

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, DC 20549

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**FORM 8-K**

**CURRENT REPORT**  
Pursuant to Section 13 or 15(d) of  
The Securities Exchange Act of 1934

**Date of Report (Date of earliest event reported): January 8, 2021**

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**Chimerix, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation)

**001-35867**  
(Commission File Number)

**33-0903395**  
(IRS Employer  
Identification No.)

**2505 Meridian Parkway, Suite 100**  
**Durham, NC 27713**  
(Address of principal executive offices, including zip code)

**(919) 806-1074**  
(Registrant's telephone number, including area code)

**N/A**  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	CMRX	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 7.01 Regulation FD Disclosure.**

On January 8, 2021, Chimerix, Inc. (the “Company”) will post a corporate presentation on its website concerning its acquisition of Oncocentics, Inc. (the “Acquisition”). A copy of the presentation is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

On January 8, 2021, the Company issued a press release announcing the Acquisition. A copy of the press release is filed as Exhibit 99.2 to this Current Report on Form 8-K, the contents of which are incorporated herein by reference.

The information contained in this Item 7.01 and in Exhibits 99.1 and 99.2 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and is not incorporated by reference into any of the Company’s filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

**Item 9.01 Exhibits.**

**(d) Exhibits**

<b>Exhibit Number</b>	<b>Exhibit Description</b>
<a href="#">99.1</a>	<a href="#">Corporate Presentation</a>
<a href="#">99.2</a>	<a href="#">Press Release dated January 8, 2021</a>
104	Cover page interactive data file (embedded within the iXBRL document)

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: January 8, 2021

**Chimerix, Inc.**

By: /s/ Michael T. Andriole  
Name: Michael T. Andriole  
Title: Chief Business and Financial Officer

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# Acquisition of Oncoceutics Adds Precision Oncology Pipeline with Near-term Registration Potential



# Forward-Looking Statements

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These slides contain 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, Chimerix's ability to develop its drug candidates including ONC201, DSTAT and BCV; the sufficiency of the data from the current clinical trial of ONC201 to support accelerated regulatory approval; Chimerix's ability to submit and/or obtain regulatory approvals for its clinical candidates; the timing and receipt of a potential procurement contract for BCV in smallpox; and the anticipated benefits of Chimerix's acquisition of Oncoceutics. 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's clinical candidates, including BCV, may not obtain regulatory approval from the FDA or such approval may be delayed or conditioned; risks that development activities related to clinical candidates may not be completed on time or at all; 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; risks that Chimerix will not obtain a procurement contract for BCV in smallpox in a timely manner or at all; risks that the anticipated benefits of the acquisition of Oncoceutics may not be realized 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.

