Chimerix Receives U.S. Food and Drug Administration Approval for TEMBEXA® (brincidofovir) for the Treatment of Smallpox

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– First smallpox antiviral approved for all age groups, including infants, and patients who have difficulty swallowing –

DURHAM, N.C., June 04, 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 U.S. Food and Drug Administration (FDA) has granted TEMBEXA® (brincidofovir) tablets and oral suspension approval for the treatment of smallpox. TEMBEXA is approved for adult and pediatric patients, including neonates.

"We are delighted to report our first FDA approved products for the treatment of smallpox, particularly as the importance of pandemic preparedness has been put into focus over the last year. With this approval in hand, we now look forward to advancing our discussions with the Biomedical Advanced Research and Development Authority (BARDA) toward a procurement contract to support national preparedness," said Mike Sherman, Chief Executive Officer of Chimerix.

Chimerix developed the TEMBEXA oral formulations as medical countermeasures for the treatment of smallpox under an ongoing collaboration with BARDA, part of the office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services, under contract number HHSO100201100013C.

TEMBEXA's approval is based on efficacy data in two lethal orthopoxvirus animal models of human smallpox disease, the rabbitpox model (New Zealand White rabbits infected with rabbitpox virus) and the mousepox model (BALB/c mice infected with ectromelia virus). In the pivotal studies in each model, TEMBEXA treatment resulted in statistically significant survival benefit versus placebo following delayed treatment after animals were infected with a lethal viral dose. The FDA's 'Animal Rule' allows for testing of investigational drugs in animal models to support effectiveness in diseases which are not ethical or feasible to study in humans. The TEMBEXA U.S. Prescribing Information has a BOXED WARNING for increased risk for mortality when used for longer duration; see below for Important Safety Information.

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. Most recently, the Company obtained FDA approval for brincidofovir as a medical countermeasure for the treatment of smallpox. The Company has two other advanced clinical-stage development programs, ONC201 and dociparstat sodium (DSTAT). ONC201 is currently in a registrational clinical program for recurrent H3 K27M-mutant glioma and a blinded independent central review is expected later in 2021. DSTAT is in development as a potential first-line therapy in acute myeloid leukemia.

About Smallpox

Smallpox is a highly contagious disease caused by the variola virus. Historically, smallpox was one of the deadliest diseases in history with a case fatality rate of approximately 30%. Despite successful eradication of smallpox in the 1970s, there is considerable concern that variola virus could reappear, either through accidental release or as a weapon of bioterrorism. According to the U.S. Centers for Disease Control and Prevention (CDC), variola virus is ranked in the highest risk category for bioterrorism agents (Category A) due to its ease of transmission, high mortality rate, and potential to cause public panic and social disruption.

About TEMBEXA

TEMBEXA is an oral antiviral formulated as 100 mg tablets and 10 mg/mL oral suspension dosed once weekly for two weeks. TEMBEXA is indicated for the treatment of human smallpox disease caused by variola virus in adult and pediatric patients, including neonates. TEMBEXA is not indicated for the treatment of diseases other than human smallpox disease. The effectiveness of TEMBEXA for the treatment of smallpox disease has not been determined in humans because adequate and well-controlled field trials have not been feasible and inducing smallpox disease in humans to study the drug's efficacy is not ethical. TEMBEXA efficacy may be reduced in immunocompromised patients based on studies in immune deficient animals.

TEMBEXA (brincidofovir) is a nucleotide analog lipid-conjugate designed to mimic a natural monoacyl phospholipid to achieve effective intracellular concentrations of the active antiviral metabolite, cidofovir diphosphate. Cidofovir diphosphate exerts its orthopoxvirus antiviral effects by acting as an alternate substrate inhibitor for viral DNA synthesis mediated by viral DNA polymerase.

IMPORTANT SAFETY INFORMATION Including BOXED WARNING

WARNING: INCREASED RISK FOR MORTALITY WHEN USED FOR LONGER DURATION

An increased incidence of mortality was seen in TEMBEXA-treated subjects compared to placebo-treated subjects in a 24-week clinical trial when TEMBEXA was evaluated in another disease.

WARNINGS AND PRECAUTIONS

Elevations in Hepatic Transaminases and Bilirubin: May cause increases in serum transaminases (ALT or AST) and serum bilirubin. Monitor liver

laboratory parameters before and during treatment.

Diarrhea and Other Gastrointestinal Adverse Events: Diarrhea and additional gastrointestinal adverse events including nausea, vomiting, and abdominal pain may occur. Monitor patients, provide supportive care, and if necessary, do not give the second and final dose of TEMBEXA.

Coadministration with Related Products: TEMBEXA should not be co-administered with intravenous cidofovir.

Carcinogenicity: TEMBEXA is considered a potential human carcinogen. Do not crush or divide TEMBEXA tablets and avoid direct contact with broken or crushed tablets or oral suspension.

Male Infertility: Based on testicular toxicity in animal studies, TEMBEXA may irreversibly impair fertility in individuals of reproductive potential.

ADVERSE REACTIONS

Common adverse reactions (adverse events assessed as causally related by the investigator in ≥ 2% of subjects) experienced in the first 2 weeks of dosing with TEMBEXA were diarrhea, nausea, vomiting and abdominal pain.

USE IN SPECIFIC POPULATIONS

Pregnancy

Based on findings from animal reproduction studies, TEMBEXA may cause fetal harm when administered to pregnant individuals. Pregnancy testing should be performed before initiation of TEMBEXA in individuals of childbearing potential to inform risk. An alternative therapy should be used to treat smallpox during pregnancy, if feasible.

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 advancement of discussions with BARDA toward a procurement agreement for the sale of TEMBEXA to the SNS and the timing of the confirmatory response rate assessment for ONC201. Among the factors and risks that could cause actual results to differ materially from those indicated in the forward-looking statements are risks that Chimerix will not obtain a procurement contract for TEMBEXA 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.

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