



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

June 12, 2023

- ***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 (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 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](https://www.clinicaltrials.gov/ct2/show/study/NCT03945318), 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)

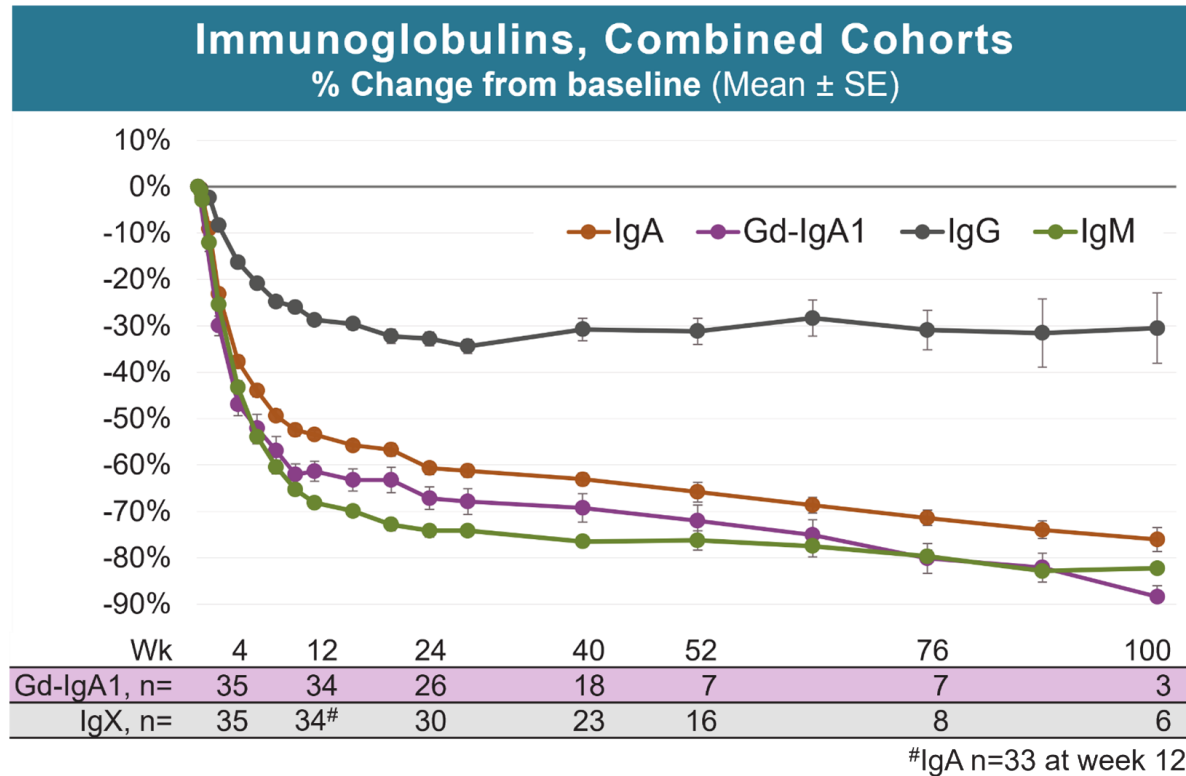
- The median baseline 24-hour urine protein excretion for patients enrolled in Cohort 1 was 1.2 g/day, with a range of 0.7 – 6.5 g/day, and the median baseline 24-hour urine protein excretion for patients enrolled in Cohort 2 was 1.1 g/day, with a range of 0.3 – 7.0 g/day. With a median baseline 24-hour 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