# Acquisition adds portfolio of precision oncology therapies

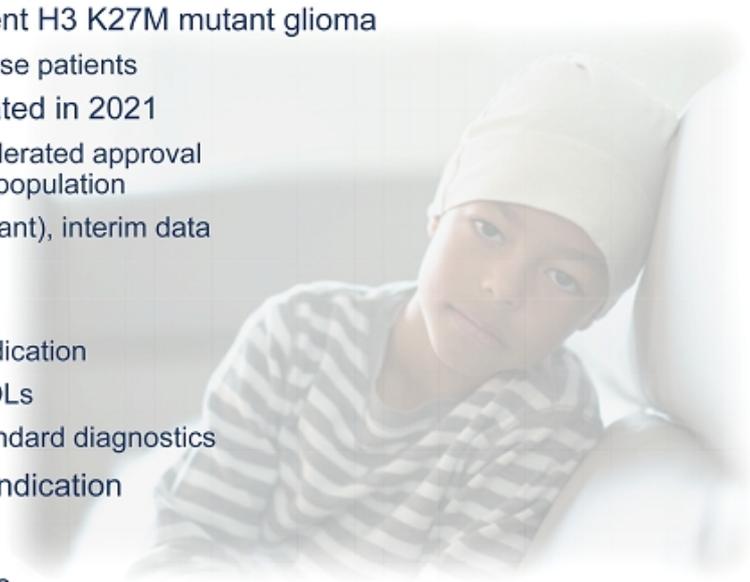


1 Recurrent diffuse midline glioma H3 K27M mutant  
2 Pheochromocytoma/paraganglioma

Denotes US FDA Fast Track Designation

## ONC201 provides attractive near-term opportunity

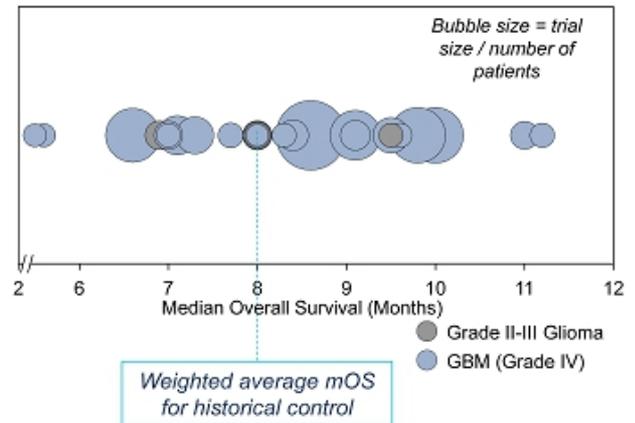
- Unprecedented single agent activity in recurrent H3 K27M mutant glioma
  - Currently no effective therapeutic options for these patients
- Clear path to registration, pivotal data anticipated in 2021
  - FDA discussions highlight path to potential accelerated approval using Overall Response Rate (ORR) in defined population
  - Registration cohort enrolled (diffuse midline mutant), interim data available
- Attractive commercial market potential
  - >\$500M global peak sales opportunity in first indication
  - Extraordinary awareness of ONC201 among KOLs
  - Mutation already routinely identified through standard diagnostics
- Compelling single agent response in second indication
- Strong IP portfolio into mid to late 2030s
- Path ahead leverages organizational strengths



# Recurrent H3 K27M+ recurrent glioma, a devastating disease where single agent responses are rare and lack durability

- Most frequent histone mutation in glioma
  - Frequent (>50%) in younger patients with midline brain tumors
  - Classified as grade IV by WHO, regardless of diffuse glioma histology
  - Mutation routinely identified via immunohistochemistry (IHC) or next generation sequencing (NGS), e.g. Foundation One
- No effective therapy
  - Often not possible to resect
  - Recurrence inevitable after first-line radiation
  - Invariably lethal; ~8 months median overall survival
  - Chemotherapy ineffective; objective responses by RANO-HGG<sup>1</sup> rarely observed

Median overall survival weighted average:  
~8 months in recurrent glioma<sup>2</sup> post TMZ



<sup>1</sup> Response Assessment in Neuro-Oncology-High Grade Glioma

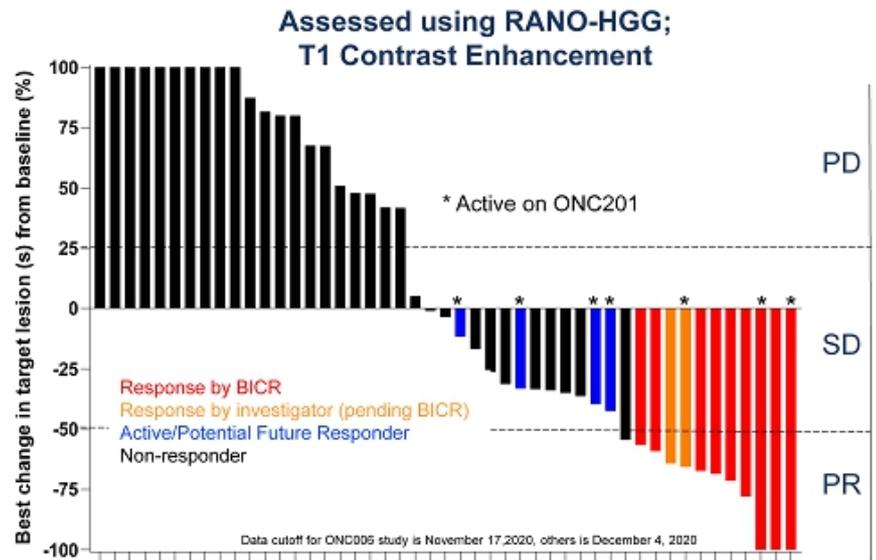
<sup>2</sup> Data collected from 17 literature sources since 2010 with trial arms size >30 pts each reporting data on 1937 pts with recurrent, unstratified disease. 13 trials were in post-TMZ patients and four trials with 282 pts did not explicitly declare prior TMZ, rather 'radiotherapy + chemo'

# H3 K27M-mutant glioma: market dynamics and opportunity

- Addressable market
  - U.S. incidence (annual): ~2,000
- Market research
  - Nearly all mid-line glioma patients tested for H3 K27M-mutation; rate to increase with targeted therapy
  - Oncologists consider a therapy for recurrent H3 K27M-mutant gliomas to be clinically meaningful if it demonstrates ~20% ORR and/or clinically relevant durability
  - ONC201 use expected in >80% of H3 K27M-mutant glioma patients based on current profile
  - There is interest in using ONC201 in combination with radiation if possible, in the front-line setting
- Competitive landscape: chemotherapy and bevacizumab ineffective; targeted agents, vaccines and CAR-T therapies are in early development with limited efficacy analysis available
- Low barriers to adoption
  - No effective treatment options available
  - K27M already on commercial and site-specific NGS panels, oral dosing (QW), good safety profile
  - High unaided awareness of ONC201 among neuro-oncologists
  - Longer-term, potential combinable with other glioma therapies

