UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

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): November 3, 2022

Chimerix, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-35867**	**33-0903395**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 3, 2022, Chimerix, Inc. (the "Company") announced our financial results for the three months ended September 30, 2022 in the press release attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Item 2.02 and the attached Exhibit 99.1 is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Item 2.02 and the attached Exhibit 99.1 shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended.

Item 7.01 Regulation FD Disclosure.

On November 3, 2022, the Company made available an updated corporate presentation (the "Presentation") that the Company intends to use, in whole or in part, in meetings with investors, analysts and others. The Presentation can be accessed through the "Investors" section of the Company's website. A copy of the Presentation is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

The information in this Item 7.01 and the attached Exhibit 99.2 is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Item 7.01 and the attached Exhibit 99.2 shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Chimerix, Inc., dated November 3, 2022.
99.2	Chimerix, Inc. Corporate Presentation, dated November 3, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: November 3, 2022

Chimerix, Inc.

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

Chimerix Reports Third Quarter 2022 Financial Results and Provides Operational Update

– ONC201 Phase 3 ACTION Study On-Track to Open Enrollment in November –

– Meeting with U.S. Food and Drug Administration (FDA) Set for Fourth Quarter –

– Strong Financial Position with ~$285 Million in Cash at September 30 –

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

DURHAM, N.C., November 3, 2022 – Chimerix (NASDAQ:CMRX), a biopharmaceutical company whose mission is to develop medicines that meaningfully improve and extend the lives of patients facing deadly diseases, today reported financial results for the third quarter ended September 30, 2022 and provided an operational update.

“Having executed an intentional strategy to narrow the focus of the company on oncology therapies most likely to have profound impact on patients and create the greatest value for shareholders, we are pleased with our strong execution and progress in the third quarter,” said Mike Sherman, Chief Executive Officer of Chimerix.

“During the quarter, we completed agreements with Biomedical Advanced Research and Development Authority (BARDA) and Emergent BioSolutions (Emergent), and booked our first product revenue with international governments which collectively secured over $270 million in non-dilutive funding to support our oncology pipeline. We also completed discussion with the FDA on the design of our global Phase 3 ACTION study of ONC201 in patients with H3 K27M-mutant glioma. We are targeting initiation of that study during the upcoming Society for Neuro Oncology Annual Meeting later this month, where we plan to have a significant presence among thought leaders in the field. With the expected initiation of the randomized Phase 3 ACTION study, we now plan to discuss the potential for an accelerated approval path with the FDA based upon the strength of the Phase 2 efficacy data, additional safety data, and the continued significant unmet need for patients with this rare brain tumor,” continued Mr. Sherman.

“With our lead program fully funded through potential commercial launch, we will continue to exercise financial discipline with regard to capital allocation,” added Mike Andriole, Chief Business Officer and Chief Financial Officer. “We are primarily relying on external, non-dilutive sources of capital to fund our earlier stage pipeline programs. As such, any acceleration of investment in these programs will follow promising data. In the meantime, we remain disciplined with spend across the organization as we complete the transition of TEMBEXA®to Emergent.”

ONC201 for Treatment of H3 K27M-Mutant Diffuse Glioma

The Phase 3 ACTION study is a randomized, double-blind, placebo-controlled, multicenter international study of ONC201 in newly diagnosed diffuse glioma patients whose tumor harbors an H3 K27M-mutation. Treatment with ONC201 will occur shortly after completion of radiation therapy. The study is designed to enroll 450 patients randomized 1:1:1 to receive ONC201 at one of two dosing frequencies or placebo. Participants will be randomized to receive 625mg of ONC201 once per week (the Phase 2 dosing regimen), 625mg twice per week on two consecutive days or placebo. The dose will be scaled by body weight for pediatric patients.

“We view a higher probability of success for the ACTION trial relative to other Phase 3 trials in neuro oncology,” said, Allen Melemed, M.D., Chief Medical Officer of Chimerix. “Our Phase 2 data demonstrated single agent durable responses in the relapse setting, which strictly followed FDA’s guidance for patient selection. This change in disease progression among responders included consistent and strong association between response and other clinical endpoints, including overall survival. Moving to an earlier line of treatment in this same genetically defined patient population and adding a more frequent dose arm in the ACTION study should enhance clinical activity beyond what was observed in the positive Phase 2 study results. In addition, the ACTION study design includes a number of interim readouts to claim significance in an expedited fashion.”

The Company has scheduled a meeting with the FDA to discuss the potential for an accelerated approval submission for ONC201. In addition to efficacy data previously provided to the FDA, this discussion will build on Chimerix’ recent alignment with the Agency for the Phase 3 ACTION study design and the Company’s plans to enroll this study while the accelerated approval review process is underway. New information supporting this discussion include a 211-patient safety dataset and a healthy volunteer dose escalation study, which both support the attractive safety profile of ONC201 and inform its overall benefit/risk assessment. Chimerix will incorporate FDA feedback into its decision to proceed with a New Drug Application (NDA) for accelerated approval.

TEMBEXA®

In September, Chimerix announced the closing of its sale of TEMBEXA to Emergent and received a payment of $238 million with the potential for additional milestones of up to $136.5 million. Chimerix is also eligible for double-digit royalties on gross profit internationally and on gross profit associated with volumes greater than 1.7 million treatment courses in the U.S.

Third Quarter 2022 Financial Results

For the quarter ending September 30, 2022, Chimerix reported net income of $241.4 million, or $2.75 per basic and diluted share. Chimerix recorded a net loss of $18.6 million, or $0.21 per basic and diluted share, for the third quarter of 2021.

Revenues for the third quarter of 2022 increased to $32.6 million, compared to $0.1 million for the same period in 2021 related to the international procurement sales of TEMBEXA.

Research and development expenses increased to $15.3 million for the third quarter of 2022, compared to $13.8 million for the same period in 2021 driven primarily by ongoing development expenses related to ONC201.

General and administrative expenses increased to $5.3 million for the third quarter of 2022, compared to $4.9 million for the same period in 2021.

The sale of TEMBEXA to Emergent BioSolutions, Inc. was recorded as a $229.7 million gain on a sale. Chimerix utilized net operating losses to offset federal tax liabilities and will incur nominal state tax expense.

Chimerix's balance sheet as of September 30, 2022, included approximately $285 million of capital available to fund operations, no debt and approximately 88.0 million outstanding shares of common stock.

Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss third quarter 2022 financial results and provide a business update today at 8:30 a.m. ET. To access the live conference call, please dial (646) 307-1963 (domestic) or (800) 715-9871(international) at least five minutes prior to the start time and refer to conference ID 2765632.

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 biopharmaceutical company with a mission to develop medicines that meaningfully improve and extend the lives of patients facing deadly diseases. The Company's most advanced clinical-stage development program, ONC201, is in development for H3 K27M-mutant glioma.

