

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 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): October 30, 2024

DAY ONE BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation)

001-40431  
(Commission File Number)

83-2415215  
(IRS Employer  
Identification No.)

2000 Sierra Point Parkway, Suite 501  
Brisbane, California  
(Address of principal executive offices)

94005  
(Zip Code)

Registrant's telephone number, including area code: (650) 484-0899

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 \$0.0001 per share	DAWN	Nasdaq Global Select 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 October 30, 2024, Day One Biopharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2024. A copy of the press release is attached as Exhibit 99.1 to this report. A copy of the Company's presentation with respect to its financial results for the quarter ended September 30, 2024 is attached as Exhibit 99.2 to this report.

**Item 7.01 Regulation FD Disclosure.**

On October 30 2024, the Company updated its corporate presentation. A copy of the updated presentation is attached as Exhibit 99.3 to this report.

The information in this Current Report on Form 8-K, including Exhibit 99.1, Exhibit 99.2 and Exhibit 99.3 to this report, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The information contained in this Current Report on Form 8-K and in the accompanying Exhibit 99.1, Exhibit 99.2 and Exhibit 99.3 shall not be incorporated by reference into any other filing under the Exchange Act or under the Securities Act, except as shall be expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

Exhibit Number	Description
99.1	<a href="#">Press release issued by Day One Biopharmaceuticals, Inc. regarding its financial results for the quarter ended September 30, 2024, dated October 30, 2024.</a>
99.2	<a href="#">Financial Results Presentation.</a>
99.3	<a href="#">Corporate Presentation.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL 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 thereunto duly authorized.

**DAY ONE BIOPHARMACEUTICALS, INC.**

Date: October 30, 2024

By: /s/ Charles N. York II, M.B.A.  
Charles N. York II, M.B.A.  
Chief Operating Officer and Chief Financial Officer

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## Day One Reports Third Quarter 2024 Financial Results and Corporate Progress

*Achieved \$20.1 million in OJEMDA™ (tovorafenib) net product revenue*

*Ended the third quarter with \$558.4 million in cash, cash equivalents and short-term investments*

*Company to host conference call and webcast today, October 30, 4:30 p.m. Eastern Time*

**BRISBANE, Calif., Oct. 30, 2024** – Day One Biopharmaceuticals, Inc. (Nasdaq: DAWN) (“Day One” or the “Company”), a biopharmaceutical company dedicated to developing and commercializing targeted therapies for people of all ages with life-threatening diseases, today announced its third quarter 2024 financial results and highlighted recent corporate achievements.

“Our third quarter results demonstrate continued patient demand for OJEMDA, driven by the need for new therapies for children living with pediatric low-grade glioma,” said Jeremy Bender, Ph.D., chief executive officer of Day One. “Looking ahead to 2025, we plan to continue to drive growth by advancing our programs and pipeline, including DAY301, a potential first-in-class ADC targeting PTK7 that we expect to be in the clinic in the coming months.”

### Program Highlights

- Strong growth in OJEMDA net revenue with \$20.1M in the third quarter of 2024, representing a 145% increase over the second quarter of 2024.
  - Quarterly prescriptions (TRx) grew to 619 in the third quarter of 2024, representing a 159% increase over the second quarter of 2024.
  - Day One expects to dose the first patient in the Phase 1a portion of the Phase 1a/b clinical trial of DAY301 by the end of 2024 or in the first quarter of 2025.
  - Day One provided updated duration of response data from the registrational Phase 2 FIREFLY-1 trial investigating tovorafenib in patients with BRAF-altered, relapsed or progressive pLGG. For the 77 patients enrolled on Arm 1, which was the dataset used to assess OJEMDA’s efficacy, the median duration of response is 18 months.
  - The pivotal Phase 3 FIREFLY-2/LOGGIC clinical trial evaluating tovorafenib as a front-line therapy in patients aged 6 months to 25 years with pLGG continues to enroll patients in the United States, Canada, Europe, Australia and Asia, with more than 100 sites activated.
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### Corporate Highlights and Upcoming Milestones

- Day One and Ipsen entered into an exclusive licensing agreement to commercialize tovorafenib outside of the U.S. in July 2024. Under the agreement, Day One received approximately \$111 million upfront in cash and equity investment at a premium with up to approximately \$350 million in additional launch and sales milestone payments as well as tiered double-digit royalties starting at mid-teens percentage on net sales.
- Day One entered into a definitive agreement for an oversubscribed private placement of its securities for total gross proceeds of approximately \$175 million in July 2024.