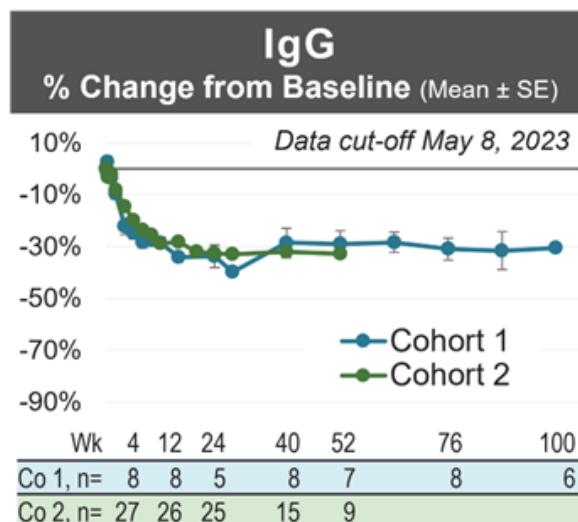
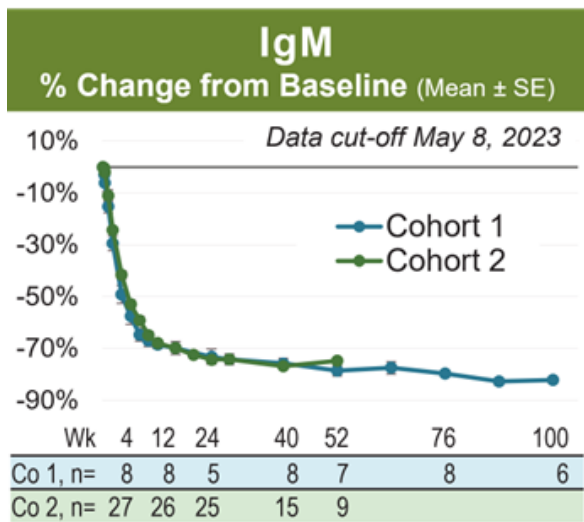
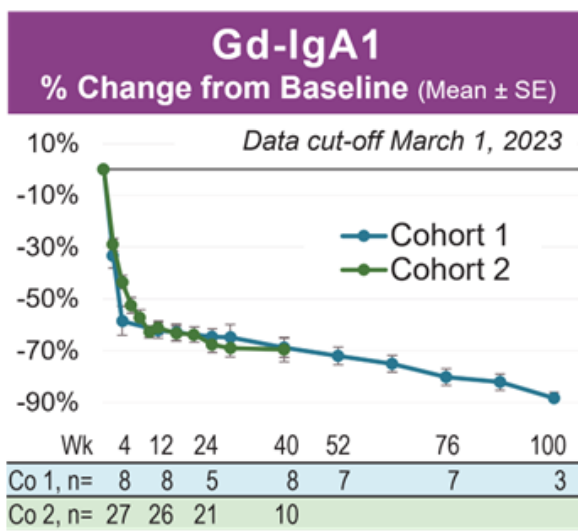
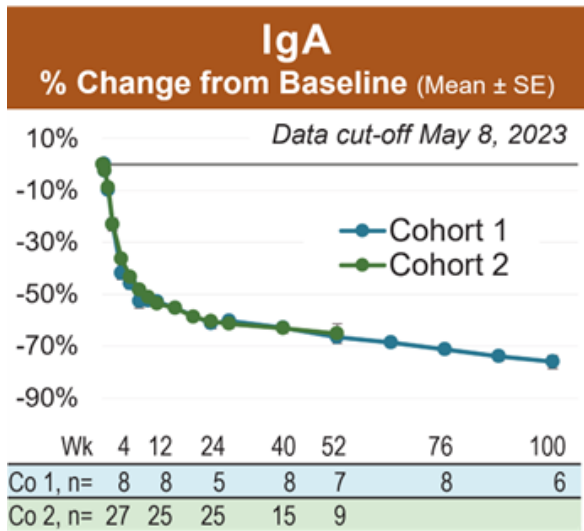
- As of the May 8, 2023 data cutoff, zigakibart has been well tolerated, with no deaths or treatment discontinuations due to adverse events. Of all 40 patients enrolled in both Cohorts 1 and 2:
 - All infections have been Grade 1 or 2 in severity and only one subject had infections deemed treatment-related (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).