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 initiation and probability of success of the Phase 3 ACTION study, the potential for accelerated approval of ONC201, and potential future payments in connection with the TEMBEXA sale transaction. Among the factors and risks that could cause actual results to differ materially from those indicated in the forward-looking statements are risks related to the timing and completion of the Phase 3 ACTION study of ONC201; risks associated with the availability of accelerated approval for ONC201; risks that future payments in connection with the TEMBEXA sale transaction will not be made; 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)
(unaudited)

	September, 30 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 274,261	$ 15,397
Short-term investments, available-for-sale	10,369	72,970
Accounts receivable	468	-
Inventories	-	2,760
Prepaid expenses and other current assets	6,022	4,678
Total current assets	291,120	95,805
Long-term investments	-	2,022
Property and equipment, net of accumulated depreciation	252	253
Operating lease right-of-use assets	2,078	2,404
Other long-term assets	430	56
Total assets	$ 293,880	$ 100,540
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,282	$ 2,788
Accrued liabilities	14,428	13,108
Note payable	-	14,000
Total current liabilities	17,710	29,896
Loan Fees	250	-
Lease-related obligations	1,968	2,392
Total liabilities	19,928	32,288
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at September 30, 2022 and December 31, 2021; no shares issued and outstanding as of September 30, 2022 and December 31, 2021; no shares issued and outstanding as of September 30, 2022 and	-	-
Common stock, $0.001 par value, 200,000,000 shares authorized at September 30, 2022 and December 31, 2021; 88,045,127 and 86,884,266 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	88	87
Additional paid-in capital	966,370	953,782
Accumulated other comprehensive loss, net	(37)	(21)
Accumulated deficit	(692,469)	(885,596)
Total stockholders' equity	273,952	68,252
Total liabilities and stockholders' equity	$ 293,880	$ 100,540

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues:				
Procurement revenue	$ 31,971	$ -	$ 31,971	$ -
Contract and grant revenue	503	105	503	1,928
Licensing revenue	81	2	536	5
Total revenues	32,555	107	33,010	1,933
Cost of goods sold	333	-	447	-
Gross Profit	32,222	107	32,563	1,933
Operating expenses:				
Research and development	15,263	13,820	52,350	39,480
General and administrative	5,313	4,887	16,785	13,431
Acquired in-process research and dvelopment	-	-	-	82,890
Total operating expenses	20,576	18,707	69,135	135,801
Income (loss) from operations	11,646	(18,600)	(36,572)	(133,868)
Other income (loss) income:				
Interest income and other, net	199	40	182	130
Gain on sale of business, net	229,670	-	229,670	-
Income (loss) before income taxes	241,515	(18,560)	193,280	(133,738)
Income tax expense	153	-	153	-
Net income (loss)	241,362	(18,560)	193,127	(133,738)
Other comprehensive income (loss):				
Unrealized gain (loss) on debt investments, net	31	11	(16)	-
Comprehensive income (loss)	$ 241,393	$ (18,549)	$ 193,111	$ (133,738)
Per share information:				
Net income (loss), basic	$ 2.75	$ (0.21)	$ 2.21	$ (1.59)
Net income (loss), diluted	$ 2.75	$ (0.21)	$ 2.17	$ (1.59)
Weighted-average shares outstanding, basic	87,634,888	86,335,357	87,388,624	84,277,555
Weighted-average shares outstanding, diluted	87,814,330	86,335,357	89,070,831	84,277,555

Exhibit 99.2

Chimerix Corporate Presentation

Forward-Looking Statements

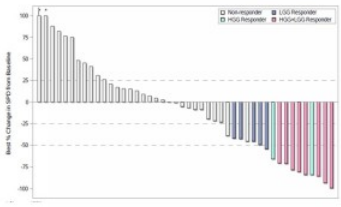
This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include those relating to, among other things: the timing of initiation, progress and completion of ONC201 Phase 3 clinical development; the timing and results of FDA meetings; the potential for accelerated approval for ONC201 and Chimerix's financial strength. 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 Emergent Transaction will not be completed as planned; risks that the initial delivery or any subsequent deliveries of TEMBEXA will not occur as planned, or at all; the anticipated benefits of the sales of TEMBEXA may not be realized; the anticipated benefits of the acquisition of Oncoceutics may not be realized; risks that 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.

Strong balance sheet to fund ongoing oncology franchise

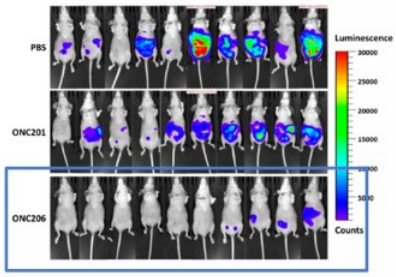
TEMBEXA®
brincidofovir
10 mg/mL oral suspension | 100 mg tablets

- TEMBEXA sale to Emergent BioSolutions and other international sales yielded ~$270 million non-dilutive capital
- CMRX to participate in future potential milestones (up to $136.5 million) and royalties
- Leverages Emergent's government contracting process to maximize future value

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



ONC201
- Ph 3 trial (ACTION study) planned to initiate November 2022
- Positive Phase 2 ORR data in recurrent H3 K27M-mutant glioma
- New indications

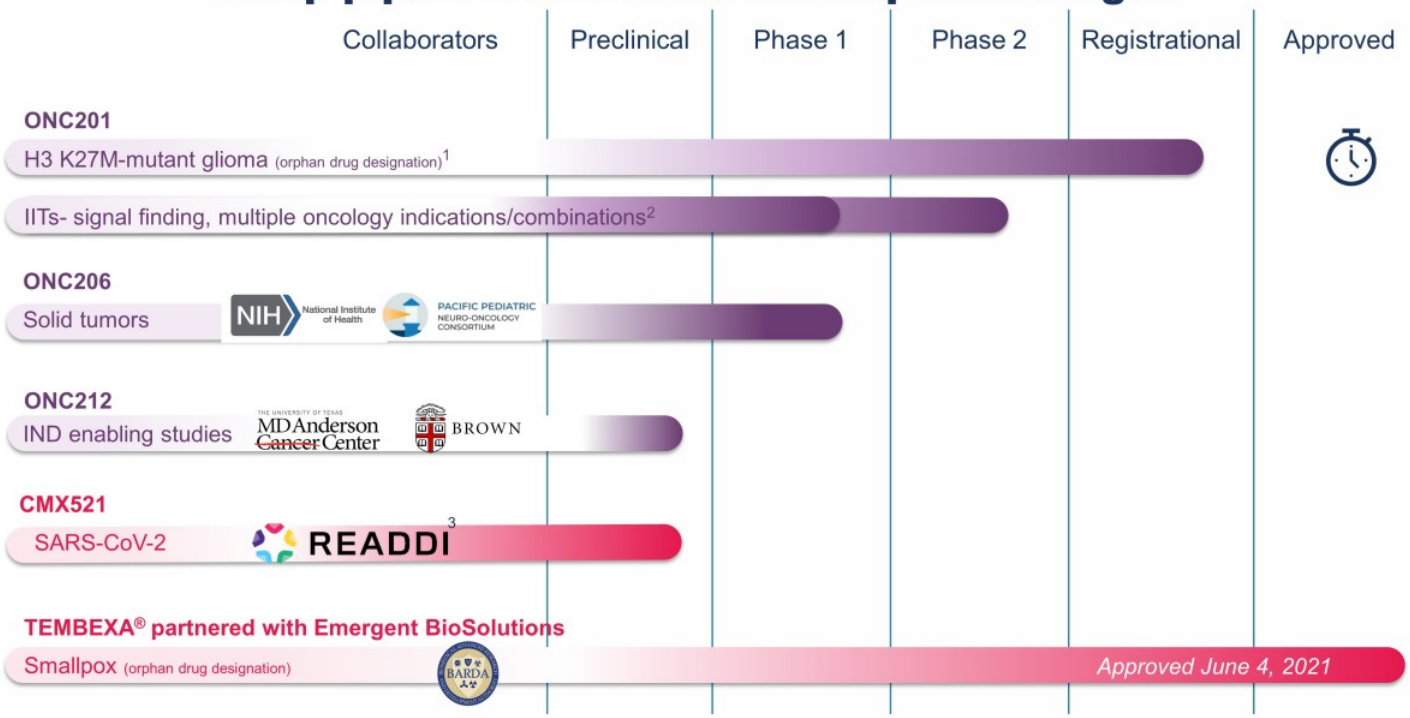


ONC206
- Phase 1 dose escalation
- Supported by NIH, PNOC funding
- Efficacy in tumor xenografts