# Compelling ONC201 responses in recurrent H3 K27M mutant disease drives strong KOL engagement

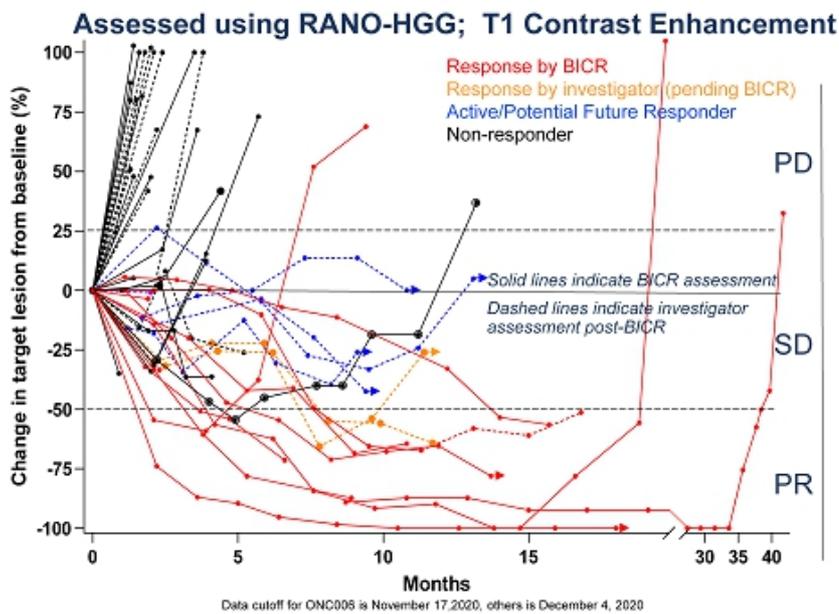
- 30% ORR by BICR in first 30 patients
- Maturing data from the next 20 patients so far demonstrated:
  - 2 additional responders by investigator assessment
  - 4 additional patients remain on therapy >6 months
- ORR from full cohort supported by
  - Clinically relevant durability
  - Clinically relevant disease control in non-responders
  - Other clinical benefits (e.g., reduction in steroid use, improved performance status)
  - Complete responses
  - Objective responses in CNS tumors exclusive to H3 K27M mutations



Waterfall plot reflects 47 subjects; 3 subjects do not have on-treatment tumor assessments available but were PD  
Some eligibility and response data is based on unlocked CRFs that are subject to change with additional monitoring

# Meaningful durability of response

Expected  $\geq 20\%$  ORR in registration cohort (n=50)



## Response Summary\*

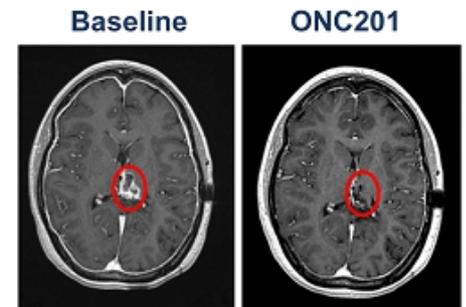
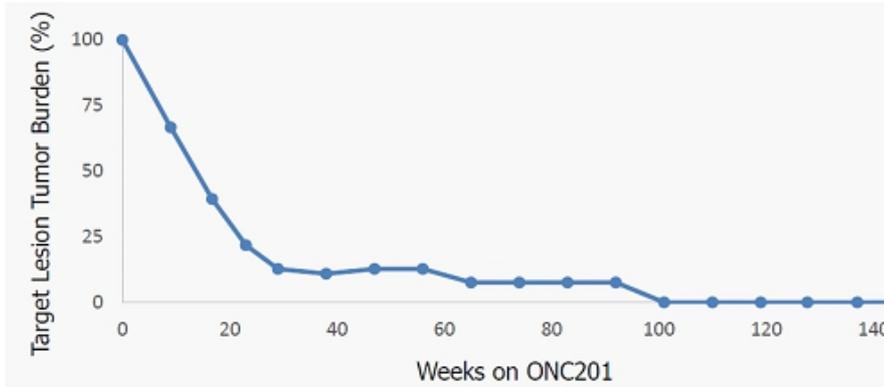
- Subject to change with maturing data
- Meaningful duration of response
  - mPFS among responders: > 15 months
- 9 responses by BICR
- 2 new responses by investigator assessment (to be assessed by BICR)
- 4 patients on therapy >6 months who could still achieve response

\* All responses planned to be reconfirmed by a three-party adjudicated blinded independent central review in 2021

Waterfall plot reflects 47 subjects; 3 subjects do not have on-treatment tumor assessments available but were PD. Some eligibility and response data is based on unlocked CRFs that are subject to change with additional monitoring