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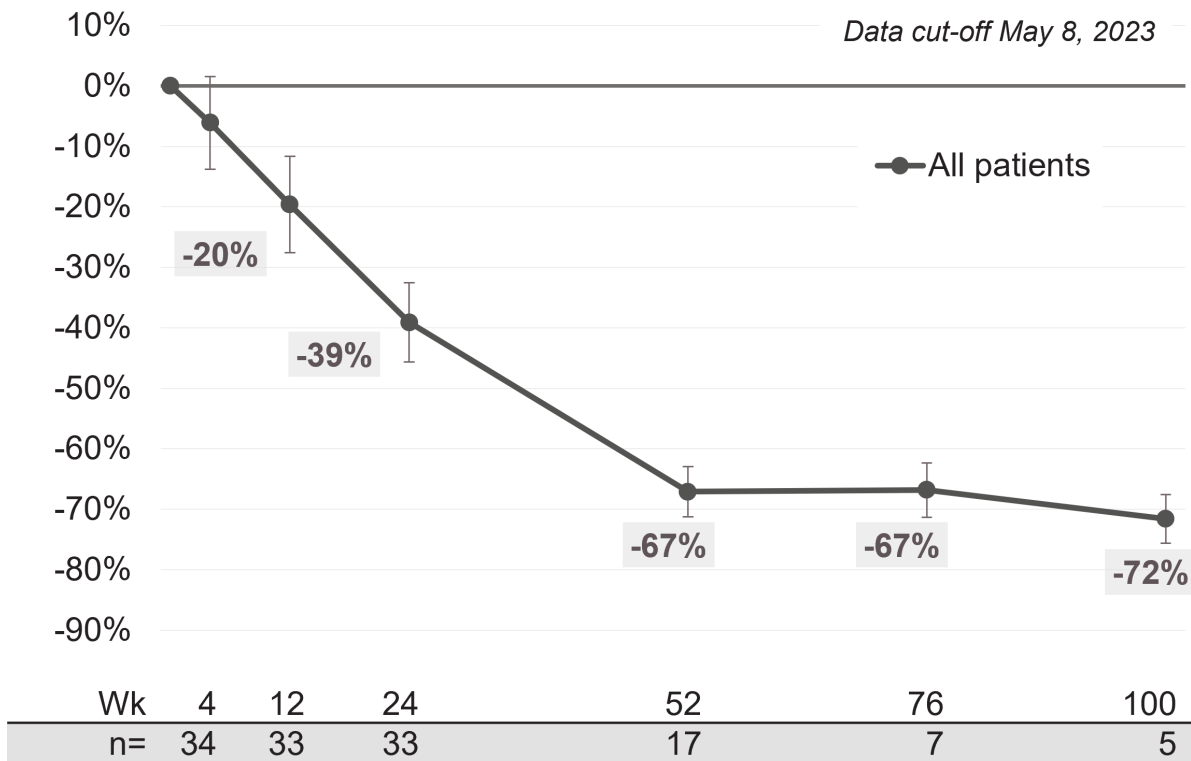
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24-hour UPCR

- 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).

UPCR, Combined Cohorts

% Reduction (Geometric Mean \pm SE)



Median (range) baseline protein excretion: 1.1 (0.3, 7.0) g/day

<https://www.globenewswire.com/NewsRoom/AttachmentNg/dca0b8df-b710-4f2c-b410-33f8aeafaf01>

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 Jonathan Barratt, PhD, FRCP
 Author: 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 Vlado Perkovic, MBBS, PhD, FRACP, FASN
 Author: 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 Hidjo J. L Heerspink, PhD, PharmD
 Author: 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 Vincent Tong, PhD

Author: 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 Eric Olson, PhD

Author: 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](#).

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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.

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 or Chinook'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 Chinook 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 Chinook'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 Chinook'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 Chinook 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.

Additional Information and Where to Find It

In connection with the proposed merger between Novartis and Chinook, Novartis and Chinook intend to file relevant materials with the SEC, including a preliminary and definitive proxy statement to be filed by Chinook. The definitive proxy statement and proxy card will be delivered to the stockholders of Chinook in advance of the special meeting relating to the proposed merger. CHINOOK'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 CHINOOK 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 Chinook, once such documents are filed with the SEC, through the website maintained by the SEC at www.sec.gov. Novartis and Chinook make available free of charge at the Novartis website and Chinook'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, Chinook and their respective directors, executive officers and certain employees may be deemed to be participants in the solicitation of proxies from the stockholders of Chinook 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 Chinook's directors and executive officers in Chinook'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 Chinook's securities by Chinook's directors and executive officers have changed since the amounts set forth in Chinook'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 Chinook'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.