ONC212
- Completing ongoing tox studies
- Supported by Brown Univ, MDA

Legacy antiviral library
- Potential to monetize
- Grant awards and collaboration with UNC fund screen/development

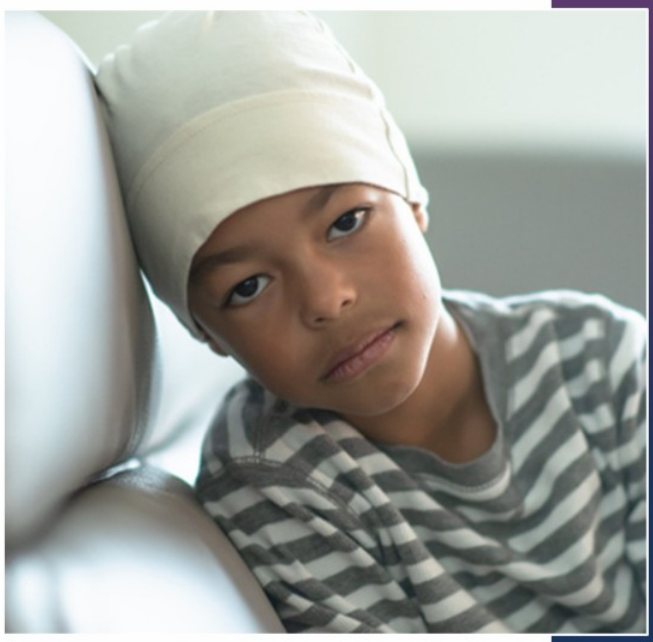
Deep pipeline across all development stages



1. Malignant glioma
2. Nueroendocrine Pheochromocytoma/paraganglioma at Brown University,
3. Rapidly Emerging Antiviral Drug Development Initiative

Denotes US FDA Fast Track Designation

ONC201 Phase 2 Primary Efficacy Analysis

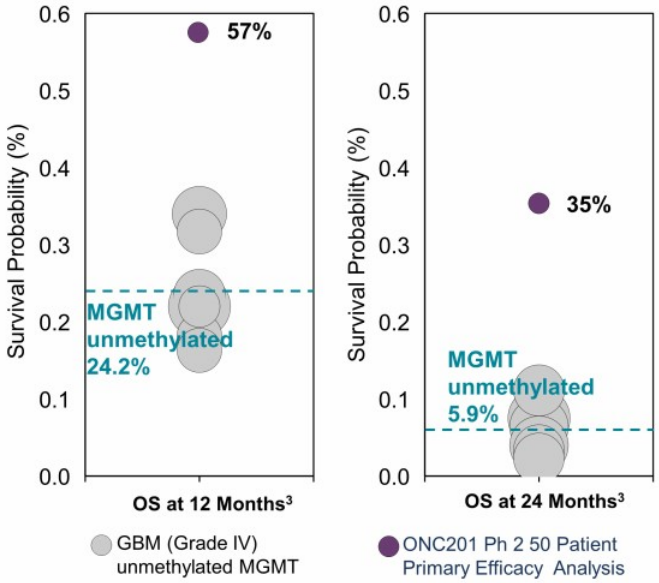


CHIMERIX

Recurrent H3 K27M glioma remains a high unmet need

- Mutation present in ~10% of gliomas, ~2,000 US patients
- Affects mainly young adults and children
- H3 K27M DMG[1] classified by WHO as Grade IV
- Available therapy in recurrent setting is palliative
- H3 K27M gliomas are predominantly MGMT[2] unmethylated[3]
  - Survival MGMT unmethylated Grade IV Glioma: 24.2% at 12 months[4] and 5.9% at 24 months[4]
- Meta analysis of recurrent H3 K27M glioma reported no survival at 24 months[5]
- Survival in ONC201-treated recurrent H3 K27M DMG was 57% OS at 12 months, 35% at 24 months

ONC201 Ph 2 survival compares favorably to historical data



1. Diffuse midline glioma
2. O6methylguanine-DNA methyltransferase is a DNA "suicide" repair enzyme
3. Banan et al. Acta Neuropathol Commun. (2017)
4. MGMT-OS data from 4 studies Reardon, D. A. et al. JAMA Oncol. (2020); Van Den Bent, M. et al. Neuro. Oncol. (2020); Wick, W. et al. N. Engl. J. Med. (2017); Weller, M. et al. Clin. Cancer Res. (2015)
   OS 12 collected from 8 data points (each n > 40 patients) across these four publications
   OS 24 collected from 6 data points (each n > 40 patients) across three of the four publications (Wick et al. did not report OS24)
5. Koschmann et al, 2020; DOI:10.21203/rs.3.rs-69706/v1

Topline results for ONC201 in recurrent H3 K27M DMG

- ONC201 monotherapy exhibited durable, clinically meaningful efficacy in recurrent H3 K27M-mutant DMG
  - Overall Response Rate (ORR) of 30% (95% CI: 18 - 45%) by RANO HGG and/or LGG dual reader BICR
  - RANO-HGG criteria assessed by dual reader BICR
    - ORR 20% (95% CI: 10 – 34%)
    - Median Duration of Response (DOR) 11.2 months (95% CI: 3.8 – not reached)
    - Median time to response 8.3 months (range 1.9 – 15.9)
    - Disease control rate 40% (95% CI: 26 – 55%)
    - PFS at 6 months 35% (95% CI: 21 – 49%); PFS at 12 months 30% (95% CI: 17 – 44%)
  - RANO-LGG criteria assessed by dual reader BICR
    - ORR 26% (95% CI: 15 – 40%)
  - Overall survival
    - 12 months: 57% (95% CI:41 – 70%)
    - 24 months: 35% (95% CI: 21 – 49%)
- Improvements observed in performance status and reduction in corticosteroid use
- All SAEs considered not related to ONC201 by sponsor

FDA-aligned criteria for Phase 2 efficacy analysis to isolate ONC201 single agent activity