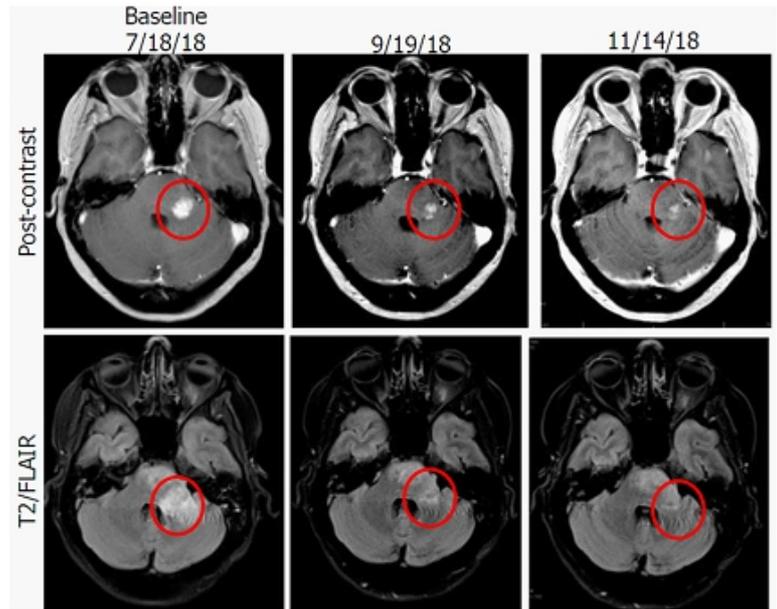
# ONC201 patient: near complete tumor regression

- 22-year-old with recurrent H3 K27M mutant glioma
- Started single agent ONC201 treatment after recurrence of tumor in March 2016
- Experienced deep and durable complete regression in the primary lesion



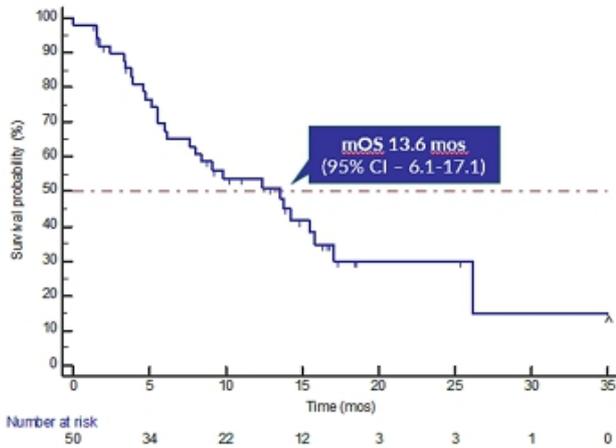
# ONC201 partial responses have driven clinical benefit in recurrent H3 K27M-mutant glioma

- 55-year-old received single agent ONC201 at recurrence following radiation therapy (RT) and temozolomide (TMZ)
- Objective partial response was associated with normalization of neurological deficits by NANO<sup>1</sup> within two cycles
  - Improved gait
  - Improved facial strength
  - Improved language
- Radiographic response and neurologic response >7 months



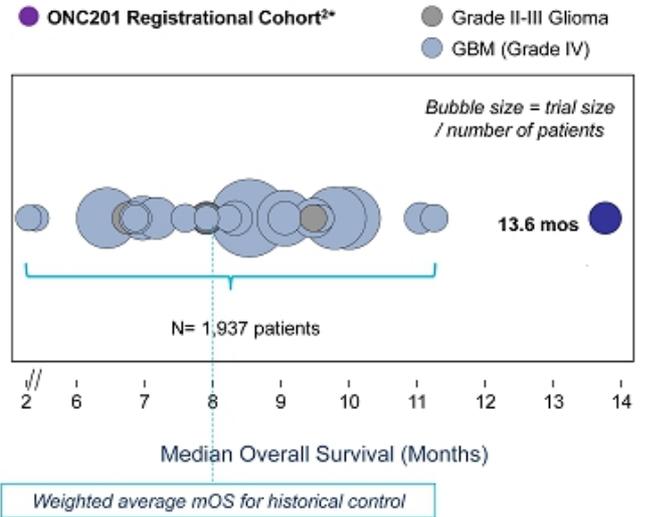
# Upon full maturation, ONC201 median overall survival data is expected to compare favorably to historical controls

## ONC201 OS by line of therapy in recurrent H3 K27M+ glioma patients



<sup>^</sup> last patient is censored at 53.3 months

## ONC201 OS compares favorably with historical benchmarks in recurrent patients<sup>1</sup>



1 Data collected from 17 literature sources since 2010 with trial arms size >30 pts each reporting data on 1,937 pts with recurrent, unstratified disease. 13 trials were in post-TMZ patients while four trials with 282 pts did not explicitly declare prior TMZ, rather "radiotherapy + chemo"

2 50 K27M+ recurrent patients treated with ONC201 (38% GBM)

# ONC201 demonstrates attractive safety profile, oral administration

- Integrated safety database for NDA will consist of >350 glioma patients
- No discontinuations due to drug-related adverse events (AEs)
- Single weekly dosing until progression
- Safety profile and oral dosing enable:
  - Fixed dosing in adults
  - High rate of compliance
  - Multiple therapeutic settings
  - Combination therapies

