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): June 12, 2023

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 8.01. Other Events.

On June 12, 2023, Chinook Therapeutics, Inc. (the "Company") issued a press release announcing updated interim results from its zigakibart (BION-1301) Phase 1/2 trial for patients with IgA Nephropathy (IgAN).

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Important Additional Information

Forward-Looking Statements

In addition to historical information, this communication contains forward-looking statements within the meaning of applicable securities law, including statements regarding the advancement of its product candidates and product pipeline, and the clinical development of its product candidates, including expectations regarding the results of clinical trials. In addition, when used in this communication, the words "will," "expects," "could," "would," "may," "anticipates," "intends," "plans," "believes," "seeks," "targets," "estimates," "looks for," "looks to," "continues" and similar expressions, as well as statements regarding our focus for the future, are generally intended to identify forward-looking statements. Each of the forward-looking statements we make in this communication involves risks and uncertainties that could cause actual results to differ materially from these forward-looking statements. Factors that might cause or contribute to such differences include, but are not limited to: expected revenues, cost savings, synergies and other benefits from the proposed merger might not be realized within the expected time frames or at all and costs or difficulties relating to integration matters, including but not limited to employee retention, might be greater than expected; the requisite regulatory approvals and clearances for the proposed transaction may be delayed or may not be obtained (or may result in the imposition of conditions that could adversely affect the combined company or the expected benefits of the proposed merger); the requisite approval of Company stockholders may be delayed or may not be obtained, the other closing conditions to the proposed merger may be delayed or may not be obtained, or the merger agreement may be terminated; business disruption may occur following or in connection with the proposed merger; Novartis AG ("Novartis") or the Company's businesses may experience disruptions due to transaction-related uncertainty or other factors making it more difficult to maintain relationships with employees, other business partners or governmental entities; the milestones for the proposed CVRs may not be achieved; the possibility that the proposed merger is more expensive to complete than anticipated, including as a result of unexpected factors or events; and diversion of management's attention from ongoing business operations and opportunities as a result of the proposed merger or otherwise. Additional factors that may affect the future results of Novartis and the Company are set forth in their respective filings with the U.S. Securities and Exchange Commission (the "SEC"), including in the most recently filed annual report of Novartis on Form 20-F, subsequently filed Current Reports on Form 6-K and other filings with the SEC, which are available on the SEC's website at www.sec.gov, and the Company's most recently filed Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the SEC, which are available on the SEC's website at www.sec.gov. The risks described in this communication and in Novartis and the Company's filings with the SEC should be carefully reviewed. Undue reliance should not be placed on these forward-looking statements, which speak only as of the date they are made. Novartis and the Company undertake no obligation to publicly release any revisions to the forward-looking statements or reflect events or circumstances after the date of this communication, except as required by law.

No Offer or Solicitation

This communication does not constitute an offer to sell or the solicitation of an offer to buy any securities or a solicitation of any vote or approval with respect to the proposed merger or otherwise. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

Additional Information and Where to Find It

In connection with the proposed merger between Novartis and the Company, Novartis and the Company intend to file relevant materials with the SEC, including a preliminary and definitive proxy statement to be filed by the Company. The definitive proxy statement and proxy card will be delivered to the stockholders of the Company in advance of the special meeting relating to the proposed merger. THE COMPANY'S STOCKHOLDERS ARE URGED TO READ THE DEFINITIVE PROXY STATEMENT IN ITS ENTIRETY WHEN IT BECOMES AVAILABLE AND ANY OTHER DOCUMENTS FILED BY EACH OF NOVARTIS AND THE COMPANY WITH THE SEC IN CONNECTION WITH THE PROPOSED MERGER OR INCORPORATED BY REFERENCE THEREIN BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION AND THE PARTIES TO THE PROPOSED TRANSACTION. Investors and security holders will be able to obtain a free copy of the proxy statement and such other documents containing important information about Novartis and the Company, once such documents are filed with the SEC, through the website maintained by the SEC at www.sec.gov. Novartis and the Company make available free of charge at the Novartis website and the Company's website, respectively (in the "Investors" section), copies of materials they file with, or furnish to, the SEC. The contents of the websites referenced above are not deemed to be incorporated by reference into the proxy statement.