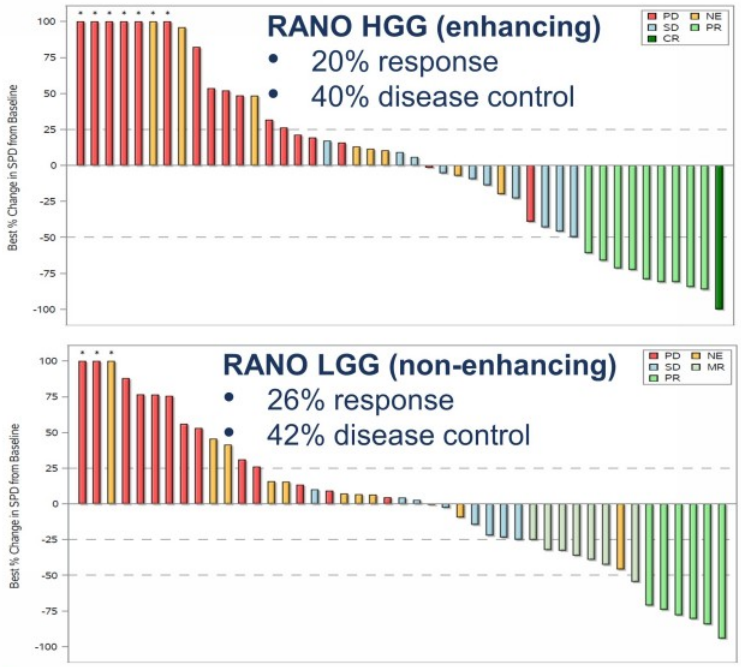
Objective

- To evaluate monotherapy efficacy of ONC201 in recurrent H3 K27M-mutant diffuse midline glioma

Eligibility

- Age ≥2yo and received ONC201 under studies ONC006, ONC013, ONC014, ONC016, or ONC018
- Diffuse glioma with a known H3 K27M mutation and involvement of a midline structure of the brain
- Progressive and measurable disease on contrast-enhanced brain MRI by RANO-High Grade Glioma (HGG) criteria
- Prior therapy with at least radiation
- Washouts prior to first ONC201 dose:
  - Radiation: 90 days
  - Temozolomide: 23 days / Antibodies (e.g., bevacizumab): 42 days / Other anticancer therapies: 28 days
- Baseline Performance Status ≥60
- Corticosteroids stable or decreasing for at least 3 days prior to baseline scan
- Excluded: DIPG, primary spinal tumors, atypical and non-astrocytic hist., leptomeningeal spread, CSF dissemination

ONC201 waterfall plot – 30% RANO HGG / LGG response



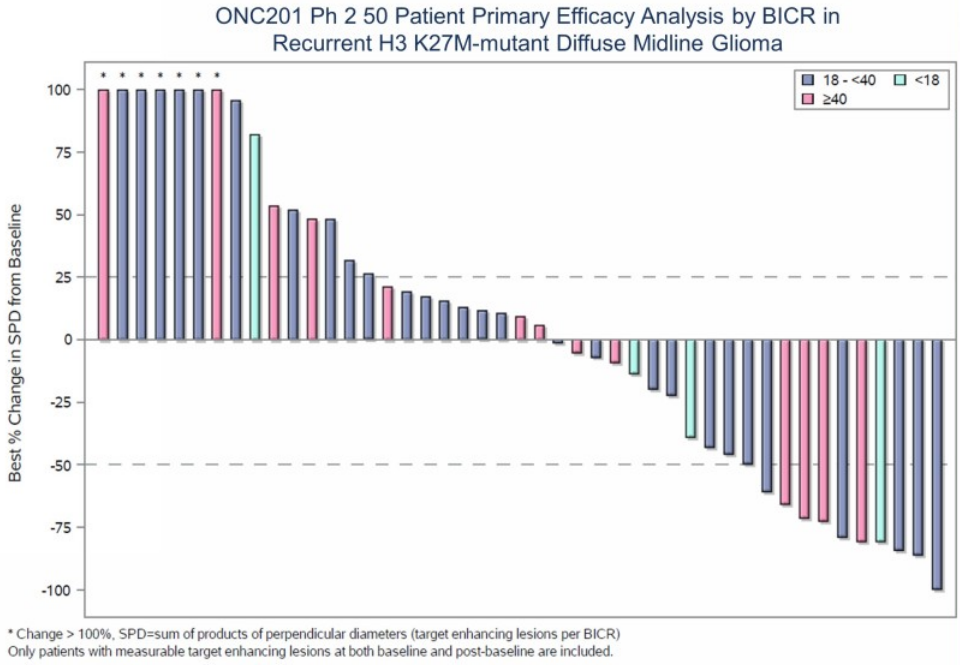
- Strict treatment inclusion to ensure responses attributable to single agent treatment
- Responses require both imaging and clinical criteria
- Blinded independent central review
- Growing consensus that both RANO HGG and RANO LGG are meaningful measures of patient benefit

RANO-HGG responses observed across age groups

Responses by age group:

- <18 years: 1/4 (25%)
- 18-40 years: 5/32 (16%)
- ≥40 years: 4/14 (29%)

RANO-HGG response of 8-year-old subject suggests activity in this population

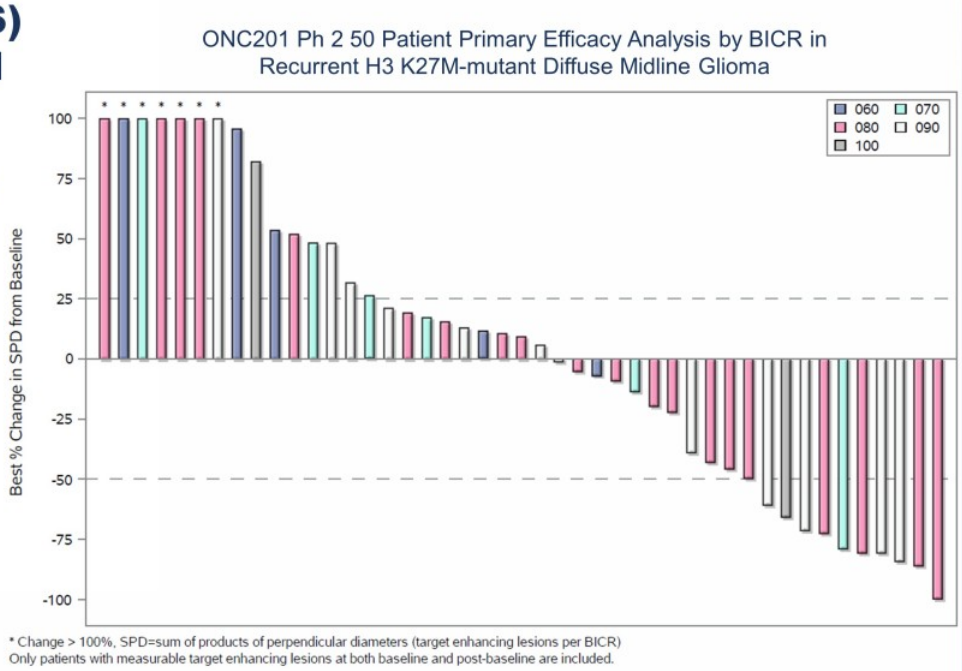


RANO HGG response correlation to performance status (PS) supports early-line trial