### Third Quarter 2024 Financial Highlights

- **Product Revenue, Net:** OJEMDA net product revenues were \$20.1 million for the third quarter of 2024, the first full quarter of the U.S. launch.
- **License Revenue:** License revenue from the sale of ex-U.S. commercial rights for tovorafenib was \$73.7 million for the third quarter of 2024.
- **R&D Expenses:** Research and development expenses were \$33.6 million for the third quarter of 2024 compared to \$33.2 million for the third quarter of 2023. The increase was primarily due to the clinical trial activities related to tovorafenib and additional employee compensation costs.
- **SG&A Expenses:** Selling, general and administrative expenses were \$29.0 million for the third quarter of 2024 compared to \$18.3 million for the third quarter of 2023. The increase was primarily due to employee compensation costs, commercial launch activities, and professional service expenses to support the launch of OJEMDA.
- **Net Income/Loss:** Net income totaled \$37.0 million for the third quarter of 2024 with non-cash stock-based compensation expense of \$11.6 million, compared to a net loss of \$46.2 million for the third quarter of 2023, with non-cash stock-based compensation expense of \$9.6 million.
- **Cash Position:** The Company's cash, cash equivalents and short-term investments totaled \$558.4 million as of September 30, 2024.

### Upcoming Events

- Two posters on health-related quality of life and drug holiday from the registrational Phase 2 FIREFLY-1 trial investigating tovorafenib in patients with BRAF-altered, relapsed or progressive pLGG will be presented at the Society for Neuro-Oncology Annual Meeting on November 22, 2024.
- Piper Sandler 36<sup>th</sup> Annual Healthcare Conference, December 3-5, 2024.

### Conference Call

Day One will host a conference call and webcast today, October 30 at 4:30 p.m. Eastern Time. To access the live conference call by phone, dial 877-704-4453 (domestic) or 201-389-0920 (international), and

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provide the access code 13745150. Live audio webcast will be accessible from the Day One Investors & Media page. To ensure a timely connection to the webcast, it is recommended that participants register at least 15 minutes prior to the scheduled start time. An archived version of the webcast will be available for replay on the Events & Presentations section of the Day One Investors & Media page for 30 days following the event.

**About OJEMDA™**

OJEMDA (tovorafenib) is a Type II RAF kinase inhibitor of mutant BRAF V600, wild-type BRAF, and wild-type CRAF kinases.

OJEMDA is indicated for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (LGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Tovorafenib was granted Breakthrough Therapy and Rare Pediatric Disease designations by the FDA for the treatment of patients with pLGG harboring an activating RAF alteration, and it was evaluated by the FDA under priority review. Tovorafenib has also received Orphan Drug designation from the FDA for the treatment of malignant glioma and from the European Commission for the treatment of glioma.

For more information, please visit [www.ojemda.com](http://www.ojemda.com).

**About Day One Biopharmaceuticals**

Day One Biopharmaceuticals believes when it comes to pediatric cancer, we can do better. The Company was founded to address a critical unmet need: the dire lack of therapeutic development in pediatric cancer. Inspired by “The Day One Talk” that physicians have with patients and their families about an initial cancer diagnosis and treatment plan, Day One aims to re-envision cancer drug development and redefine what’s possible for all people living with cancer—regardless of age—starting from Day One.

Day One partners with leading clinical oncologists, families, and scientists to identify, acquire, and develop important targeted cancer treatments. The Company’s pipeline includes tovorafenib (OJEMDA™), DAY301 and a VRK1 inhibitor program.

Day One is based in Brisbane, California. For more information, please visit [www.dayonebio.com](http://www.dayonebio.com) or find the Company on LinkedIn or X.

