Chimerix Acquires Oncoceutics to Expand Pipeline with Late-Stage Oncology Program

January 8, 2021

ONC201 Registrational Trial for Recurrent H3 K27M-mutant Glioma

Compelling Response Rates to Date; Defined Regulatory Path to Registration

Pivotal Data Anticipated in 2021 to Support Potential Registration, Addressing an Estimated Market Opportunity of Greater than $500 Million

Management to Host Conference Call at 8:30 a.m. ET Today

DURHAM, N.C., Jan. 08, 2021 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company focused on accelerating the development of medicines to treat cancer and other serious diseases, today announced that the Company has acquired Oncoceutics, Inc., a privately-held, clinical-stage biotechnology company developing imipridones, a novel class of compounds. Oncoceutics' lead product candidate, ONC201, has been shown in clinical testing to selectively induce cell death in multiple cancer types. ONC201 is currently in a registrational clinical trial for recurrent H3 K27M-mutant glioma and a confirmatory response rate assessment is expected in 2021.

ONC201 is an orally administered small molecule dopamine receptor D2 (DRD2) antagonist and caseinolytic protease (ClpP) agonist in late-stage clinical development for recurrent gliomas that harbor the H3 K27M mutation. Recurrent glioma is a form of brain cancer with a particularly poor prognosis having a median overall survival of approximately eight months. Recurrent pediatric patients, with cancer that carries the H3 K27M mutation, have an even worse prognosis with median overall survival of approximately four months. Compelling responses at this stage of disease are rare and lack durability. Patients with this mutation are considered grade IV by the World Health Organization, regardless of underlying histology or age. Initial evaluation of data from the full 50-subject registration cohort, which remains subject to full maturation and confirmation by Blinded Independent Central Review (BICR), indicate a compelling and particularly durable single agent Overall Response Rate (ORR) of at least 20% as assessed by Response Assessment in Neuro-Oncology-High Grade Glioma (RANO-HGG). The final confirmatory data analysis is expected in 2021.

"Patients with H3 K27M-mutant glioma are in desperate need of better therapeutic alternatives," said Dr. Patrick Wen, Director, Center for Neuro-Oncology at the Dana-Farber Cancer Institute and professor of Neurology at Harvard Medical School. "The tumor responses and safety profile we have observed with ONC201 in this devastating disease are compelling and I look forward to the possibility of accelerating its delivery to patients."

"Glioma remains one of the highest areas of unmet need in oncology where even first-line radiation therapy, as well as temozolomide in eligible patients, is not meaningfully effective and subsequent therapies are considered palliative. Further, there are no molecularly-targeted therapies for patients which harbor the H3 K27M mutation in this life-limiting disease. Given the urgent need and based on discussions with the FDA, there is a potential accelerated path to approval based on overall response. With a registration cohort of patients fully enrolled, treated, and preliminary data in hand, ONC201 offers an exciting near-term opportunity to quickly bring a potentially life-saving therapy and hope to patients with limited or no options," said Mike Sherman, Chief Executive Officer of Chimerix. "Our team is uniquely positioned to advance ONC201 given our considerable experience bringing targeted oncology products through the regulatory process."

"Oncoceutics represents a transformative acquisition for Chimerix, positioning the company with five assets across all stages of development and delivering on our goal to focus on oncology opportunities, complementing our Phase 3 study in acute myeloid leukemia with DSTAT.

With the upcoming Prescription Drug User Fee Act (PDUFA) date of April 7, 2021 for brincidofovir in smallpox and the confirmatory response rate assessment of ONC201 in 2021, we expect these near-term milestones to accelerate delivery of two new therapies in areas of particularly high unmet need," concluded Mr. Sherman.

"We are thrilled to join the Chimerix team to help accelerate ONC201 to glioma patients in urgent need of effective treatments. Chimerix has the leadership and resources to bring this program successfully through to approval and to further develop other promising assets in the Oncoceutics pipeline," said Lee Schalop, M.D., Chief Executive Officer of Oncoceutics. "This acquisition builds upon the vision of my co-founder Wolfgang Oster, M.D., Ph.D., scientific founder Wafik El-Deiry, M.D., Ph.D., FACP and all the employees at Oncoceutics in developing a therapy for patients for which there is no available treatment."

Clinical Development Plan for ONC201 in H3 K27M-mutant Glioma

The current Phase 2 clinical program for ONC201 includes a 50 subject registration cohort comprised of patients greater than 2 years of age with recurrent diffuse midline glioma that harbor the H3 K27M mutation, that have measurable disease, received radiation at least 90 days prior to enrollment and displayed evidence of progressive disease, and certain other criteria. This registration cohort is comprised of patients from multiple clinical trials and has completed enrollment. A BICR analysis is expected to take place in 2021 which, if favorable, may form the basis for regulatory approval of ONC201 in the United States. A BICR of the first 30 patients was completed and presented at the Society of Neuro-Oncology meeting held in November 2020. ONC201 has demonstrated a favorable safety profile with a database of over 350 treated patients. ONC201 has been generally well tolerated during extended periods of administration and the most commonly reported adverse events (AEs) were nausea/vomiting, fatigue and decreased lymphocyte counts.

