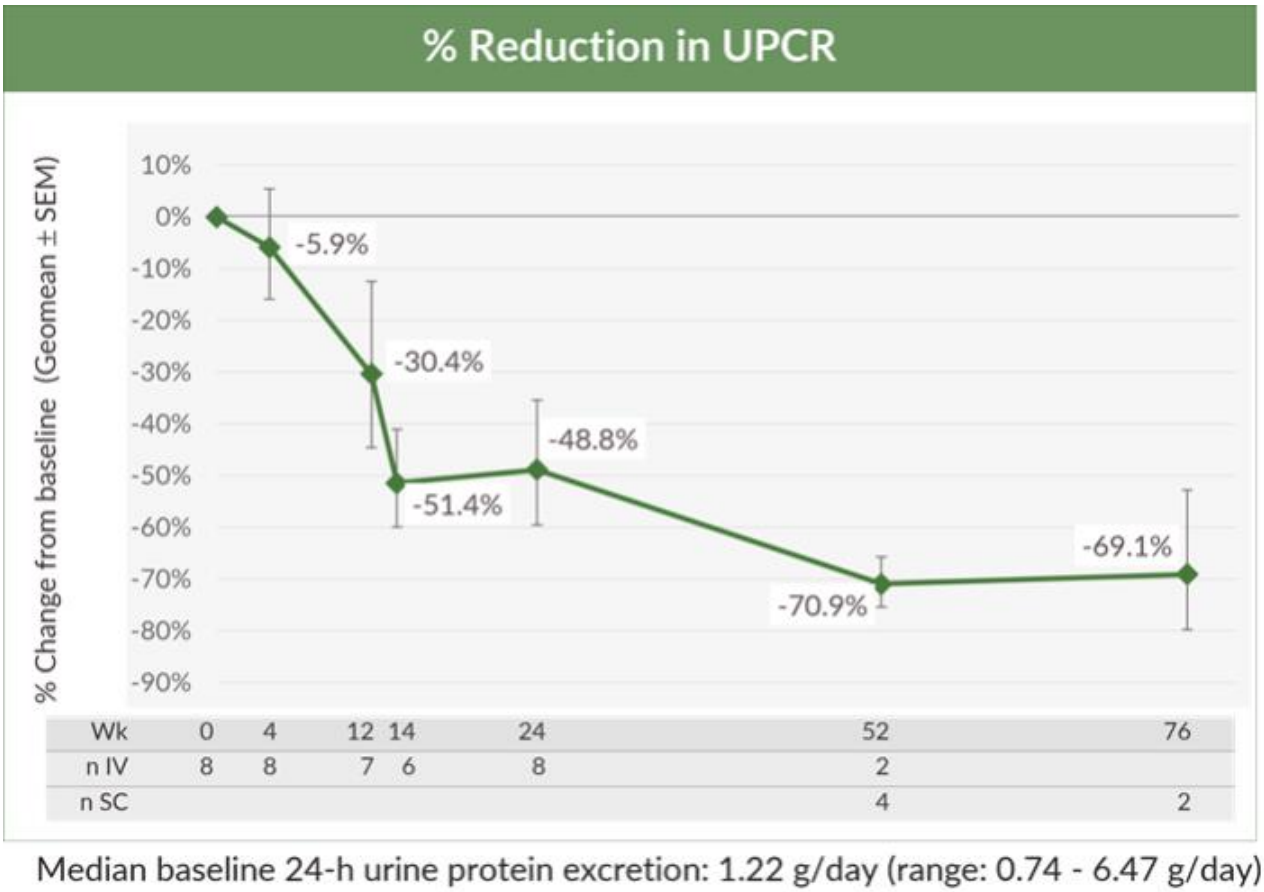
BION-1301 is a novel anti-APRIL monoclonal antibody currently in phase 1/2 clinical development for patients with IgAN. Blocking APRIL is a potentially disease-modifying approach to treating IgAN by reducing circulating levels of galactose-deficient IgA1 (Gd-IgA1).

Additional 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 initially received an intravenous (IV) dose of 450 mg of BION-1301 every two weeks. After at least 24 weeks of IV dosing, all Cohort 1 patients transitioned to SC therapy at 600 mg every two weeks for up to a total treatment duration of two years.