Predictably, patients with higher PS were more likely to respond to treatment

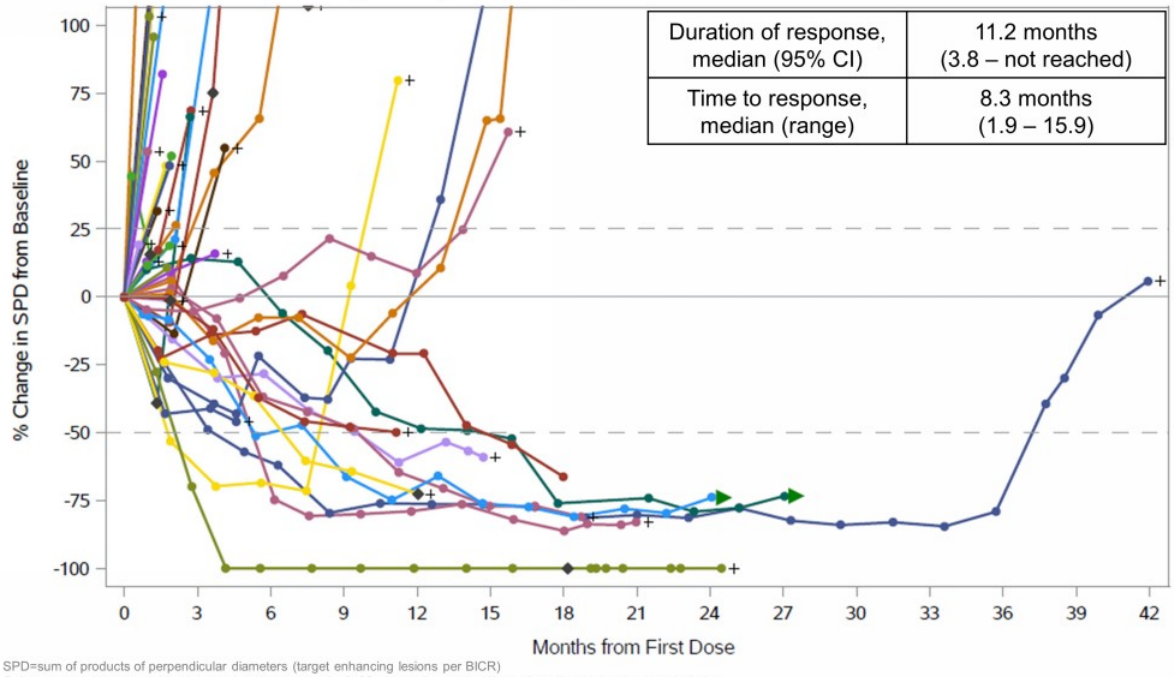
- 100: 1/2 (50%)
- 90: 4/14 (29%)
- 80: 4/20 (20%)
- 70: 1/7 (14%)
- 60: 0/7 (0%)

Supports hypothesis that treating earlier in disease course may enhance efficacy



Clinically meaningful and durable responses measured from first dose of ONC201 (RANO-HGG by BICR)

ONC201 Ph 2 50 Patient Primary Efficacy Analysis by BICR in Recurrent H3 K27M-mutant Diffuse Midline Glioma



Duration of response, median (95% CI)	11.2 months (3.8 – not reached)
Time to response, median (range)	8.3 months (1.9 – 15.9)

SPD=sum of products of perpendicular diameters (target enhancing lesions per BICR)
Only patients with measurable target enhancing lesions by BICR at baseline and with post-baseline evaluations are included.
Three patients did not have on-treatment monotherapy MRIs available for BICR; one patient censored prior to first on-treatment MRI ; one patient did not have measurable target lesion.

ONC201 Safety

Treatment-related Adverse Events in ≥ 3% patients

Treatment-related Adverse Events, Integrated Safety Data Set, (N=211 patients) [1]	Related TEAEs	
	All grades	Grade > 3
Any Treatment-related AE	55.5%	11.8%
Fatigue	21.8%	2.8%
Nausea	20.4%	0
Vomiting	14.2%	0.5%
Headache	8.5%	0.5%
Lymphocyte count decreased	6.6%	0.5%
Decreased appetite	5.7%	0
White blood cell count decreased	4.7%	0.5%
ALT increased	4.3%	0.5%
Hypophosphataemia	4.3%	0
Neutrophil count decreased	3.8%	0.5%
Anaemia	3.3%	0
Diarrhea	3.3%	0

Healthy Adult Study[2]
Incidence of ONC201-related Adverse Events

	125 mg N=33	375 mg N=15	625 mg N=45
Any treatment-related AE	33.0%	20.0%	49.0%
Grade 1	33.0%	20.0%	49.0%
Grade 2	0	0	0
Grade 3-5	0	0	0

- Dose modifications and discontinuations were uncommon
- Most common events were headache, fatigue, nausea and vomiting
- Treatment-related AEs generally Grades 1 & 2
- Most common treatment-related event was fatigue

1. Reported in ONC201 Investigator Brochure
2. Preliminary results from ONC201-101, Part A

RANO responses correspond with survival & clinical benefit

ONC201 Ph 2 50 Patient Primary Efficacy Analysis by BICR in Recurrent H3 K27M-mutant Diffuse Midline Glioma

	All patients	RANO HGG Responders	RANO HGG and/or LGG Responders	All Other Patients
N	50	10	15	35
PFS at 12 months (number of patients censored)	30%[1]	90% (0)	67% (2)	0% (8)
OS at 24 months (number of patients censored)[2]	35%[1]	80% (2)	53% (5)	0% (8)
Corticosteroids response[3] (number of patients evaluable)	47% (15)	100% (4)	100% (5)	20% (10)
Performance status response[4] (number of patients evaluable)	21% (34)	60% (5)	67% (9)	4% (25)

1. Kaplan-Meier median Progression-Free Survival or Overall Survival
2. Censored patients include those who are lost to follow-up or have withdrawn prior to the time point, as well as those who have not yet reached the time point. These patients are counted in the denominator but not counted as survivors (i.e., imputed as failure)
3. Corticosteroid response: ≥50% reduction in average daily corticosteroid dose compared to baseline with stable or improved KPS/LPS. Must be confirmed at next analysis timepoint. Corticosteroids converted into a dexamethasone equivalent dose. Baseline ≥4mg dexamethasone at baseline were evaluable.
4. Performance status response: increase in KPS/LPS compared to baseline with stable or reduced corticosteroid use. Must be confirmed at next analysis timepoint. Baseline KPS/LPS ≤80 were evaluable.

Strong rationale for phase 3 success relative to recent GBM trials

1. Durable and unconfounded single agent responses unique to ONC201

Experimental Agent	Ph2 Design	Biomarker	Response criteria	Confounded by anti-angiogenic pseudo response	ORR	Duration of response	6 month PFS	Approved?
ONC201 – Ph2 rDMG	Single agent	H3 K27M	RANO BICR	No	20-30%	11.2	35%	To be determined
Temodar® temozolomide	Single agent	-	Levin	No	5%	?	21%	Yes (OS)
AVASTIN® bevacizumab	Various	-	Various	Yes	20-70%	4-6	18-50%	Yes (AA per ORR, PFS)
Cediranib	Single agent	-	MacDonald	Yes	27%	?	26%	No
Rindopepimut	Combo+ TMZ	EGFRv3	RANO	Yes	30%	7.8	28%	No
Depatuxizumab mafodotin	Single agent	-	RANO	No	7%	6.7	29%	No
Enzastaurin	Combo + Avastin	-	RANO	Yes	22%	?	21%	No

Positive Neutral Negative Characteristics

WKA Yung, et al, British Journal Cancer, Aug 8, 2000; Teri Kreisl, et all, Journal Clinical Onocoloy,2009, Feb 10;27(5);740-5; Tracy Batchelor, et. all, Journal of Clinical Oncology, vol28, issue 17, Jun 10, 2010; David Reardon, et al, Clin Cancer Research Apr 2020; 26(7)1586-1594; Martin van den Bent, et al, Cancer Chemo & Pharma, 26 Oct 2017 80, 1209-1217; Yazmin Odia, et al, Journal Neuro-Oncology 127, 127-125 (2016)