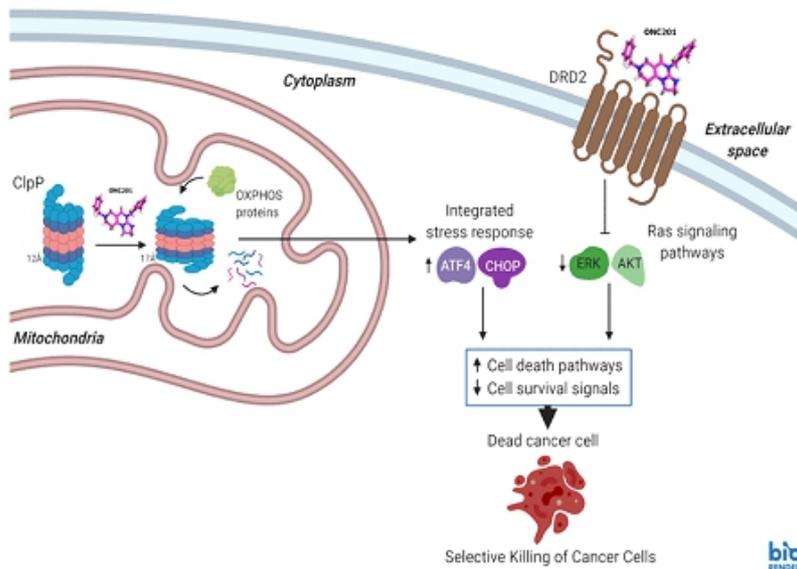
AEs in Recurrent H3 K27M-mutant Glioma Patients (N=30)

	All TEAE N (%)	Gr3-4 TEAE N (%)	ONC201-Related All TEAE N (%)
Subjects with at least one TEAE	30 (100%)	18 (60%)	6 (20%)
<b>Nervous system disorders</b>	24 (80%)	8 (26.7%)	-
Headache	7 (23.3%)	1 (3.3%)	-
Hemiparesis	7 (23.3%)	2 (6.7%)	-
Paraesthesia	7 (23.3%)	-	-
Dizziness	5 (16.7%)	-	-
<b>Gastrointestinal disorders</b>	19 (63.3%)	-	4 (13.3%)
Nausea	9 (30.0%)	-	3 (10.0%)
Vomiting	8 (26.7%)	-	2 (6.7%)
<b>General disorders and administration site conditions</b>	17 (56.7%)	6 (20.0%)	3 (10.0%)
Fatigue	14 (46.7%)	4 (13.3%)	3 (10.0%)
Gait disturbance	8 (26.7%)	3 (10.0%)	-
<b>Investigations</b>	17 (56.7%)	6 (20.0%)	3 (10.0%)
Lymphocyte count decreased	6 (20.0%)	2 (6.7%)	1 (3.3%)
Platelet count decreased	5 (16.7%)	-	1 (3.3%)
Weight increased	4 (13.3%)	1 (3.3%)	-
<b>Metabolism and nutritional disorders</b>	15 (50.0%)	4 (13.3%)	2 (6.7%)
Hyperglycaemia	5 (16.7%)	1 (3.3%)	1 (3.3%)
Hypoalbuminaemia	4 (13.3%)	-	1 (3.3%)
<b>Infections and infestations</b>	12 (40.0%)	2 (6.7%)	-
Urinary tract infection	4 (13.3%)	1 (3.3%)	-
Upper respiratory tract infection	3 (10.0%)	-	-

All AEs reported in >10% of pts with at least one event attributed by investigator as a least possibly-related to study drug

# ONC201 targets ClpP and DRD2

ONC201 upregulates integrated stress response, inactivates Akt/ERK, selectively inducing tumor cell death

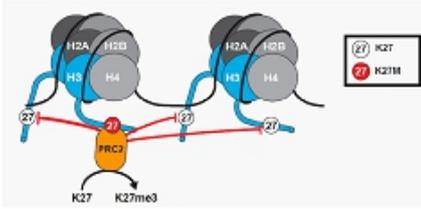


- ONC201 can selectively induce apoptosis in cancer cells by altering activity of two proteins
- ClpP agonism
  - ClpP normally degrades misfolded proteins in mitochondria
  - ONC201 modifies ClpP conformation, promoting excess degradation of specific mitochondrial proteins important for cancer cell viability
- DRD2 antagonism
  - DRD2 is a G protein-coupled neuroreceptor that regulates Ras signaling
  - ONC201 antagonizes DRD2, inhibiting Ras signaling pathways

ClpP=caseinolytic protease P; DRD2=Dopamine receptor D2; ATF4=activating transcription factor 4; CHOP=C/EBP-homologous protein; ERK=extracellular-regulated kinase; AKT=protein kinase B

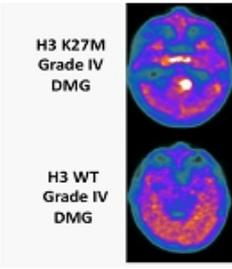
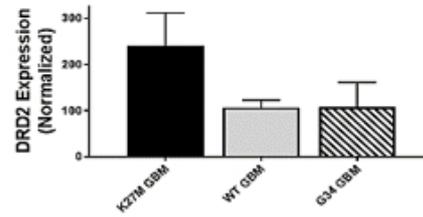
# H3 K27M-mutant gliomas exhibit enhanced sensitivity to ONC201