Key highlights from the mini oral presentation include the following:

- Median baseline 24-hour urine protein excretion for the patients enrolled in Cohort 1 was 1.22 g/day, with a range of 0.74 – 6.47 g/day, representing a population of patients with IgAN at high risk of kidney disease progression.
- All eight patients currently on trial have transitioned to SC administration with a mean SC treatment duration of 22 weeks (range five to 28 weeks).
- As of the May 6, 2022 data cutoff, BION-1301 has been well-tolerated, with no serious adverse events or treatment discontinuations due to adverse events.
    - Three patients experienced mild (grade 1) treatment-related AEs, including one injection site reaction.
    - Four patients experienced mild (grade 1) infections, considered not related to treatment.
    - To date, no anti-drug antibodies have been observed in patients.
- BION-1301 durably reduced serum IgA and IgM levels, and to a lesser extent, IgG levels in all patients.
    - BION-1301 demonstrated mean IgA and IgM reductions at steady-state of greater than 65%, while mean IgG levels were reduced by only 30-40%.
    - In one patient, IgG level fell below the study-defined threshold, necessitating protocol-mandated withholding of BION-1301. There have been no infections reported in this patient. The protocol did not include entry criteria for minimum IgG levels.
- BION-1301 treatment resulted in steady-state reductions in Gd-IgA1 in the range of 70-80%, demonstrating depletion of the pathogenic IgA variant, and establishing the potentially disease-modifying mechanism of BION-1301 by directly targeting Hit 1 in the multi-hit pathogenesis of IgAN.
- BION-1301 demonstrated a 48.8% geometric mean reduction in 24-hour urine protein creatinine ratio (UPCR) in all eight patients at six months of treatment, a 70.9% geometric mean reduction in 24-hour UPCR in six patients at one year of treatment and a 69.1% geometric mean reduction in 24-hour UPCR in two patients at 1.5 years of treatment (see figure below).

Cohort 2 in Part 3 of this study is currently enrolling additional patients with IgAN who are receiving a SC dose of 600 mg of BION-1301 every two weeks. Initial data from Cohort 2 is expected in the second half of 2022. Part 3 also includes the option for a third cohort of patients to receive a SC dose of BION-1301 at a dose and schedule to be determined based on data from Cohorts 1 and 2. Data generated from this phase 1/2 study will inform the design of a phase 3 trial of BION-1301 for patients with IgAN that Chinook plans to initiate in 2023.



MO264 - Selective Endothelin A Receptor Antagonist Atrasentan Attenuates Mesangial Cell Injury, Proteinuria and Intra-Renal Proliferative, Inflammatory and Fibrotic Transcriptional Networks in a Rat Model of Mesangioproliferative Glomerulonephritis (MPGN)

Mesangial cell activation is considered the initiating intra-renal event in the pathogenesis of IgAN and occurs in response to the deposition of pathogenic Gd-IgA1-containing immune complexes. Mesangial cell activation is characterized by increased cellular proliferation and overproduction of inflammatory cytokines and chemokines as well as extracellular matrix. This activation results in cellular crosstalk that leads to podocyte injury and proteinuria and ultimately to tubulointerstitial inflammation and fibrosis, resulting in kidney function loss. To assess the role of the endothelin A (ET_A) receptor in mesangial cell activation, subsequent proteinuria and the transcriptional networks that drive disease progression, the effect of atrasentan was investigated in a rat model of mesangioproliferative glomerulonephritis (MPGN) as a surrogate for IgAN.

Induction of MPGN in rats was characterized by glomerular and tubulointerstitial injury histologically, marked proteinuria, and a transcriptional down-regulation of metabolism gene networks and up-regulation of networks associated with proliferation, inflammation and fibrosis, consistent with the hallmark genesets dysregulated in the glomeruli of IgAN patients. Atrasentan treatment attenuated the mesangial cell response, glomerular injury and secondary tubulointerstitial injury observed histologically, and prevented proteinuria. Atrasentan down-regulated intra-renal proliferative, inflammatory and fibrotic transcriptional networks and restored metabolism networks, reversing

hallmark gene set enrichments that are also observed in the glomerular transcriptome of IgAN patients. This study suggests an important role of the ET_A receptor in mesangial cell activation, subsequent proteinuria and activation of pathogenic proliferative, inflammatory and fibrotic intra-renal transcriptional networks in MPGN. This further supports the therapeutic potential of atrasentan, a selective ET_A receptor antagonist, to attenuate mesangial cell activation, proteinuria and pathogenic intra-renal signaling in MPGNs such as IgAN.

MO207 - A Phase 1/2, Multicenter Study to Investigate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of BION-1301 in Healthy Volunteers and Adults with IgA Nephropathy

A trial-in-progress overview for the ongoing phase 1/2 study of BION-1301 was delivered as a mini-oral presentation at the 59th ERA Congress 2022.

All three presentations can be found in the Scientific Publications section of Chinook's website.

Live Conference Call and Webcast

Chinook will host a live conference call and webcast on Friday, May 20, 2022 at 4:15 pm EDT to discuss the presentations at the 59th ERA Congress 2022 and provide program updates. Members of the Chinook executive team will be joined by Dr. Muh Geot Wong, associate professor of nephrology at Concord Repatriation General Hospital at University of Sydney in Sydney, Australia and Dr. Jonathan Barratt, Mayer Professor of Renal Medicine at University of Leicester in Leicester, UK.