The FDA has granted ONC201 Fast Track Designation for the treatment of adult recurrent H3 K27M-mutant high-grade glioma, Rare Pediatric Disease Designation for treatment of H3 K27M-mutant glioma, and Orphan Drug Designations for the treatment of glioblastoma and for the treatment of malignant glioma.

Over 300 subjects with recurrent high-grade gliomas, including gliomas with H3 K27M mutations, have been treated with ONC201 across three company-sponsored studies and an expanded access program.

Transaction Terms

Under the terms of the acquisition, Chimerix will pay Oncoceutics shareholders $78 million, of which $39 million is payable in Chimerix stock and $39 million is payable in cash, subject to certain customary adjustments. The payment of $39 million in cash is split $25 million at closing and $14 million on the first anniversary of closing. Oncoceutics shareholders will also potentially earn development, regulatory and sales milestones totaling up to $360 million across three development programs and royalties on combined sales of ONC201 and ONC206 of 15% up to $750 million in annual revenue and 20% above $750 million in annual revenue.

The Boards of Directors of both companies have approved the transaction and the transaction closed simultaneously with execution of definitive agreements on January 7, 2021.

Cooley LLP served as legal advisor to Chimerix. Evercore and Morgan Lewis served as exclusive financial advisor and legal advisor, respectively, to Oncoceutics. Spring Mountain Capital is the lead Oncoceutics investor.

Conference Call and Webcast

Chimerix will host a conference call and live audio webcast today at 8:30 a.m. ET. Slides that support the conference call are available in the Investors section of the Chimerix website, www.chimerix.com. To access the live conference call, please dial 877-354-4056 (domestic) or 678-809-1043 (international) at least five minutes prior to the start time and refer to conference ID 1877809.

A live audio webcast of the call will also be available on the Investors section of Chimerix's website, www.chimerix.com. An archived webcast will be available on the Chimerix website approximately two hours after the event.

About Oncoceutics

Oncoceutics, Inc. is a clinical-stage drug discovery and development company with a novel class of compounds called imipridones that selectively induce cell death in cancer cells. ONC201 is an orally active small molecule DRD2 antagonist and ClpP agonist in late-stage clinical development for H3 K27M-mutant glioma with additional indications under clinical investigation. ONC206 is the second clinical-stage imipridone that is under clinical investigation for central nervous system tumors. The company has received grant support from NCI, FDA, The Musella Foundation, Michael Mosier Defeat DIPG Foundation, Dragon Master Foundation, The ChadTough Foundation, the National Brain Tumor Society, and a series of private and public partnerships.

About Chimerix

Chimerix is a development-stage biopharmaceutical company dedicated to accelerating the advancement of innovative medicines that make a meaningful impact in the lives of patients living with cancer and other serious diseases. Its two clinical-stage development programs are dociparstat sodium (DSTAT) and brincidofovir (BCV).

DSTAT is a potential first-in-class glycosaminoglycan compound derived from porcine heparin that, compared to commercially available forms of heparin, may be dosed at higher levels without associated bleeding-related complications. DSTAT is being studied in a Phase 2/3 trial to assess safety and efficacy in adults with acute lung injury with underlying COVID-19. A Phase 3 trial protocol to study DSTAT in acute myeloid leukemia has been developed in alignment with the US Food and Drug Administration (FDA) and the first patient visit is expected in early 2021. BCV is an antiviral drug candidate developed as a potential medical countermeasure for smallpox and is currently under review for regulatory approval in the United States. For further information, please visit the Chimerix website, www.chimerix.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include those relating to, among other things, the timing of the confirmatory response rate assessment for ONC201; the sufficiency of the data from the current Phase 2 clinical trial of ONC201 to support accelerated regulatory approval; the anticipated benefits of Chimerix's acquisition of Oncoceutics; the completion of a Phase 3 study in acute myeloid leukemia with DSTAT and Chimerix's ability to obtain regulatory approval for its clinical candidates, including ONC201 and BCV. Among the factors and risks that could cause actual results to differ materially from those indicated in the forward-looking statements are risks that the current Phase 2 clinical trial data for ONC201 will not support accelerated, or any, regulatory approval; the anticipated benefits of the acquisition of Oncoceutics may not be realized; BCV may not obtain regulatory approval from the FDA or such approval may be delayed or conditioned; risks that Chimerix will not obtain a procurement contract for BCV in smallpox in a timely manner or at all; Chimerix's reliance on a sole source third-party manufacturer for drug supply; risks that ongoing or future trials may not be successful or replicate previous trial results, or may not be predictive of real-world results or of results in subsequent trials; risks and uncertainties relating to competitive products and technological changes that may limit demand for our drugs; risks that our drugs may be precluded from commercialization by the proprietary rights of third parties; and additional risks set forth in the Company's filings with the Securities and Exchange Commission. These forward-looking statements represent the Company's judgment as of the date of this release. The Company disclaims, however, any intent or obligation to update these forward-looking statements.

CONTACT:
Investor Relations:
Michelle LaSpaluto
919 972-7115
ir@chimerix.com

Will O'Connor
Stern Investor Relations
212-362-1200

will@sternir.com

Media:
David Schull
Russo Partners
858-717-2310
David.Schull@russopartnersllc.com

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