Participants in the Solicitation

This document does not constitute a solicitation of proxy, an offer to purchase or a solicitation of an offer to sell any securities. Novartis, the Company and their respective directors, executive officers and certain employees may be deemed to be participants in the solicitation of proxies from the stockholders of the Company in connection with the proposed merger. Information regarding the special interests of these directors and executive officers in the proposed merger will be included in the definitive proxy statement referred to above. Security holders may also obtain information regarding the names, affiliations and interests of the Novartis directors and executive officers in the Novartis Annual Report on Form 20-F and Form 20-F/A for the fiscal year ended December 31, 2022, which were filed with the SEC on February 1, 2023, and May 15, 2023, respectively. Security holders may obtain information regarding the names, affiliations and interests of the Company's directors and executive officers in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, which was filed with the SEC on February 27, 2023, and its definitive proxy statement for the 2023 annual meeting of stockholders, which was filed with the SEC on April 28, 2023. To the extent the holdings of the Company's securities by the Company's directors and executive officers have changed since the amounts set forth in the Company's definitive proxy statement for its 2023 annual meeting of stockholders, such changes have been or will be reflected on Statements of Change in Ownership on Form 4 filed with the SEC. Additional information regarding the interests of such individuals in the proposed merger will be included in the definitive proxy statement relating to the proposed merger when it is filed with the SEC. These documents (when available) may be obtained free of charge from the SEC's website at www.sec.gov, the Novartis website at https://www.novartis.com and the Company's website at https://www.chinooktx.com. The contents of the websites referenced above are not deemed to be incorporated by reference into the proxy statement.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press Release, dated June 12, 2023.
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, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: June 12, 2023

Chinook Therapeutics, Inc.

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

Chinook Therapeutics to Present Updated Data from Zigakibart (BION-1301) Phase 1/2 Trial in Patients with IgA Nephropathy (IgAN) at the 60th European Renal Association (ERA) Congress

- ***Zigakibart treatment continues to demonstrate rapid and sustained reductions in mechanistic biomarkers, including IgA and Gd-IgA1 levels, which correspond to clinically meaningful proteinuria reductions in patients with IgAN across Cohorts 1 and 2***
- ***Zigakibart is well-tolerated, with no ADAs observed or treatment discontinuations due to adverse events (AEs) in patients with IgAN across Cohorts 1 and 2***
- ***In all patients combined from both Cohorts 1 and 2, zigakibart demonstrated mean proteinuria reductions of 20% at 12 weeks of treatment, 39% at 24 weeks of treatment and 67% at 52 weeks of treatment***
- ***Extended treatment with zigakibart resulted in sustained clinical benefit, with 67% mean proteinuria reduction in seven patients at 76 weeks of treatment and 72% in five patients at 100 weeks of treatment***
- ***Additional presentations on the phase 2 ASSIST and phase 3 BEYOND study designs, initial data from the phase 1 study of CHK-336 in healthy volunteers, as well as research on the impact of maladaptive tubular epithelial cells on disease progression in chronic kidney diseases will also be presented at the 60th ERA Congress***
- ***Due to the pending acquisition of Chinook by Novartis AG, the investor conference call and webcast previously scheduled for Friday, June 16, 2023 at 8:15 am EDT (2:15 pm CEST) has been cancelled***

SEATTLE June 12, 2023 – Chinook Therapeutics, Inc. (Nasdaq: KDNY), a biopharmaceutical company focused on the discovery, development and commercialization of precision medicines for kidney diseases, today announced a focused oral presentation on zigakibart (BION-1301) will be presented on Friday, June 16, 2023 at the 60th ERA Congress being held virtually and live in Milan, Italy.

“The strong data we will be presenting at the ERA Congress from the ongoing phase 1/2 study of zigakibart continue to demonstrate its disease-modifying potential in patients with IgAN,” said Eric Dobmeier, president and chief executive officer of Chinook Therapeutics. “In addition to sustained reductions in mechanistic biomarkers and correlating clinically meaningful proteinuria reductions observed in patients with IgAN with a wide range of baseline proteinuria levels, the phase 1/2 study has provided us additional key learnings that we look forward to implementing in the phase 3 BEYOND trial, including dose, schedule and route of administration and patient selection.”

Updated Interim Results of a Phase 1/2 Study of Zigakibart (BION-1301) in Patients with IgA Nephropathy

Zigakibart is a novel anti-APRIL monoclonal antibody currently in phase 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).

Updated data from both Cohorts 1 and Cohort 2 will be presented from 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 clinical responses of open-label zigakibart treatment in patients with IgAN.