Multiple unique aspects to ONC201 data support translation to phase 3 success

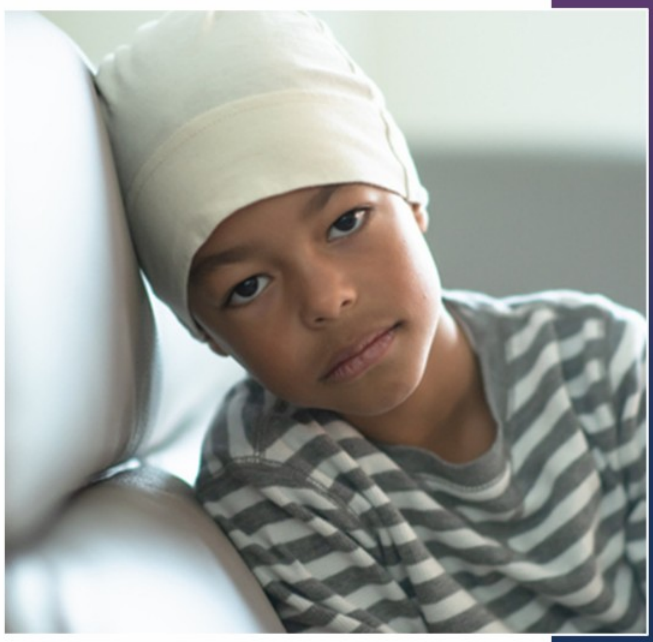
- ✓ Used most robust assessment of response (RANO vs RECIST or McDonald or Levine)
- ✓ Response consistency across distinct imaging assessments (HGG and LGG)
- ✓ Isolation of single agent activity (progression declared, prior therapy washout)
- ✓ Responses: gradual, durable, multi-factorial
- ✓ Consistency across clinical endpoints (steroid use, performance status, survival)
- ✓ Outcomes should be improved in earlier treatment setting (performance status, tumor volume)
- ✓ Lack of active alternatives
- ✓ Stability and homogeneity of biomarker
- ✓ Definitive single agent activity in mechanistically-related second relapsed cancer indication

4Q review of possible accelerated filing in 2023

- 4Q22 FDA meeting to review potential to pursue accelerated approval
- FDA sentiment on recent ODACs[1] emphasized the importance of addressing multiple considerations during an accelerated approval application
- ONC201 fact pattern addresses all considerations

1. Oncologic Drugs Advisory Committee

ONC201 Phase 3 ACTION Study Summary



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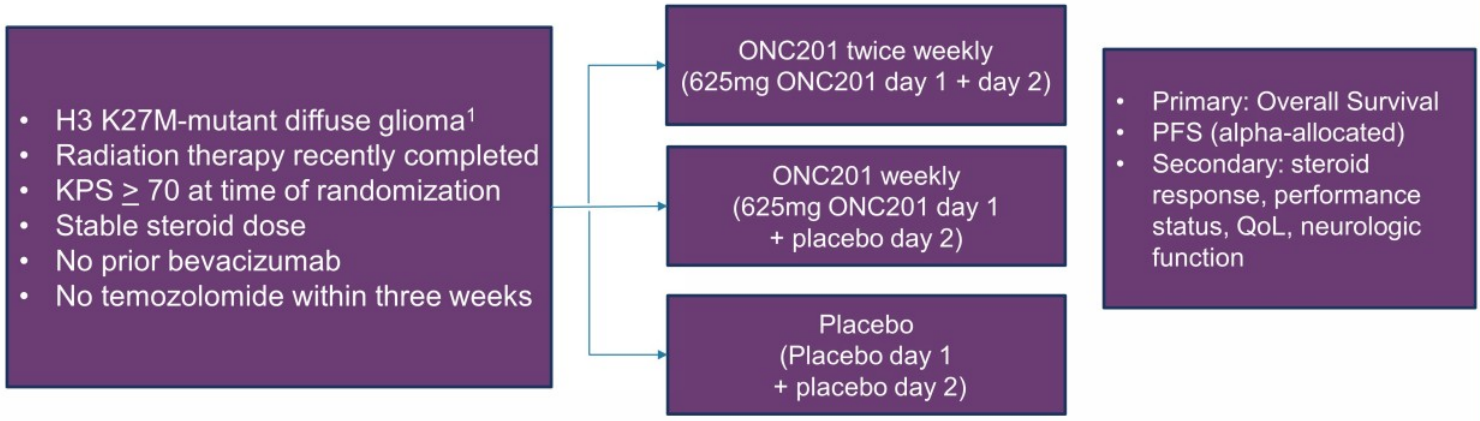
Pivotal Phase 3 ACTION trial design

A randomized, double-blind, placebo-controlled, multicenter international study in 450 newly diagnosed diffuse glioma patients whose tumor harbors an H3 K27M-mutation.



1. Excludes DIPG and spinal tumors

Design provides multiple paths for success

Endpoints expected in early 2025 and final data in 2026

Independent comparisons for each ONC201 arm versus control will be made at each timepoint.

First OS[1] Interim
- ~164 events
- Success at HR[3]=0.52

PFS by RANO HGG[2]
- ~286 events
- Success at HR=0.68

Second OS Interim
- ~246 events
- Success at HR=0.64

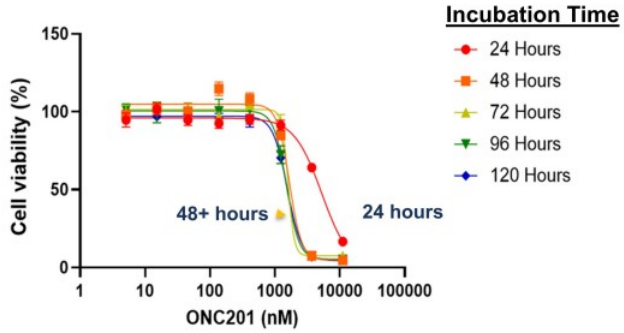
Final OS
- ~327 events
- Success at HR=0.73

Powering assumptions 0.65 expected HR for OS and 0.60 expected HR for PFS

[1] Overall Survival (OS)
[2] Progression-free survival (PFS). PFS may provide valuable confirmatory data for regulatory discussions.
[3] Hazard Ratio

Once weekly dosing shows activity; twice weekly dosing has potential for enhanced efficacy

ONC201 IC50 at 48 hours of exposure was less than half the IC50 of the 24-hour incubation



Preclinical

Maximum in vitro efficacy achieved with 48 hours of ONC201 incubation in HGG cell viability assays (~2500 to 3000 nM)

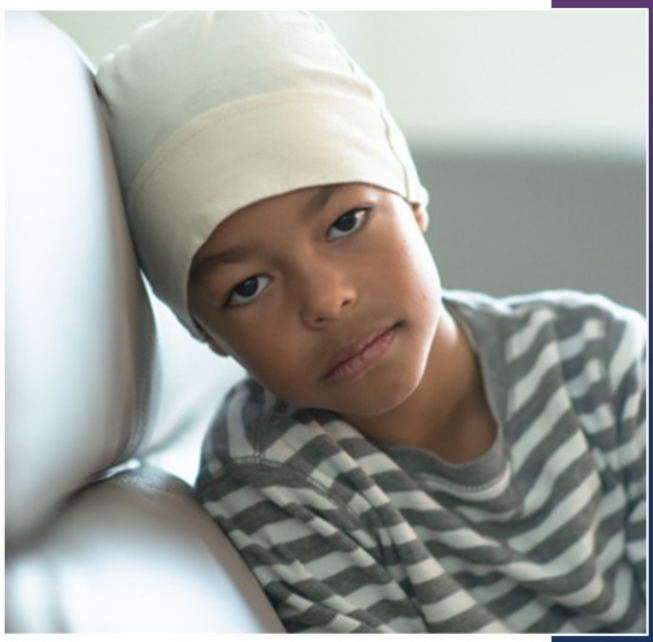
Clinical

Human brain tumor samples show 2675nM ONC201 (mean) 24 hours post-dose in range of the in vitro IC50