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 9428716 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. 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 timing of results of clinical trials and the readthrough to topline data. 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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Chinook Therapeutics Presents Data from Atrasentan Phase 2 AFFINITY IgA Nephropathy (IgAN) Patient Cohort and Evotec Collaboration at the 59th European Renal Association (ERA) Congress 2022

- ***The AFFINITY IgAN cohort of 20 patients is fully enrolled, with 70% of patients in the study having baseline proteinuria over one gram per day despite maximal RAS inhibitor treatment, representing an IgAN patient population at high risk for progression***
- ***Atrasentan was well-tolerated with no treatment-related serious adverse events (SAEs)***
- ***Atrasentan demonstrated 38.0% proteinuria reduction at six weeks of treatment, 49.9% proteinuria reduction at 12 weeks of treatment and 58.5% reduction at 24 weeks of treatment***
- ***There were no meaningful changes in blood pressure or acute eGFR, suggesting proteinuria reductions were not primarily due to hemodynamic effects of atrasentan, and there were no increases in brain natriuretic peptide (BNP) or mean bodyweight, suggesting minimal fluid retention***
- ***Data was also presented on the approach used under Chinook's Evotec collaboration to leverage the NURTuRE CKD biobank to generate mechanistic disease understanding for target and biomarker discovery that will enable the development of novel precision treatments for CKD patient subsets***
- ***Chinook to host investor conference call and webcast today at 4:15 pm EDT with Dr. Muh Geot Wong, associate professor of nephrology at Concord Repatriation General Hospital at University of Sydney and Dr. Jonathan Barratt, Mayer Professor of Renal Medicine at University of Leicester***

SEATTLE May 20, 2022 – Chinook Therapeutics, Inc. (Nasdaq: KDNY), a biopharmaceutical company focused on the discovery, development and commercialization of precision medicines for kidney diseases, today announced two oral presentations on the atrasentan clinical program and Evotec collaboration at the 59th ERA Congress 2022 being held virtually and live in Paris, France.

"We are very encouraged by the data we presented today on atrasentan from the IgAN patient cohort of the phase 2 AFFINITY basket trial, demonstrating highly consistent and clinically meaningful proteinuria reductions at weeks six, 12 and 24 of treatment in patients with IgAN already on a maximally tolerated and stable dose of a RAS inhibitor. This level of proteinuria reduction is likely to translate into significant clinical benefit for patients with IgAN who currently have limited treatment options and high unmet need," said Eric Dobmeier, president and chief executive officer of Chinook Therapeutics. "The magnitude and deepening of response observed over time is distinct from the previous treatment experience with atrasentan in DKD where proteinuria reductions plateaued after a few weeks of treatment. We believe this dataset provides strong readthrough to the topline proteinuria data from the phase 3 ALIGN trial expected in 2023."

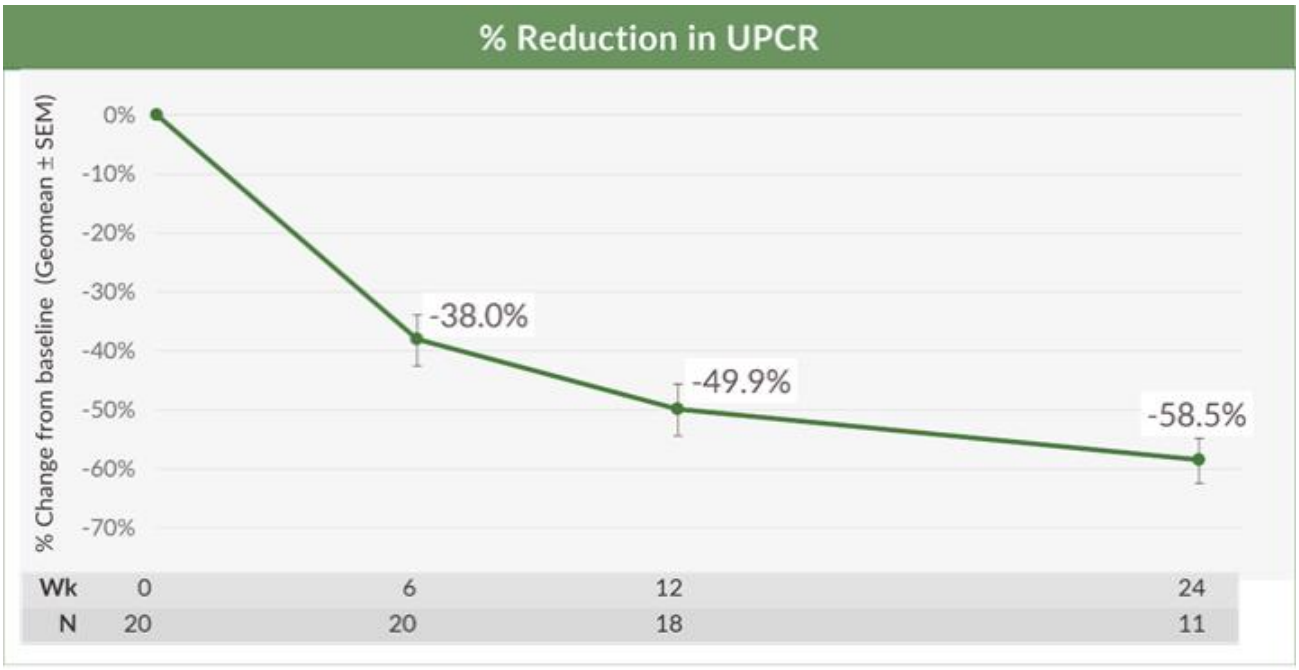
FC052 - Atrasentan for the Treatment of IgA Nephropathy: Interim Results from the AFFINITY Study