Key highlights from the presentation include the following:

Patients in Cohort 1 initially received a 450mg intravenous (IV) dose of zigakibart every two weeks. After at least 24 weeks of IV dosing, patients in Cohort 1 transitioned to a 600 mg subcutaneous (SC) dose every two weeks for a total treatment duration of up to two years. Cohort 1 enrolled 10 patients, of which two patients withdrew from the study for reasons unrelated to study drug, and eight patients continued receiving treatment.

Patients in Cohort 2 are receiving a SC dose of 600 mg of zigakibart every two weeks for a total treatment duration of up to two years. Cohort 2 enrolled 30 patients, of which three patients were discontinued for not meeting the eligibility criterion of having biopsy-confirmed IgAN, and 27 patients continued receiving treatment.

Baseline 24-hour Urine Protein Excretion (g/day)

- The median baseline 24-hour urine protein excretion for patients enrolled in Cohort 1 was 1.2 g/day, with a range of 0.7 – 6.5 g/day, and the median baseline 24-hour urine protein excretion for patients enrolled in Cohort 2 was 1.1 g/day, with a range of 0.3 – 7.0 g/day. With a median baseline 24-hour urine protein excretion for patients enrolled in both Cohorts 1 and 2 of 1.1 g/day, this population represents patients with IgAN at high risk of kidney disease progression.

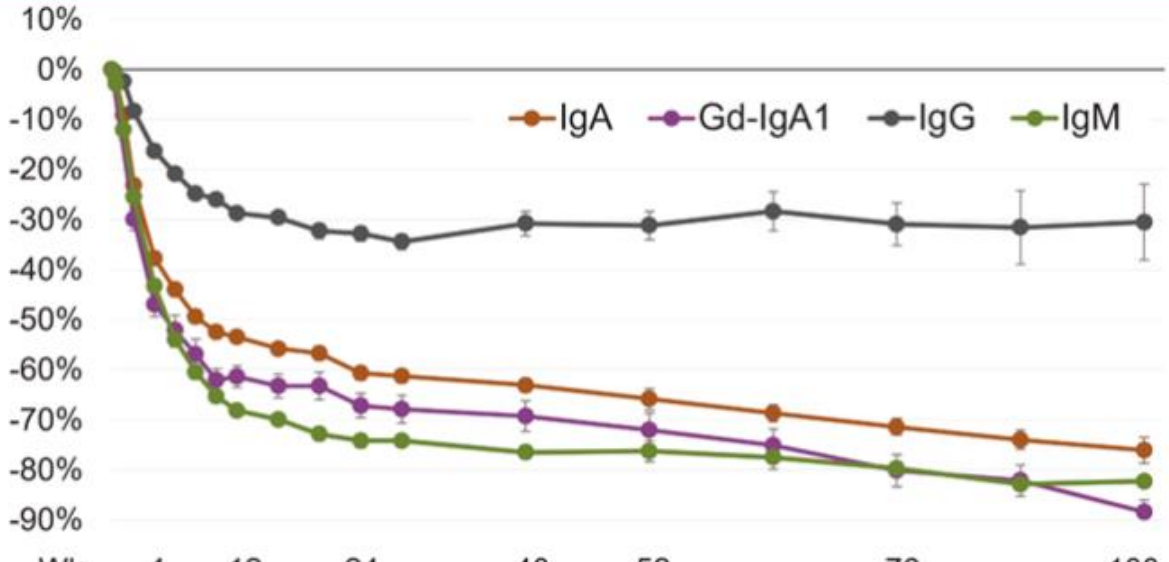
Safety and Tolerability

- As of the May 8, 2023 data cutoff, zigakibart has been well tolerated, with no deaths or treatment discontinuations due to adverse events. Of all 40 patients enrolled in both Cohorts 1 and 2:
    - All infections have been Grade 1 or 2 in severity and only one subject had infections deemed treatment-related (Grade 1 viral upper respiratory tract infection and influenza).
    - There were no anti-drug antibodies observed in any patients.
    - Two patients had IgG levels that fell below 3 g/L. One patient in Cohort 1 required protocol-mandated withholding of study drug. The patient reached end-of-treatment prior to re-initiation of study drug. One patient in Cohort 2 had IgG levels below 3g/L at their week 12 follow-up after permanent discontinuation due to not meeting eligibility criteria for having biopsy-confirmed IgAN. No infections were reported in either patient while their IgG levels were below 3g/L.
    - There were 16 injection site reactions (ISRs) reported from a total of 875 SC doses administered (<2%). All ISRs were Grade 1 or Grade 2.
    - One serious adverse event occurred (amnesia) that was not treatment-related and did not result in interruption of study drug.