Day One uses its Investor Relations website ([ir.dayonebio.com](http://ir.dayonebio.com)), its X handle ([x.com/DayOneBio](https://x.com/DayOneBio)), and LinkedIn Home Page ([linkedin.com/company/dayonebio](https://linkedin.com/company/dayonebio)) as a means of disseminating or providing notification of, among other things, news or announcements regarding its business or financial performance, investor events, press releases, and earnings releases, and as a means of disclosing material nonpublic information and for complying with its disclosure obligations under Regulation FD.

**Cautionary Note Regarding Forward-Looking Statements**

This press release contains “forward-looking” statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to: Day One’s plans to develop and commercialize cancer therapies, expectations from current and planned

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clinical trials, the execution of the Phase 2 and Phase 3 clinical trial for tovorafenib as designed, expectations with respect to the timing of Day One's Phase 1a/b clinical trial of DAY301, any expectations about safety, efficacy, timing and ability to complete clinical trials, release data results and to obtain regulatory approvals for tovorafenib and other candidates in development, and the ability of tovorafenib to treat pLGG or related indications.

Statements including words such as "believe," "plan," "continue," "expect," "will," "develop," "signal," "potential," or "ongoing" and statements in the future tense are forward-looking statements. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they do not fully materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements.

Forward-looking statements are subject to risks and uncertainties that may cause Day One's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties in this press release and other risks set forth in our filings with the Securities and Exchange Commission, including Day One's ability to develop, obtain and retain regulatory approval for or commercialize any product candidate, Day One's ability to protect intellectual property, the potential impact of global business or macroeconomic conditions, including as a result of inflation, rising interest rates, instability in the global banking system, geopolitical conflicts and the sufficiency of Day One's cash, cash equivalents and investments to fund its operations. These forward-looking statements speak only as of the date hereof and Day One specifically disclaims any obligation to update these forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events or otherwise, except as required by law.

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**Day One Biopharmaceuticals, Inc.**  
**Condensed Statements of Operations**  
(in thousands, except share and per share amounts)  
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
<b>Revenue:</b>				
Product revenue, net	\$ 20,070	\$ —	\$ 28,262	\$ —
License revenue	73,691	—	73,691	—
Total revenues	93,761	—	101,953	—
<b>Cost and operating expenses:</b>				
Cost of product revenue	1,590	—	2,297	—
Research and development	33,563	33,163	165,879	93,173
Selling, general and administrative	28,972	18,275	85,715	53,374
Total cost and operating expenses	64,125	51,438	253,891	146,547
Income (loss) from operations	29,636	(51,438)	(151,938)	(146,547)
<b>Non-operating income:</b>				
Gain from sale of priority review voucher	—	—	108,000	—
Investment income, net	5,322	5,291	13,649	12,163
Other income (expense), net	1,197	(3)	1,177	(22)
Total non-operating income, net	6,519	5,288	122,826	12,141
Income (loss) before income taxes	36,155	(46,150)	(29,112)	(134,406)
Income tax benefit (expense)	882	—	(670)	—
Net income (loss)	37,037	(46,150)	(29,782)	(134,406)
Net income (loss) per share - basic	\$ 0.38	\$ (0.54)	\$ (0.33)	\$ (1.73)
Net income (loss) per share - diluted	\$ 0.38	\$ (0.54)	\$ (0.33)	\$ (1.73)
Weighted-average number of common shares used in net income (loss) per share - basic	96,623,123	85,952,501	90,164,895	77,682,237
Weighted-average number of common shares used in net income (loss) per share - diluted	96,937,759	85,952,501	90,164,895	77,682,237

**Day One Biopharmaceuticals, Inc.**  
**Selected Condensed Balance Sheet Data**  
(in thousands)  
(unaudited)

	September 30, 2024	December 31, 2023
Cash, cash equivalents and short-term investments	\$ 558,383	\$ 366,347
Total assets	600,807	376,048
Total liabilities	45,344	29,508
Accumulated deficit	(488,367)	(458,585)
Total stockholders' equity	555,463	346,540