Lysine to methionine (“K-to-M”) histone H3 mutation reduces H3 K27 methylation



K27M mutants bind PRC2 which normally methylates H3 K27 via EZH1/2; binding/tethering PRC2 prevents methylation of even nonmutant H3 K27

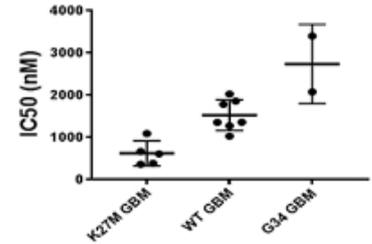
H3 K27M elevates DRD2 expression



Midline tumors occur in dopamine-rich regions of the brain

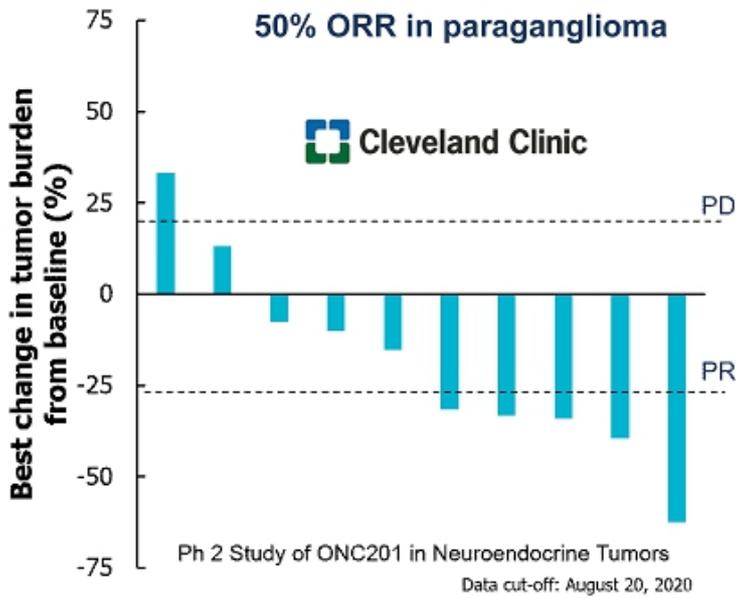
18F-DOPA PET

High sensitivity to ONC201



Lowe et al., *Cancers*, 2019; Chi et al., *Society of Neuro-Oncology*, 2017; Kawakibi et al., *Society of Neuro-Oncology*, 2019; Koschmann et al., *Pediatric Society of Neuro-Oncology* 2019; Prabhu et al., *Clinical Cancer Research*, 2018; Ishizawa et al., *Cancer Cell*, 2019; Prabhu et al., *Society of Neuro-Oncology*, 2019; Piccardo et al., *Eur J. Nucl Med Mol Imaging*, 2019

# ONC201 efficacy in dopamine-secreting tumors outside the brain



- Strongest single agent responses in Ph 2 neuroendocrine trial of ONC201 observed in subset (paraganglioma)
- Paraganglioma are adrenal-related tumors with elevated DRD2 expression
- Demonstrates that efficacy is not restricted to brain tumors
- Endorses use of biomarkers and microenvironment to identify additional highly responsive indications

# Key regulatory communications: potential path to approval

- Homogenously defined population in recurrent diffuse midline glioma, H3 K27M-mutant, as defined by cIMPACT NOW Update 2, may be acceptable for approval
- FDA acknowledged that “available therapy” is considered palliative (i.e. there is no available treatment for recurrent H3 K27M mutant diffuse midline glioma)
- FDA acknowledged integrated safety database of approximately 350 patients
- Approval may be granted based on Overall Response Rate (ORR) by RANO-HGG<sup>1</sup>
- Based on FDA discussions, the registration cohort will be comprised of 50 subjects pooled across multiple company-sponsored clinical studies and expanded access
- Initial EMA discussions have indicated durable ORR may be an acceptable endpoint for EU marketing authorization

# ONC201 FDA designations



Orphan Drug Designation (ODD) (treatment of glioblastoma and treatment of malignant glioma)



Fast Track Designation (FTD) for adult recurrent H3 K27M-mutant high-grade glioma



Rare Pediatric Disease Designation for treatment of H3 K27M mutant glioma

- Potential to receive rare pediatric voucher<sup>1</sup>

<sup>1</sup> Subject to continuation of Rare Pediatric Disease Voucher Program and proceeds from voucher will be split 50/50 with legacy Oncocentrics shareholders

# Promising pipeline in development

## ONC206:

- Differentiated DRD2 antagonist + ClpP agonist
- Phase 1 for recurrent CNS tumors



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## ONC212:

- GPR132 agonist + ClpP agonist
- IND-enabling studies



# Deal terms

- Acquisition of Oncoceutics, Inc. including ONC201, ONC206 and ONC212
- Financial Terms
  - Upfront Consideration = \$78M
    - \$39M in equity ~8.7M shares
    - \$39M in cash (\$14M deferred for one year)
  - Milestones (m/s)
    - Efficacy m/s: \$20M with ONC201 BICR<sup>1</sup> ORR<sup>1</sup> ≥ 20%
    - Regulatory approval (US and EU) m/s for ONC201 up to \$60M<sup>2</sup>
    - Regulatory approval (US and EU) m/s for ONC206 and ONC-212 up to \$30M
    - Sales m/s on combined net sales of ONC201/ONC206 totaling up to \$250M
  - Royalty:
    - 15% royalty on combined net sales of ONC201/ONC206 up to \$750M, 20% in excess of \$750M
- Simultaneous signing and closing

1 Blinded Independent Central Review; Overall Response Rate by RANO-HGG

2 US: \$30M first indication, \$10M second indication, \$5M third indication. EU: \$15M first indication. No milestone to be paid more than once

# Financial Summary

Dollars (millions)	Sept YTD 2020
R&D	\$ 27.5
G&A	9.5
Total operating expenses	37.0
Net income(loss)	(31.8)
Ending Cash balance	\$ 87.8
Shares outstanding	62.6

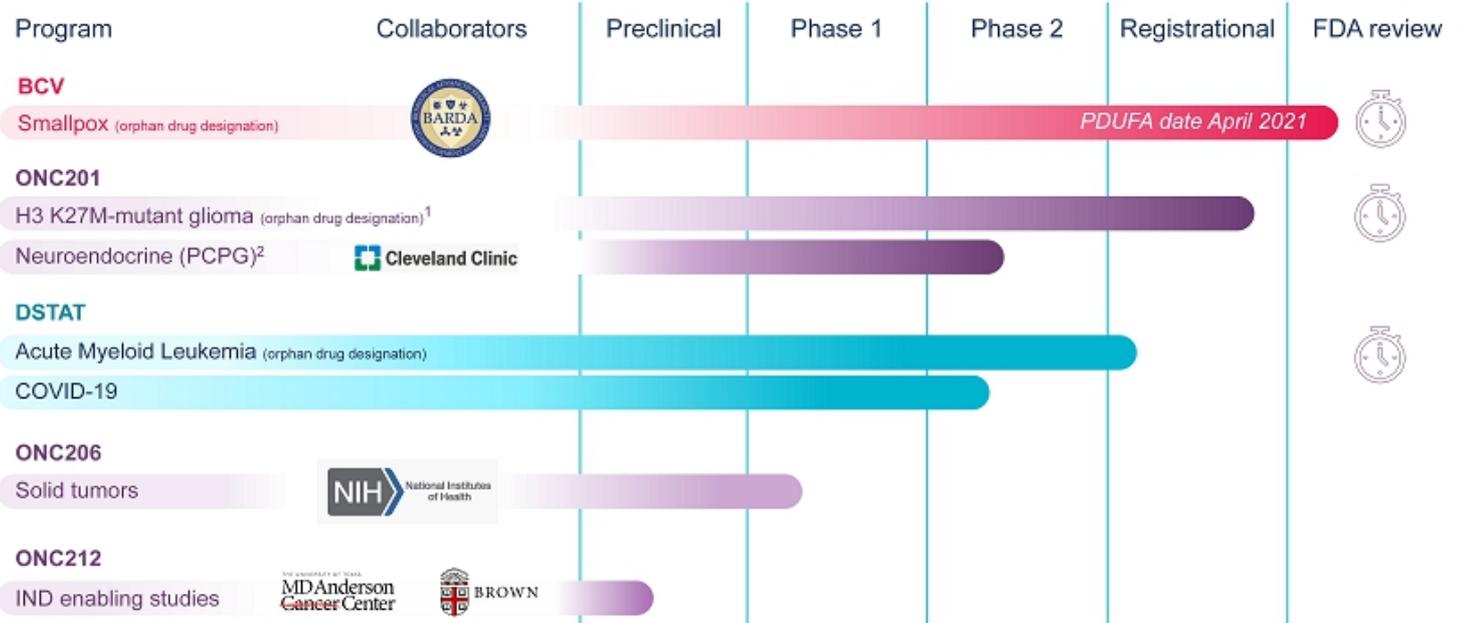
- Cash balance of approx. \$78M at 12/31/2020
- Several levers available for additional capital:
  - Expected significant non-dilutive proceeds from potential BCV stockpiling in 2021
  - Global rights to most programs
  - Several 2021 catalysts provides additional optionality
- ~71 million shares outstanding post transaction

# Corporate Summary

## Major, near-term paths to value

- Final steps toward BCV (smallpox) potential commercialization
  - NDA filed, April 7, 2021 PDUFA date
  - Satisfies second mandate for 2<sup>nd</sup> countermeasure for strategic national stockpile
  - Potential \$80-\$100m annual cash flow for next 5-12 years
- Synergistic acquisition of precision oncology platform
  - Potential near-term registration path
  - Blinded independent central review of ONC201 data in 2021 (recurrent H3 K27M mutant glioma)
  - Opportunities for new indications and pipeline expansion
- DSTAT development in two therapeutic areas with significant unmet need
  - Phase 3 front-line AML trial to initiate early this year
  - Enrolled first cohort in COVID-19 Phase 2 trial – preliminary data expected in 1Q2021