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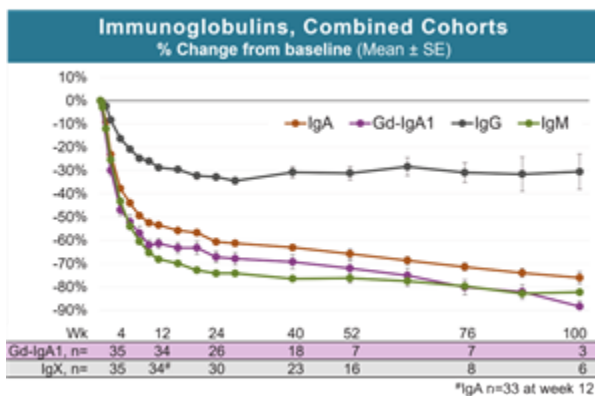
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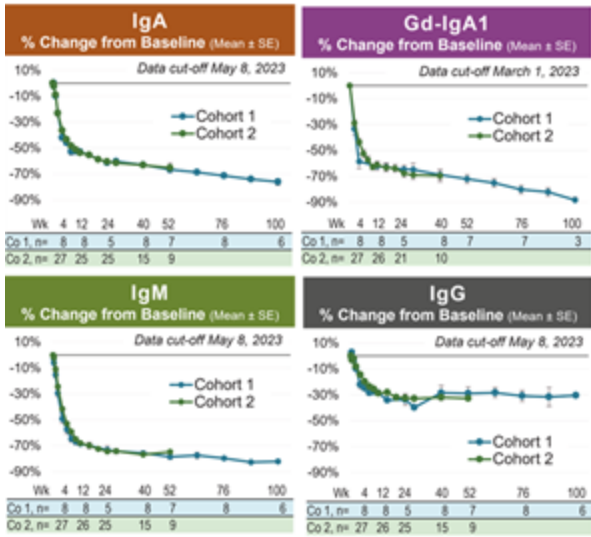


Zigakibart Treatment Results in Rapid and Sustained Reductions in IgA and Gd-IgA1 in Patients with IgA Nephropathy



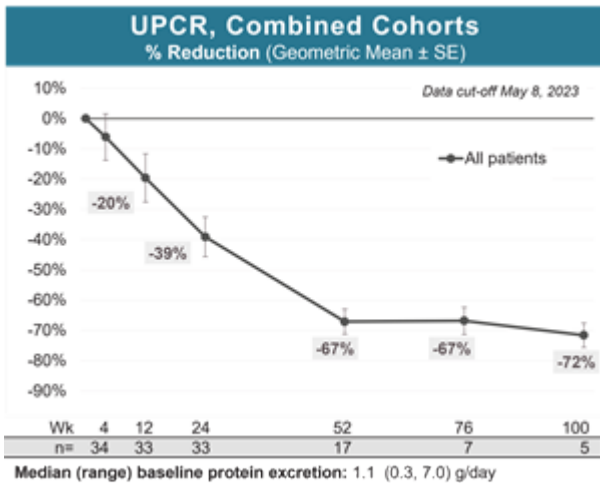
Zigakibart produced rapid and sustained reductions in IgA and Gd-IgA1, the pathogenic variant of IgA nephropathy

Zigakibart Treatment Results in Rapid and Sustained Reductions in IgA and Gd-IgA1 in Patients with IgA Nephropathy



Zigakibart produced rapid and sustained reductions in IgA and Gd-IgA1, the pathogenic variant of IgA nephropathy

Zigakibart Treatment Results in Clinically Meaningful Proteinuria Reductions in Patients with IgAN



Zigakibart treatment resulted in sustained, clinically meaningful proteinuria reductions in patients with IgA nephropathy across a wide range of baseline proteinuria levels

Source: Chinook Therapeutics, Inc.