Atrasentan is a potent and selective 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. Chinook selected IgAN as the lead indication for 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 AFFINITY Study (see www.clinicaltrials.gov, identifier NCT04573920) is an ongoing global phase 2, open-label, basket study to evaluate the efficacy and safety of atrasentan in patients with proteinuric glomerular disease who are at risk of progressive loss of renal function. The four AFFINITY cohorts consist of patients with: biopsy-proven IgAN with urine protein to creatinine ratio (UPCR) of 0.5 to 1.0 g/g, focal segmental glomerulosclerosis (FSGS), Alport syndrome and diabetic kidney disease (DKD) in combination with an SGLT2 inhibitor. The 20 patients enrolled in each cohort receive 0.75 mg oral atrasentan daily for 52 weeks while continuing to receive a maximally tolerated and stable dose of a RAS inhibitor as standard of care.

Key highlights from the presentation include the following:

- In the IgAN cohort, median baseline 24-hour urine protein excretion was 1.17 g/day. Overall, 14 of 20 patients enrolled had baseline total urine protein over one gram per day despite optimized RAS inhibitor treatment, representing an IgAN patient population at high risk for progression.
- As of the April 22, 2022 data cutoff, atrasentan has been well-tolerated to date in patients with IgAN, with no treatment-related SAEs. Eighteen of 20 patients remained on treatment, with time on treatment ranging from six to 52 weeks.
    - One patient discontinued study treatment due to headache, which was considered a moderate related adverse event by the investigator, and one patient completed 52 weeks of treatment.
    - One patient had an unrelated serious adverse event of a traffic accident.
    - Five patients had a treatment-related adverse event, all of which were considered mild or moderate.
    - Two patients experienced peripheral edema—one mild and one moderate—which resolved in less than seven days with temporary use of low-dose diuretics.
    - All other treatment-emergent adverse events have resolved.
- There were no meaningful changes in blood pressure or acute eGFR effects, suggesting proteinuria reductions were not primarily due to hemodynamic effects of atrasentan. There were no increases in BNP or mean bodyweight, suggesting minimal fluid retention.
- Atrasentan demonstrated a 38.0% geometric mean reduction in 24-hour urine protein creatinine ratio (UPCR) in 20 patients at six weeks of treatment, 49.9% geometric mean reduction in 24-hour UPCR in 18 patients at 12 weeks of treatment and 58.5% geometric mean reduction in 24-hour UPCR in 11 patients at 24 weeks of treatment (see figure below). After 24 weeks of treatment, ten of the 11 patients (91%) who had completed this visit had greater than a 40% cumulative reduction in UPCR.



Median baseline 24-h urine protein excretion: 1.17 g/day (Q1,Q3: 0.85, 1.46 g/day)

FC080 - A Systems Nephrology Framework for the Molecular Classification of Chronic Kidney Disease

Conventional stratification by clinical and histopathological phenotypes is insufficient to describe the heterogeneity of chronic kidney diseases (CKD). Integration of intra-renal molecular and morphological features with clinical outcomes is required to drive discovery of disease-modifying therapies. The NURTuRE biobank comprises matched patient samples from a broad range of diagnoses and kidney functional states, that are associated with rich clinical data. Chinook and Evotec aim to generate mechanistic disease understanding for a patient-centric, integrated target and biomarker discovery that will enable the development of novel precision treatments.

Unsupervised characterization of NURTuRE kidney transcriptomes inferred 5 clusters with distinct molecular landscapes. Molecular stratification aligned with clinical and histopathological parameters of disease progression. Dimensionality reduction suggested transitions between molecular clusters that can be interpreted as pseudotime disease trajectories. Detailed characterization of gene expression and tissue remodeling dynamics along these trajectories will reveal new insights into cellular and molecular mechanisms of CKD progression.

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