# Chimerix Reports Fourth Quarter and Year End 2020 Financial Results and Provides Operational Update

February 25, 2021

*– Acquisition of Oncoceutics Adds Late-Stage Precision Oncology Pipeline –*

*– Recently Completed Financing Supports Broad Investment Across Pipeline –*

*– Conference Call at 8:30 a.m. ET Today –*

DURHAM, N.C., Feb. 25, 2021 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company focused on accelerating the development of medicines to treat cancer and other serious diseases, today reported financial results for the fourth quarter and full-year ended December 31, 2020 and provided an operational update.

“Our execution during the last several months has positioned Chimerix to capitalize on several significant milestones in 2021 and our recent financing strengthens our balance sheet which allows us to support our pipeline through key data readouts,” said Mike Sherman, Chief Executive Officer of Chimerix. “Following our recent acquisition of Oncoceutics, we have integrated the complementary capabilities of the organizations to accelerate development of the imipridone pipeline. As a single agent, ONC201 has demonstrated compelling, durable responses in clinical trials for recurrent H3 K27M-mutant glioma, one of the most difficult to treat and life-limiting cancers that affects both children and adults. We look forward to the confirmatory response rate assessment later this year which, if positive, sets the stage for a pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA).

“We received notification from the FDA that the Prescription Drug User Fee Act (PDUFA) goal date for review of brincidofovir (BCV) as a medical countermeasure for smallpox has been extended three months to July 7, 2021. The FDA previously requested we provide data supporting a dose recommendation for infants up to three months of age. In response, we submitted to the FDA the requested modelled analyses, which resulted in the same weight-based dosing recommendation previously proposed for older pediatric patients. The ability to dose across all pediatric age groups with a convenient oral suspension formulation is a unique aspect of the BCV smallpox treatment. The FDA required an additional three months to review this information. We do not expect a later FDA action date will impact the timing of the BARDA request for proposal, which is expected this quarter, nor the potential timing of first shipments of BCV to the strategic national stockpile, expected in the second half of this year.

“Chimerix enters 2021 in a strong position as we approach the updated PDUFA date for BCV, advance ONC201 toward a key data readout, continue enrollment of our Phase 3 trial of dociparstat sodium (DSTAT) for the treatment of acute myeloid leukemia (AML) and look forward to additional data from DSTAT in COVID-19 patients with Acute Lung Injury trial,” continued Mr. Sherman.

**Recent Highlights**

**Acquisition of Oncoceutics**

In January, Chimerix announced the acquisition of 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. Final analysis of results from the registration cohort of 50 patients in clinical trials for recurrent H3 K27M-mutant glioma and a confirmatory response rate assessment is expected in 2021. In addition, Phase 1 clinical trials for ONC206, the second product candidate in Oncoceutics’ pipeline, were recently initiated and IND-enabling work for ONC212 is ongoing.

**Strengthened Balance Sheet**

In January, Chimerix closed an underwritten public offering of 13.5 million shares of common stock. The gross proceeds to Chimerix from the offering, before deducting underwriting discounts and commissions and other offering expenses, was $115.0 million.

**BCV for Smallpox**

In December 2020, Chimerix announced that the FDA accepted the filing of an NDA for BCV as a medical countermeasure for smallpox. The FDA granted Priority Review and in February 2021, revised the PDUFA date to July 7, 2021.

**DSTAT for AML**

Chimerix recently opened clinical trial sites and is ready to begin screening patients for its 570-subject Phase 3 **D**ociparstat in **A**ML with **S**tandard C**h**emotherapy (DASH AML) study of DSTAT for the treatment of AML. The multicenter, randomized, double-blind, placebo-controlled, parallel-group study will evaluate the efficacy and safety of DSTAT in combination with standard intensive induction and consolidation chemotherapy for the treatment of newly-diagnosed AML patients. Chimerix expects to unblind data following enrollment of the first 80 evaluable patients in this study to assess complete response rates and minimal residual disease rates between the study arm and the control arm. This analysis is expected to take place in 2022.