Twice weekly dosing has been generally well tolerated

- No instances of dose-limiting toxicity
- No AEs leading to dose discontinuation or reduction

ONC201 Market Opportunity Assessment



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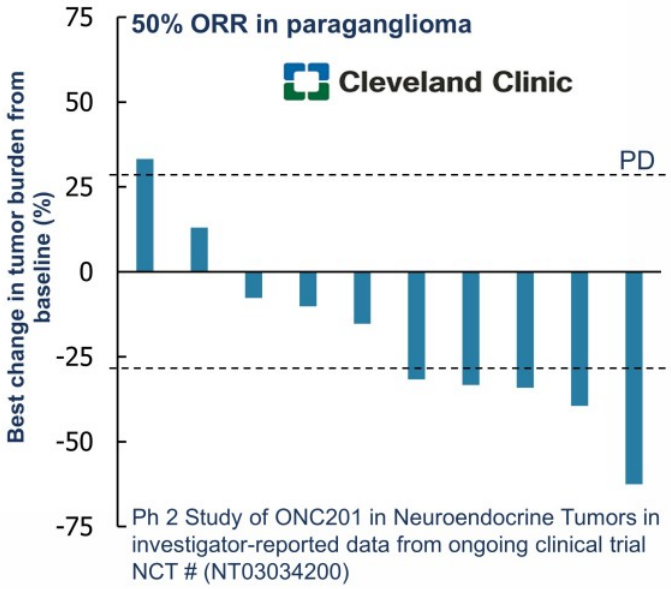
H3 K27M-mutant glioma: market dynamics and opportunity

- Potential market opportunity up to ~$750 million
- U.S. annual incidence of ~2,000
- Patent protection for lead indication into 2037 - potential U.S. patent term extension (up to five years)
- Market research
  - Nearly all midline glioma patients tested for H3 K27M-mutation
  - ~20% ORR and/or clinically relevant durability deemed clinically meaningful
  - ONC201 use expected in >80% of H3 K27M-mutant glioma patients based on current profile
- ONC201 most advanced program targeting H3 K27M-mutant glioma, no other approved agents
- Low barriers to adoption - High unaided awareness of ONC201 among neuro-oncologists
  - KOL interest in exploring new front-line therapies (enrollment criteria in ACTION trial)
  - H3 K27M-mutant already on commercial and site-specific NGS panels, oral dosing, safety profile
  - Longer-term, potentially combinable with other glioma therapies
- H3 K27M mutations are most often in children and young adults, expecting little to no exposure to Medicare

ONC201 interim efficacy results in dopamine-secreting tumors outside the brain

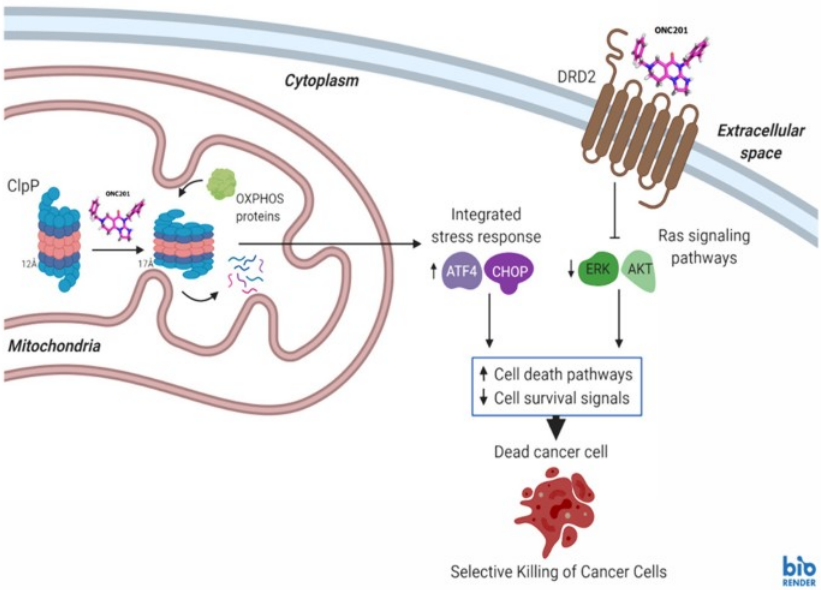


- Single agent responses in Ph 2 neuroendocrine trial of ONC201 observed in subset (paraganglioma)
- Paraganglioma are adrenal-related tumors with elevated DRD2 expression
- Five patients have been treated > 1 year
- Fewer short-term and potential long-term toxicities than other paraganglioma therapies

1. ASCO oral presentation June 2021

ONC201 directly engages DRD2 and ClpP

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

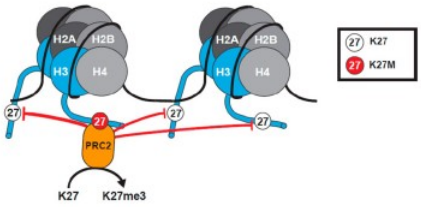


- ONC201 can selectively induce apoptosis in cancer cells by altering activity of two proteins
- DRD2 antagonism
  - DRD2 is a G protein-coupled neuroreceptor that regulates Ras signaling
  - ONC201 antagonizes DRD2, inhibiting Ras signaling pathways
- ClpP agonism
  - ClpP normally degrades misfolded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

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

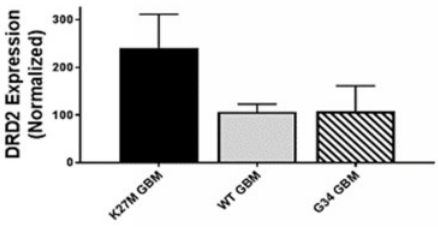
H3 K27M glioma cell lines exhibit enhanced sensitivity to ONC201

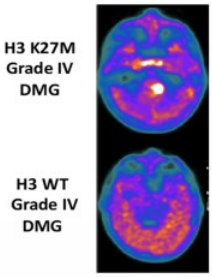
Lysine to methionine ("K-to-M") histone H3 mutation reduces H3 K27 methylation



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

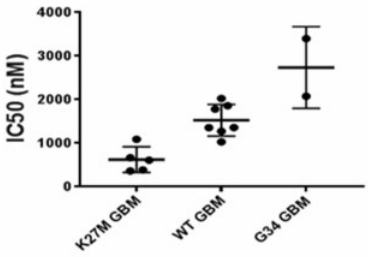




18F-DOPA PET

Midline tumors occur in dopamine-rich regions of the brain

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 FDA designations

Orphan Drug Designation (ODD) (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[1]

1. Subject to continuation of Rare Pediatric Disease Voucher Program and proceeds from voucher will be split 50/50 with legacy Oncoceutics shareholders