DAY ONE MEDIA  
Laura Cooper, Head of Communications  
media@dayonebio.com

DAY ONE INVESTORS  
LifeSci Advisors, PJ Kelleher  
pkelleher@lifesciadvisors.com

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# Third Quarter 2024

## Financial Results and Corporate Progress

October 2024



Nasdaq: **DAWN**

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## Forward-Looking Statements

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This presentation and the accompanying oral commentary contain forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to our management. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "intend," "potential," "would," "continue," "ongoing" or the negative of these terms or other comparable terminology. Forward-looking statements include all statements other than statements of historical fact contained in this presentation, including information concerning our future financial performance, including the sufficiency of our cash, cash equivalents and short-term investments to fund our operations, business plans and objectives, the anticipated gross proceeds of our private placement offering, timing and success of our commercialization and marketing efforts, timing and success of our planned nonclinical and clinical development activities, the results of any of our strategic collaborations, including the potential achievement of milestones and provision of royalty payments thereunder, timing and results of nonclinical studies and clinical trials, efficacy and safety profiles of our products and product candidates, the ability of OJEMDA™ (tovorafenib) to treat pediatric low-grade glioma (pLGG) or related indications, the potential therapeutic benefits and economic value of our products and product candidates, potential growth opportunities, competitive position, industry environment and potential market opportunities, our ability to protect intellectual property and the impact of global business or macroeconomic conditions, including as a result of inflation, changing interest rates, cybersecurity incidents, potential instability in the global banking system, changes in the U.S. presidential administration, uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto and global regional conflicts, on our business and operations.

Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. These factors, together with those that are described under the heading "Risk Factors" contained in our most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) and other documents we file from time to time with the SEC, may cause our actual results, performance or achievements to differ materially and adversely from those anticipated or implied by our forward-looking statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this presentation, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.



# Agenda & Day One Participants

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## Opening Remarks

- Jeremy Bender (Chief Executive Officer)

## OJEMDA™ (tovorafenib)

- Lauren Merendino (Chief Commercial Officer)

## Financial Performance

- Charles York (Chief Operating Officer & Chief Financial Officer)

## Q&A Session

- All, joined by: Sam Blackman (Co-Founder & Head of R&D)





# Opening Remarks

Jeremy Bender

*Chief Executive Officer*

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# Executing On Our Priorities As A Commercial-Stage Company

## OJEMDA

- **\$20.1M** in net product revenue
- **+145%** quarter over quarter growth
- Steady cadence of **new patient starts** and **favorable payer access**

## Pipeline Progress

- Continued focus on **fully enrolling frontline FIREFLY-2 trial**
- Urgently working to **initiate DAY301 Phase 1a trial**, our potential first-in-class ADC targeting PTK-7

## Financial Position

- Strong financial position with **\$558.4M in cash<sup>1</sup>**



**ojemda™**  
(tovorafenib)

100 mg tablets  
25 mg/mL for oral suspension

**Building a Sustainable Company  
with Durable Growth for the Near  
and Long Term**



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<sup>1</sup> Represents cash, cash equivalents and short-term investments as of September 30, 2024.





# OJEMDA Launch Performance

Lauren Merendino

*Chief Commercial Officer*

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## Impressive Performance on Multiple Fronts



**\$28.3M**

NET REVENUES  
SINCE LAUNCH<sup>1</sup>

**855**

CUMULATIVE  
PRESCRIPTIONS  
SINCE LAUNCH<sup>1, 2</sup>

**~80%**

PAYER APPROVAL  
RATE

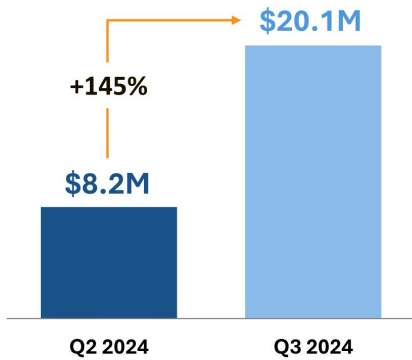


7 | <sup>1</sup> OJEMDA received U.S. FDA accelerated approval for relapsed or refractory BRAF-altered pediatric low-grade glioma on April 23, 2024. <sup>2</sup> Cumulative prescriptions are approximations based on data available on September 30, 2024.