Mechanistic Biomarkers

- Zigakibart treatment resulted in rapid and sustained reductions in IgA, pathogenic Gd-IgA1, IgM and to a lesser extent IgG, in patients with IgAN. Zigakibart's effects on mechanistic biomarkers were highly consistent between Cohorts 1 and 2 (see figures below).

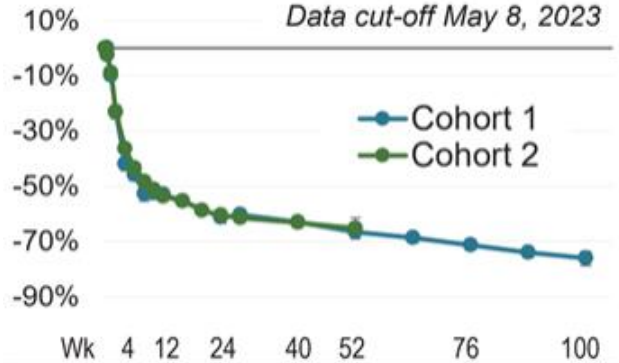
Immunoglobulins, Combined Cohorts
% Change from baseline (Mean ± SE)



Wk	4	12	24	40	52	76	100
Gd-IgA1, n=	35	34	26	18	7	7	3
IgX, n=	35	34#	30	23	16	8	6

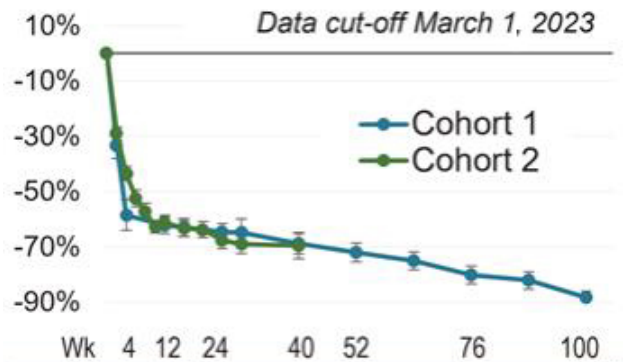
#IgA n=33 at week 12

IgA
% Change from Baseline (Mean ± SE)

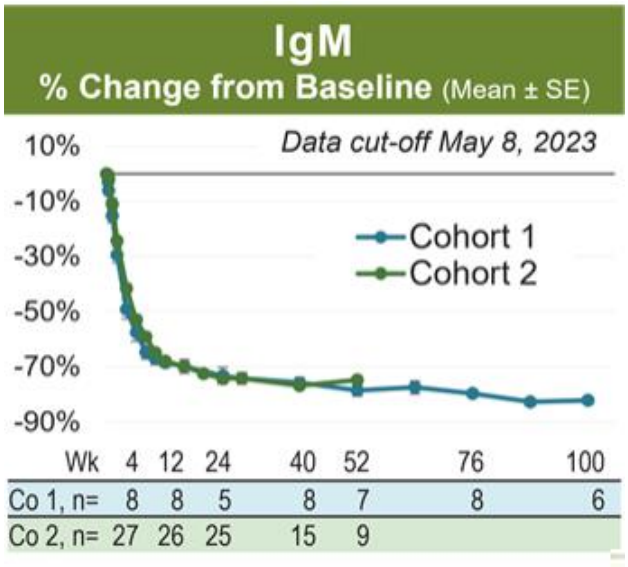


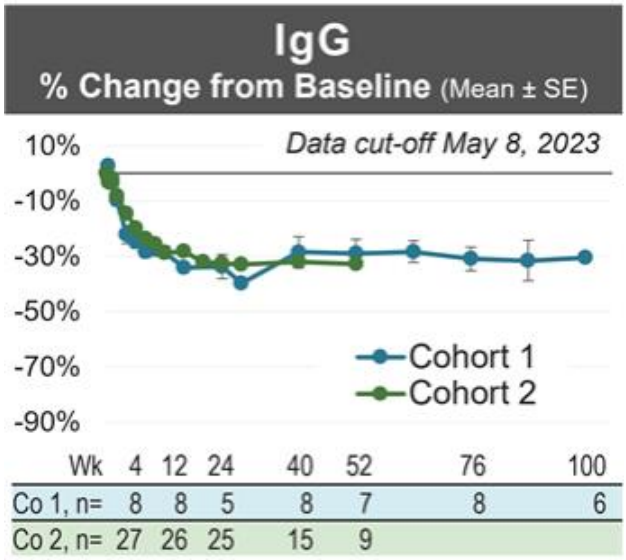
Wk	4	12	24	40	52	76	100
Co 1, n=	8	8	5	8	7	8	6
Co 2, n=	27	25	25	15	9		