# Deep pipeline across all development stages



1 Recurrent diffuse midline glioma H3 K27M mutant positive  
2 Pheochromocytoma/paraganglioma

 Denotes US FDA Fast Track Designation

# Delivery of 2020 objectives sets stage for catalyst rich 2021

	2020	2021				
<b>BCV</b>	<ul style="list-style-type: none"> <li>✓ Complete PK dose bridging studies</li> <li>✓ Pre-NDA Meeting with FDA</li> <li>✓ BARDA and FDA clearance to begin rolling NDA submission</li> <li>✓ Completion of rolling NDA Submissions</li> </ul>	<ul style="list-style-type: none"> <li>▪ FDA decision on smallpox NDA in April</li> <li>▪ Potential for BARDA procurement contract</li> <li>▪ Potential for ~\$100m of BCV for Strategic National Stockpile</li> </ul>				
<b>ONC201 ONC206 ONC212</b>	<ul style="list-style-type: none"> <li>✓ Potential registration path defined through FDA type C meetings</li> <li>✓ ONC201 registration cohort enrollment completed</li> <li>✓ 30% PR/CR in 1<sup>st</sup> 30 patients (blinded read)</li> <li>✓ ONC206 Ph 1 initiation</li> </ul>	<ul style="list-style-type: none"> <li>▪ BICR of ONC201 registration cohort</li> <li>▪ ONC201 pre-NDA meeting preparations</li> <li>▪ Potential ONC206 clinical outcomes</li> <li>▪ IND preparations for ONC212</li> </ul>				
<b>DSTAT</b>	<table border="0"> <tr> <td> <b>AML:</b> <ul style="list-style-type: none"> <li>✓ End of Ph2 FDA meeting</li> <li>✓ Confirm endpoint/Ph3 design</li> </ul> </td> <td> <b>COVID-19 Acute Lung Injury:</b> <ul style="list-style-type: none"> <li>✓ IND; FDA alignment of Ph2/3 design, endpoint</li> <li>✓ Ph2/3 study initiation</li> </ul> </td> </tr> </table>	<b>AML:</b> <ul style="list-style-type: none"> <li>✓ End of Ph2 FDA meeting</li> <li>✓ Confirm endpoint/Ph3 design</li> </ul>	<b>COVID-19 Acute Lung Injury:</b> <ul style="list-style-type: none"> <li>✓ IND; FDA alignment of Ph2/3 design, endpoint</li> <li>✓ Ph2/3 study initiation</li> </ul>	<table border="0"> <tr> <td> <b>AML:</b> <ul style="list-style-type: none"> <li>▪ Planned initiation of Ph3 study</li> </ul> </td> <td> <b>COVID-19 Acute Lung Injury:</b> <ul style="list-style-type: none"> <li>▪ Final data on Ph2 trial</li> <li>▪ Potential initiation of Ph3 study</li> </ul> </td> </tr> </table>	<b>AML:</b> <ul style="list-style-type: none"> <li>▪ Planned initiation of Ph3 study</li> </ul>	<b>COVID-19 Acute Lung Injury:</b> <ul style="list-style-type: none"> <li>▪ Final data on Ph2 trial</li> <li>▪ Potential initiation of Ph3 study</li> </ul>
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<b>AML:</b> <ul style="list-style-type: none"> <li>▪ Planned initiation of Ph3 study</li> </ul>	<b>COVID-19 Acute Lung Injury:</b> <ul style="list-style-type: none"> <li>▪ Final data on Ph2 trial</li> <li>▪ Potential initiation of Ph3 study</li> </ul>					

# Accelerating development through disciplined investment



Targeted investments gated  
by objective data assessments



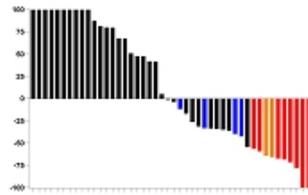
Culture of collaboration yields  
better decisions, stronger execution

## Source of non-dilutive capital directed toward innovative oncology development

BCV for strategic national  
stockpile – smallpox  
outbreak preparation,  
PDUFA date April 2021

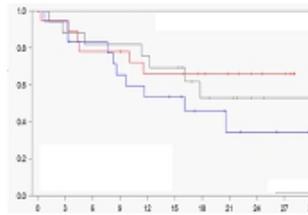


## Focus on oncology areas of high unmet need supported by strong clinical data



### ONC201/ONC206/ONC212

- Glioma registration opportunity
- New indication & pipeline expansion



### DSTAT

- Phase 3 front-line AML trial
- Phase 2 COVID-19 trial

# Acquisition of Oncoceutics Adds Precision Oncology Pipeline with Near-term Registration Potential





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

*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., January 8, 2021 -- 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](http://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](http://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](http://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.

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