# OJEMDA Patient Demand Continues to Drive Growth

## Quarterly Net Revenue



### Revenue Drivers

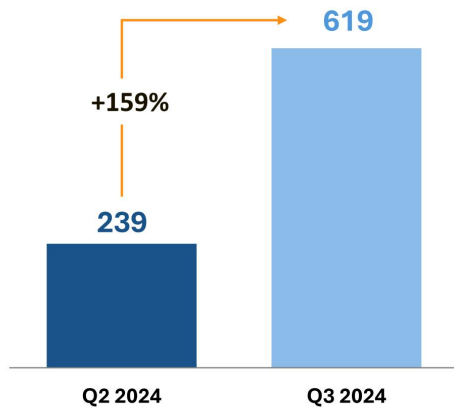
- **Consistent patient demand** & high continuation rates were primary growth drivers in Q3
- The growth rate reflects **ongoing adoption of OJEMDA** by physicians, payers, and patients.
- **High payer approval rates**

**\$28.3M Net Revenue Since Launch**



# Strong Growth in Prescriptions in 3Q 2024

## Quarterly U.S. OJEMDA Prescriptions (TRx)<sup>1,2</sup>



### Breadth of Prescribers & Patients

- **Nearly doubled** the number of HCPs who prescribed OJEMDA
- HCPs treating more than 1 patient **continues to increase**
- **Significant uptake** in both fusion & mutation patients and broad range of tumor locations in the brain
- **Continued positive feedback** from physicians and a desire to use more OJEMDA



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<sup>1</sup> Total prescriptions includes prescriptions for all patients (new & refill, paid & free drug and on-label & off-label patients). <sup>2</sup> Prescriptions are approximations based on data available on September 30, 2024. HCP – Health Care Professional.

# Momentum Continues to Build in Physicians Treating pLGG

## Feedback from pLGG Treating Physicians

100%

AWARENESS OF  
OJEMDA<sup>1</sup>

>90%

INTEND TO  
PRESCRIBE OJEMDA<sup>1</sup>

>80%

TOP TIER ACCOUNTS  
HAVE STARTED ONE  
OR MORE PATIENTS  
ON OJEMDA<sup>2</sup>

## Physician Perspectives

“Now, our paradigm is, you get your traditional chemotherapy as your upfront. Then **if you progress, you have a choice between a MEK inhibitor and tovorafenib...I think it's going to be mostly patients choosing Tovo over MEK** I also think that there's going to be patients who progress on MEK inhibitor that will go on Tovo.”<sup>3</sup>

- Neuro-Oncologist KOL

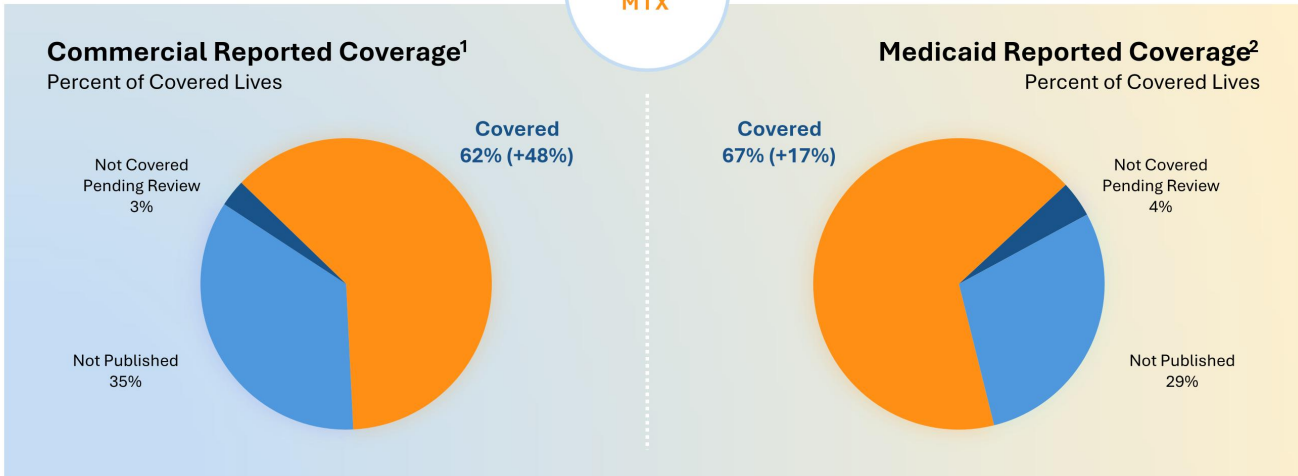
“From what I recall, over 80% of patients achieved at least stable disease and about 50%, had significant tumor shrinkage. **That's exciting when you compare it to where we've been in the past.**”<sup>4</sup>