ONC206 and ONC212

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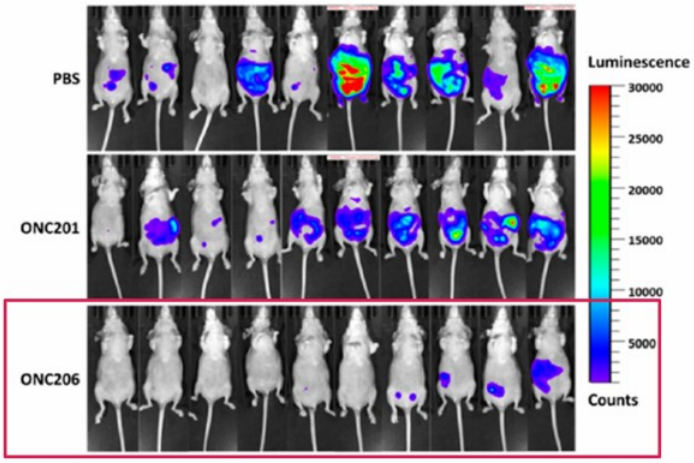
ONC206: potentially differentiated DRD2 antagonist + ClpP agonist

- Focus in current clinical trials on recurrent central nervous system (CNS) cancers
- Efficacy in preclinical models of central nervous system and other tumors
- Enrolling 2 dose escalation clinical trials for adult and pediatric CNS tumor patients
- In vivo exploration of alternative lead indications

NIH NATIONAL CANCER INSTITUTE

PACIFIC PEDIATRIC NEURO-ONCOLOGY CONSORTIUM

ONC206 Efficacy in Tumor Xenografts[1]



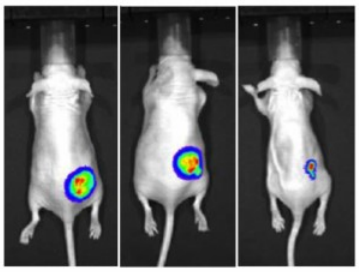
1. Wen Hu et al, August 27, 2020; Cancers

ONC212 preclinical activity in solid tumor and hematological cancer

- Distinct molecular target (GPR132) and efficacy profile relative to ONC201/ONC206
- Efficacy in preclinical models of advanced cancers
- GLP-tox studies ongoing to potentially advance to IND
- Partnerships established for early-stage clinical trials with Brown and MD Anderson

Pancreatic cancer model shows the potential of ONC212[1]

Vehicle ONC201 ONC212



BROWN
Alpert Medical School

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

1. Lev et al, Oncotarget 2017

Legacy antiviral library - CMX521

CHIMERIX

CMX521: SARS-CoV-2 antiviral with established safety profile

CMX521

- Ribonucleoside analog known to inhibit viral polymerase
- Uptake and conversion to triphosphate demonstrated in human epithelial cells
- Oral formulation developed through Phase I
- 27 kg of GMP API available for development/ clinical
- COM patent through 2038, with Method of Use through 2040

Data in SARS-CoV-2

- In vitro activity in human airway epithelial cells (EC50 = 0.3-0.9uM)
- In vivo efficacy with aerosol delivery in SARS-CoV-2-MA10 mouse model established by UNC School of Medicine
- Low µM activity across diverse coronaviruses suggests broad variant activity

Safety Profile

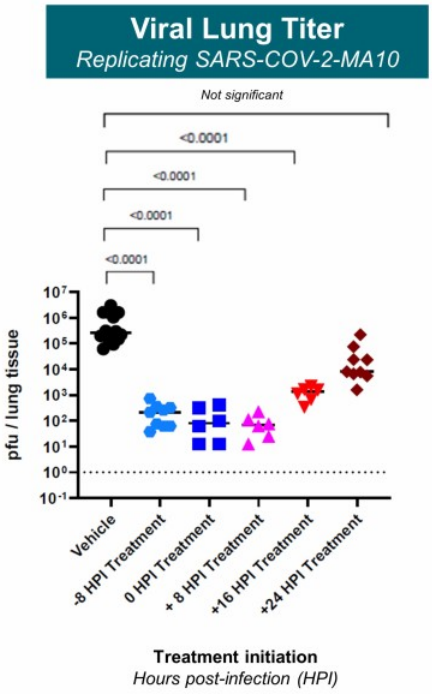
- Not mutagenic, clastogenic, cytotoxic or mitotoxic
- Excellent safety profile in IND enabling tox studies (oral) in rats and dogs
- Inhaled aerosol formulation well-tolerated in mice
- Well-tolerated in healthy volunteer Phase I study at ≤ 2400 mg oral

$2 million grant to fund prodrug formulations that could enable oral administration with improved lung delivery

1. March 23, 2022 ICAR late breaker oral presentation

Significant antiviral effect demonstrated in nonclinical SARS-CoV-2 model conducted in collaboration with UNC-CH

- Mouse-adapted SARS-CoV-2-MA10 model
  - Replicates lung pathology of human infection 4-days post infection
    - **1 day in mouse = 5-7 days in humans (adjusted disease course)**
- CMX521 delivered as inhaled nebulized liquid aerosol
  - 3x daily from initiation through Day 4
- Minimal systemic exposure
- CMX521 treatment significantly decreased lung viral titer
  - 365-fold decrease with treatment initiation 16 hours post-infection
  - 3,000-fold decrease with treatment initiation at time of infection
- Clinical scoring (animal health), lung pathology, animal weight loss and viral RNA parallel viral lung titer (plaque forming unit)
- Dose-range, PK, and combination studies ongoing



Corporate Update

CHIMERIX

TEMBEXA® deal term summary

Emergent experienced biodefense company collaborating with government agencies to protect public health.

Terms summary :

$238 million upfront at closing

Up to an additional $124 million in potential BARDA procurement milestones

20% royalty on future U.S. gross profit with volumes above 1.7 million courses of therapy

15% royalty of all international gross profit

Up to an additional $12.5 million in development milestones

TEMBEXA®
brincidofovir
10 mg/mL oral suspension | 100 mg tablets

Financial strength to achieve our objectives

~$285 million	$0	88.0 million
Cash balance at September 30,2022 inclusive of TEMBEXA proceeds	No debt outstanding or milestone payments until potential ONC201 approval	Shares outstanding at September 30, 2022

Dollars (millions)	Nine Months Ended Sept 30, 2022
Operating R&D (cash)	$(44.7)
Operating G&A (cash)	(12.5)
Op Ex (cash)	$(57.2)

Cash Expected Through Upcoming Catalysts Under Current Operational Plan

Recurrent/Second-Line (2L) H3 K27M-mutant diffuse midline glioma
- ✓ *Preliminary accelerated approval (AA) feedback from US FDA expected Q4 2022*
- ✓ *Contingent on FDA feedback, potential NDA submission for AA expected 2H 2023*

First-Line (1L) H3 K27M-mutant diffuse glioma – The ACTION Study
- ✓ *Trial initiation expected Q4 2022*
- ✓ *Interim OS data expected early 2025*
- ✓ *Full OS data expected 2026*

Pipeline beyond ONC201
- ✓ *ONC206 dose exploration efficacy signal(s)*
- ✓ *Pre-clinical programs potential advance to clinic or partner opportunities (ONC212, CMX521)*
- ✓ *Robust business development search and evaluation process*

Chimerix Corporate Presentation

CHIMERIX