Gd-IgA1
% Change from Baseline (Mean ± SE)



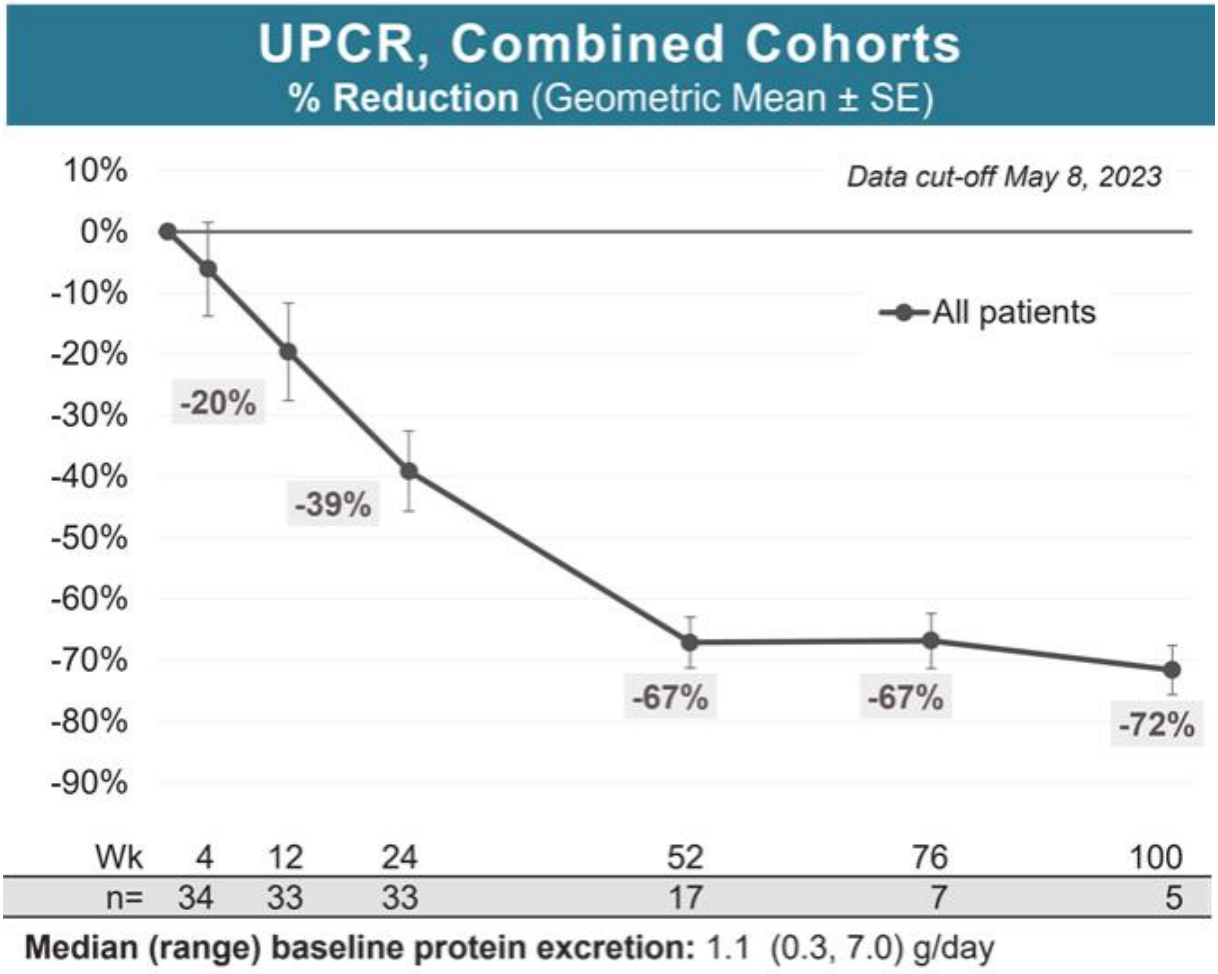
Wk	4	12	24	40	52	76	100
Co 1, n=	8	8	5	8	7	7	3
Co 2, n=	27	26	21	10			





24-hour UPCR

- Zigakibart treatment resulted in sustained, clinically meaningful proteinuria reductions in patients with IgAN across a wide range of baseline proteinuria levels.
- In the combined Cohorts 1 and 2, zigakibart demonstrated mean reductions in 24-hour urine protein creatinine ratio (UPCR) of 20% in 33 patients at 12 weeks of treatment, 39% in 33 patients at 24 weeks of treatment, 67% in 17 patients at 52 weeks of treatment, 67% in seven patients at 76 weeks of treatment and 72% in five patients at 100 weeks of treatment (see figure below).



