Chinook Therapeutics Announces First Patient Enrolled in Pivotal Phase 3 BEYOND Study of Zigakibart (BION-1301) for Patients with IgA Nephropathy

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SEATTLE, July 28, 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 that the first patient with IgA nephropathy (IgAN) has been enrolled in the BEYOND study, a pivotal phase 3 clinical trial evaluating the safety and efficacy of zigakibart (BION-1301), a potentially disease-modifying anti-APRIL monoclonal antibody.

“Initiation of the phase 3 BEYOND study is an important step towards our goal of providing an innovative treatment option for patients with IgAN, a disease with high unmet need and limited treatment options,” said Eric Dobmeier, president and chief executive officer of Chinook Therapeutics. “The data from our ongoing phase 1/2 trial of zigakibart supports our belief that binding and neutralizing APRIL in patients with IgAN plays a key role in depleting pathogenic galactose deficient-IgA1, reducing proteinuria and preserving kidney function for IgAN patients.”

“I am pleased to see Chinook enroll the first patient in the phase 3 BEYOND study of zigakibart in IgAN and look forward to the study’s continued enrollment,” said Vlado Perkovic, MBBS, PhD, FASN, FRACP, dean of medicine and health and Scientia professor at University of New South Wales and co-chair of the BEYOND study steering committee. “IgAN is the most common primary glomerular disease worldwide with limited treatment options currently available, causing many patients to progress to end-stage kidney disease, requiring dialysis or kidney transplant. With the potential to be disease-modifying based on the encouraging results observed in the phase 1/2 study, I believe zigakibart could be an important new therapeutic treatment option for patients with IgAN.”

About the BEYOND Study
The BEYOND study (see www.clinicaltrials.gov, identifier NCT05852938) is a global, randomized, multicenter, double-blind, placebo-controlled phase 3 clinical trial comparing the safety and efficacy of zigakibart versus placebo in patients with IgAN at risk of progressive loss of kidney function. Approximately 272 patients with biopsy-proven IgAN and eGFR ≥ 30 mL/min/1.73m^2 will be randomized to receive 600 mg of zigakibart or a matched placebo subcutaneously every two weeks for 104 weeks. An additional exploratory cohort, not included in the primary analysis, will be comprised of approximately 20 subjects (10 subjects per arm) with biopsy-confirmed IgAN and eGFR of ≥ 20 to < 30 mL/min/1.73 m^2.

The primary efficacy endpoint of the BEYOND study is to evaluate the effect of zigakibart versus placebo on proteinuria as measured by change in urine protein to creatinine ratio (UPCR) from baseline to 40 weeks. Secondary and exploratory objectives include evaluating change in eGFR from baseline to week 104; composite clinical outcome of 30% or 40% reduction in eGFR, eGFR < 15 mL/min/1.73m^2 or dialysis, kidney transplantation or all-cause mortality; safety and tolerability; impact of zigakibart on disease biomarkers and health-related quality of life, as well as analysis of zigakibart pharmacokinetics and immunogenicity.

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 3 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 Chinook 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 contingent value rights 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 Definitive Proxy Statement of Chinook relating to the proposed merger filed on July 10, 2023, as amended by the definitive additional materials filed with the SEC on July 26, 2023, 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.

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 Chinook, Chinook filed the Definitive Proxy Statement with the SEC on July 10, 2023, and filed definitive additional materials with the SEC on July 26, 2023. The Definitive Proxy Statement and proxy card has been 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 AND DEFINITIVE ADDITIONAL MATERIALS IN THEIR ENTIRETY 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 are able to obtain a free copy of the Definitive Proxy Statement, definitive additional materials and such other documents containing important information about Novartis and Chinook 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 Definitive 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 is 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 is included in the Definitive Proxy Statement relating to the proposed merger, which was filed with the SEC on July 10, 2023, as amended by the definitive additional materials filed with the SEC on July 26, 2023. 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 Definitive Proxy Statement.

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