Chinook Therapeutics Announces Voluntary Pause in Dosing of CHK-336 in Ongoing Phase 1 Clinical Trial in Healthy Volunteers

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SEATTLE, April 11, 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 dosing in the phase 1 clinical trial of CHK-336 in healthy volunteers has been voluntarily paused to allow a thorough investigation of a serious adverse event (SAE) that occurred in a single subject following the first dose in the 125 mg multiple ascending dose (MAD) group. Dosing was halted per trial protocol when the event occurred, followed by a voluntary pausing of the trial by Chinook to enable further investigation. The event has been reported to the U.S. Food and Drug Administration (FDA) through a Suspected Unexpected Severe Adverse Reaction (SUSAR) report.

The SAE had a rapid onset and rapid recovery; follow-up of the subject is ongoing. Based on evaluation to date with input from expert consultants, the underlying cause of the event is being investigated as a potential hypersensitivity reaction to the study drug or its excipients. Next steps will be determined once Chinook and the trial's Safety Monitoring Committee have reviewed all safety data. Previously, CHK-336 was generally well tolerated in a total of 62 subjects at single doses up to 500 mg and multiple doses up to 60 mg daily for 14 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 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 clinical trial in healthy volunteers. 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.

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, and regulatory submissions, including the timing of the results of our phase 3 ALIGN trial and phase 2 AFFINITY trial of atrasentan, phase 3 clinical trial of BION-1301, phase 1/2 trial of BION-1301, the resumption of dosing in our phase 1 clinical trial of CHK-336, and submission for potential accelerated approval for atrasentan. 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 or other strategic collaborations, whether results of early clinical trials or preclinical studies will be indicative of the results of future trials, including our phase 3 ALIGN trial, 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 macroeconomic conditions on our business operations, including rising interest rates and inflation. 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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