Overviews of the phase 3 BEYOND and phase 2 ASSIST trials are also being presented as focused oral presentations (digital poster with 3-minute presentation) on Friday, June 16, 2023. A moderated oral presentation (6-slide presentation) on research regarding the impact of maladaptive tubular epithelial cells on disease progression in chronic kidney diseases will be presented on Friday, and a free communication presentation (10-minute live oral presentation) on initial data from the phase 1 study of CHK-336 in healthy volunteers will be presented Saturday, June 17, 2023.

Focused Orals:

Abstract Title:	**Updated Interim Results of a Phase 1/2 Study of BION-1301 in Patients with IgA Nephropathy**
Presenting Author:	Jonathan Barratt, PhD, FRCP University of Leicester & Leicester General Hospital, Leicester, UK
Session:	Glomerular & Tubulo-interstitial Diseases
Date/Time:	Friday, June 16, 2023 at 8:30 – 9:45 am CEST
Location:	Focused Oral Room 2
Abstract Title:	**A Phase 3, Randomized, Double-blind, Placebo-controlled Study of BION-1301 in Adults with IgA Nephropathy**
Presenting Author:	Vlado Perkovic, MBBS, PhD, FRACP, FASN University of New South Wales, Sydney, New South Wales, Australia

Session:	Glomerular & Tubulo-interstitial Diseases
Date/Time:	Friday, June 16, 2023 at 12:00 – 1:15 pm CEST
Location:	Focused Oral Room 9
Abstract Title:	**ASSIST Study Design: A Randomized, Double-blind, Placebo-controlled, Crossover Study of Atrasentan in Patients with IgA Nephropathy (IgAN) on Sodium-glucose Cotransporter-2 Inhibitors (SGLT2i)**
Presenting Author:	Hiddo J. L Heerspink, PhD, PharmD University Medical Center Groningen, Groningen, Netherlands
Session:	Glomerular & Tubulo-interstitial Diseases
Date/Time:	Friday, June 16, 2023 at 8:30 – 9:45 am CEST
Location:	Focused Oral Room 2

Free Communication:

Abstract Title:	**CHK-336, A First-in-Class Orally Administered LDH Inhibitor: Safety, PK and Target Engagement in a First-in-Human Phase 1 Healthy Volunteer Study**
Presenting Author:	Vincent Tong, PhD Chinook Therapeutics
Session:	Something Rare, Something Special
Date/Time:	Saturday, June 17, 2023 at 12:00 – 1:15 pm CEST
Location:	Amber 3 & 4

Moderated Oral:

Abstract Title:	**Accumulation of Maladaptive Tubular Epithelial Cells (TECs) is Ubiquitous in Chronic Kidney Diseases and Represents a Common Initiating Mechanism of Disease Progression**
Presenting Author:	Eric Olson, PhD Chinook Therapeutics
Session:	Moderated Orals 1.4
Date/Time:	Friday, June 16, 2023 at 5:00 – 6:15 pm CEST
Location:	Amber 6

Once presented, all five presentations can be found in the Scientific Publications section of Chinook's website. For more information on these and other abstracts, please visit the 60th ERA Congress website.

Due to the pending acquisition of Chinook by Novartis AG, the investor conference call and webcast previously scheduled for Friday, June 16, 2023 at 8:15 am EDT (2:15 pm CEST) during the ERA Congress has been cancelled.

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 proteinuric glomerular diseases. Zigakibart (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 in phase 1 development. In addition, Chinook's research and discovery efforts are focused on building a pipeline of precision medicines for rare, severe chronic kidney diseases with defined genetic and molecular drivers. Chinook is leveraging insights from kidney single cell RNA sequencing and large CKD patient cohorts that have been comprehensively panomically phenotyped, with retained biosamples and prospective clinical follow-up, to discover and develop therapeutic candidates with mechanisms of action targeted against key kidney disease pathways. To learn more, visit www.chinooktx.com.

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