**DSTAT for Acute Lung Injury Patients with COVID-19**

In a separate release issued today, Chimerix announced results from the first cohort of patients in the randomized, blinded trial of DSTAT in patients with acute lung injury hospitalized with COVID-19. Of the 12 patients enrolled in the first cohort, six received a 4mg/kg bolus dose of DSTAT followed by a continuous infusion of 0.25mg/kg/hour and six received placebo. Although in a small number of patients, subject to demographic imbalances, early indications suggest a possible clinical benefit for patients on DSTAT compared to patients on placebo. Chimerix has also completed enrollment of the second cohort of patients randomized 2:1 to receive a 4mg/kg bolus dose of DSTAT followed by a continuous infusion of 0.325mg/kg/hour versus placebo. Based on the safety assessment of the independent safety monitoring committee after these patients have completed treatment, Chimerix will consider advancing to the third cohort of 50 patients at the selected dose. Results from the second cohort are expected to be announced in the second quarter.

**Expected 2021 Milestones**

- FDA PDUFA action date set for July 7, 2021 for BCV smallpox NDA.
- Potential procurement agreement for BCV around the time of FDA decision on smallpox NDA, if favorable.
- Completion of Phase 2 trial of DSTAT in COVID-19 related ALI.
- Completion of BCV drug product manufacturing to support potential shipments to the SNS of up to $100 million.
- Confirmatory response rate assessment of 50-subject registration cohort of ONC201 in recurrent H3 K27M-mutant glioma by blinded independent central review (BICR).

**Fourth Quarter 2020 Financial Results**

Chimerix's balance sheet at December 31, 2020 included $79.0 million of capital available to fund operations, no debt, and approximately 62.8 million outstanding shares of common stock. Capital available to fund operations as of January 31, 2021, taking into consideration the cash associated with the acquisition of Oncoceutics including closing statement adjustments, the subsequent follow-on financing and operating expenses for January, was approximately $159.8 million. Current shares outstanding as of February 25, 2021, which includes upfront consideration associated with the acquisition of Oncoceutics and the subsequent follow-on financing, is approximately 85.7 million shares.

Chimerix reported a net loss of $11.7 million, or $0.19 per basic and diluted share, for the fourth quarter of 2020. During the same period in 2019, Chimerix recorded a net loss of $3.5 million, or $0.06 per basic and diluted share.

Revenues for the fourth quarter of 2020 decreased to $1.1 million, compared to $6.8 million for the same period in 2019 due to the out-license of BCV to SymBio for indications other than orthopox in 2019.

Research and development expenses increased to $8.7 million for the three-month period ended December 31, 2020, compared to $7.5 million for the same period in 2019.

General and administrative expenses increased to $4.2 million for the fourth quarter of 2020, compared to $3.1 million for the same period in 2019.

Loss from operations was $11.8 million for the fourth quarter of 2020, compared to a loss from operations of $3.9 million for the same period in 2019.

**Full Year 2020 Financial Results**

Chimerix reported a net loss of $43.5 million, or $0.70 per basic and diluted share, for the year ended December 31, 2020. For the year ended December 31, 2019, Chimerix recorded a net loss of $112.6 million, or $2.03 per basic and diluted share.

Revenues for 2020 decreased to $5.4 million, compared to $12.5 million in 2019.

Research and development expenses decreased to $36.2 million for the year ended December 31, 2020, compared to $42.3 million for the year ended December 31, 2019.

General and administrative expenses decreased to $13.7 million for the year ended December 31, 2020, compared to $21.2 million for the year ended December 31, 2019. The decrease is related to restructuring charges which occurred in 2019.

Chimerix recorded acquired in-process research and development expenses of $65.0 million for the year ended December 31, 2019 related to the in-license of DSTAT from Cantex Pharmaceuticals in 2019.

Loss from operations was $44.5 million for the year ended December 31, 2020, compared to a loss from operations of $116.0 million for the year ended December 31, 2019.

**Conference Call and Webcast**

Chimerix will host a conference call and live audio webcast to discuss fourth quarter and full-year 2020 financial results and provide a business update today at 8:30 a.m. ET. 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 1478364.

