Chinook Receives Rare Pediatric Disease Designation from U.S. Food and Drug Administration for CHK-336 for Treatment of Primary Hyperoxaluria

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CHK-336 On Track for Phase 1 Clinical Trial Initiation in the Second Half of 2021

VANCOUVER, British Columbia and SEATTLE, Feb. 02, 2021 (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 U.S. Food and Drug Administration (FDA) has granted rare pediatric disease designation for CHK-336, an investigational oral small molecule inhibitor of lactate dehydrogenase A (LDHA) for primary hyperoxaluria (PH). PH is a group (PH1, PH2 and PH3) of ultra-rare genetic diseases caused by enzyme mutations that result in excess oxalate production in the liver, and in its most severe forms, can lead to end-stage kidney disease at a young age. Inhibition of LDHA with CHK-336 allows for the potential to treat all forms of PH and other disorders arising from excess oxalate, while its liver-targeted tissue distribution profile enables maximal inhibition of liver oxalate production with minimal systemic exposure.

The FDA defines a rare pediatric disease as a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years and the disease affects fewer than 200,000 people in the United States. Through the FDA's Rare Pediatric Disease Designation and Voucher Programs, the FDA may grant a priority review voucher at the time of product approval for a "rare pediatric disease." The priority review voucher may be redeemed to receive priority review for a subsequent marketing application for a different product candidate or may be sold or transferred.

"We are pleased the FDA has granted Chinook rare pediatric disease designation for CHK-336 for the treatment of primary hyperoxaluria, a devastating disease that usually presents in childhood, with life-threatening complications into adulthood," said Alan Glicklich, M.D., chief medical officer at Chinook. "Serious manifestations of PH include kidney stones, nephrocalcinosis, growth failure including failure to thrive and reduced linear growth, systemic oxalosis and end-stage kidney disease. Through the development of CHK-336 for all forms of PH, we aim to address the significant unmet need and burden affecting patients and caregivers."

About CHK-336
CHK-336, is a first-in-class, liver-targeted oral small molecule LDHA inhibitor for the treatment of PH. LDHA catalyzes the final step in the production of oxalate from glyoxalate in the liver, therefore LDHA inhibition has the potential to treat all forms of PH as well as other disorders arising from excess oxalate. CHK-336 has the potential for robust efficacy by rapidly distributing to the site of oxalate production, while minimizing systemic exposures and potential for off-target activity, to facilitate a favorable tolerability profile required in this chronic disease. In PH1 mouse models, CHK-336 demonstrated significant and dose-dependent reductions in urinary oxalate, with the majority of CHK-336-treated mice reaching the normal range seen in wild-type mice. CHK-336 is currently progressing through IND-enabling studies with phase 1 initiation planned for the second half of 2021.

About Primary Hyperoxaluria (PH)
Hyperoxalurias, including PH, are diseases caused by excess oxalate, a potentially toxic metabolite typically filtered by the kidneys and excreted as a waste product in urine. Symptoms of PH include recurrent kidney stones, severe pain, blood in the urine and urinary tract infections; which when left untreated, can result in kidney failure requiring dialysis or dual kidney/liver transplantation. In patients with hyperoxalurias, excess oxalate combines with calcium to form calcium oxalate crystals that deposit in the kidney, resulting in the formation of painful kidney stones and driving progressive kidney damage over time. PH1, PH2 and PH3 are ultra-rare diseases caused by genetic mutations that result in excess oxalate, and in its most severe forms, can lead to end-stage kidney disease at a young age.

About Chinook Therapeutics, Inc.
Chinook Therapeutics, Inc. is a clinical-stage biotechnology 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, an investigational phase 3 endothelin receptor antagonist for the treatment of IgA nephropathy and other primary glomerular diseases. BION-1301, an investigational anti-APRIL monoclonal antibody is being evaluated in a phase 1b trial for IgA nephropathy. In addition, Chinook is advancing CHK-336, an investigational oral small molecule LDHA inhibitor for the treatment of primary hyperoxaluria, as well as research programs for other rare, severe chronic kidney diseases, including polycystic kidney disease. 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 initiation and results of clinical trials. 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, whether results of early clinical trials or preclinical studies will be indicative of the results of future trials, our ability to obtain and maintain regulatory approval of our product candidates, the ability to obtain a priority review voucher upon approval of one of our products, 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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