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 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. Our three most advanced clinical-stage development programs are BCV, ONC201 and DSTAT. 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. ONC201 is currently in a registrational clinical program for recurrent H3 K27M-mutant glioma and a confirmatory response rate assessment is expected later this year. DSTAT is in development as a potential first-line therapy in acute myeloid leukemia and as a potential treatment for acute lung injury in hospitalized COVID-19 patients.

**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; Chimerix's ability to obtain regulatory approval for its clinical candidates, including DSTAT, ONC201 and BCV; and Chimerix's ability to enter into a procurement agreement for the sale of BCV to the SNS. 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.

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**CHIMERIX, INC.**
**CONSOLIDATED BALANCE SHEETS**
**(in thousands, except share and per share data)**

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 46,989 | $ 16,901 |
| Short-term investments, available-for-sale | 31,973 | 96,574 |
| Accounts receivable | 340 | 1,233 |
| Prepaid expenses and other current assets | 2,356 | 3,385 |
| Total current assets | 81,658 | 118,093 |
| Property and equipment, net of accumulated depreciation | 214 | 540 |
| Operating lease right-of-use assets | 2,825 | 709 |
| Other long-term assets | 26 | 34 |
| Total assets | $ 84,723 | $ 119,376 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,283 | $ 2,398 |
| Accrued liabilities | 7,250 | 6,830 |
| Total current liabilities | 8,533 | 9,228 |
| Lease-related obligations | 2,814 | 196 |
| Total liabilities | 11,347 | 9,424 |
| Stockholders' equity: | | |
| Preferred stock, $0.001 par value, 10,000,000 shares authorized at December 31, 2020 and 2019; no shares issued and outstanding as of December 31, 2020 and 2019 | - | - |
| Common stock, $0.001 par value, 200,000,000 shares authorized at December 31, 2020 and 2019; 62,816,039 and 61,590,013 shares issued and outstanding as of December 31, 2020 and 2019, respectively | 63 | 62 |
| Additional paid-in capital | 785,673 | 778,693 |
| Accumulated other comprehensive gain, net | - | 35 |
| Accumulated deficit | (712,360) | (668,838) |

| | | |
|---|---|---|
| Total stockholders' equity | 73,376 | 109,952 |
| Total liabilities and stockholders' equity | $ 84,723 | $ 119,376 |

**CHIMERIX, INC.**
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**
**(in thousands, except share and per share data)**

| | Three Months Ended December 31, | | Years Ended December 31, | |
|---|---|---|---|---|
| | **2020** | **2019** | **2020** | **2019** |
| **Revenues:** | | | | |
| Contract revenue | $ 1,116 | $ 1,852 | $ 5,274 | $ 7,604 |
| Licensing revenue | 4 | 4,915 | 98 | 4,915 |
| Total revenues | 1,120 | 6,767 | 5,372 | 12,519 |
| **Operating expenses:** | | | | |
| Research and development | 8,687 | 7,493 | 36,232 | 42,288 |
| General and administrative | 4,190 | 3,147 | 13,656 | 21,169 |
| Acquired in-process research and development | - | - | - | 65,045 |
| Total operating expenses | 12,877 | 10,640 | 49,888 | 128,502 |
| Loss from operations | (11,757) | (3,873) | (44,516) | (115,983) |
| **Other income:** | | | | |
| Interest income and other, net | 82 | 370 | 994 | 3,407 |
| **Net loss** | (11,675) | (3,503) | (43,522) | (112,576) |
| **Other comprehensive loss:** | | | | |
| Unrealized (loss) gain on investments, net | (33) | (55) | (35) | 127 |
| Comprehensive loss | $ (11,708) | $ (3,558) | $ (43,557) | $ (112,449) |
| **Per share information:** | | | | |
| Net loss, basic and diluted | $ (0.19) | $ (0.06) | $ (0.70) | $ (2.03) |
| Weighted-average shares outstanding, basic and diluted | 62,702,181 | 61,385,616 | 62,183,947 | 55,501,973 |