# Significant Progress on Payer Coverage, with Published Coverage for the Majority of Patients

~60% Commercial Patients

PAYER MIX

~40% Medicaid Patients



~80% Patients Approved for Coverage, Despite Lower Reported Coverage<sup>3</sup>



<sup>1</sup> Breakaway Partners LLC – Breakaway Partners Analytics Platform. Metrics Based on 190.5M Commercial Lives. <sup>2</sup> Artia Solutions - Medicaid Coverage Status Report and Breakaway Partners LLC – Breakaway Partners Analytics Platform. Metrics Based on 74.9M Total Medicaid Lives. <sup>3</sup> Internal prescription data.



# Well-Positioned For Continuing Commercial Execution And Sustained Growth

## Continuing Launch Trajectory

**Increase breadth & depth of prescribers**

**Position OJEMDA as the standard of care in 2nd line**

**Establish remaining payer coverage policies**



# Financial Performance

Charles York

*Chief Operating Officer and Chief Financial Officer*

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## Third Quarter 2024 Financial Results

Financial Summary (\$ in millions)	Three Months Ended 9/30/24	Three Months Ended 9/30/23	Nine Months Ended 9/30/24	Nine Months Ended 9/30/23
OJEMDA Net Revenue	20.1	--	28.3	--
License Revenue	73.7	--	73.7	--
<b>Total Revenue</b>	<b>\$93.8</b>	<b>\$--</b>	<b>\$101.1</b>	<b>\$--</b>
Cost of Product Revenue	1.6	--	2.3	--
Research and Development Expense <sup>1</sup>	33.6	33.2	165.9	93.2
Selling, General and Administrative Expense <sup>2</sup>	29.0	18.3	85.7	53.4
<b>Total Cost and Operating Expenses</b>	<b>\$64.1</b>	<b>\$51.4</b>	<b>\$253.9</b>	<b>\$146.5</b>
Non-operating Income <sup>3</sup>	6.5	5.3	122.8	12.1
Income Tax Benefit (Expense)	0.9	--	(0.7)	--
<b>Net Income (Loss)</b>	<b>\$37.0</b>	<b>(\$46.2)</b>	<b>(\$29.8)</b>	<b>(\$134.4)</b>

	9/30/24	9/30/23
Cash, cash equivalents and short-term investments	\$558.4	\$405.5

14 | All financial information is unaudited. <sup>1</sup> Includes stock-based compensation expense of \$3.8 million and \$13.2 million for the three and nine months ended 9/30/24, and \$3.3 million and \$10.1 million for the three and nine months ended 9/30/23, respectively. <sup>2</sup> Includes stock-based compensation expense of \$7.8 million and \$24.0 million for the three and nine months ended 9/30/24, and \$6.3 million and \$18.4 million for the three and nine months ended 9/30/23, respectively. <sup>3</sup> Includes sale of Priority Review Voucher of \$108.0 million for the nine months ended 9/30/24.

**Thank You**



# Day One Biopharmaceuticals

Targeted Therapies for People of All Ages

October 2024



## Disclaimer

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This presentation and the accompanying oral commentary contain forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to our management. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "intend," "potential," "would," "continue," "ongoing" or the negative of these terms or other comparable terminology. Forward-looking statements include all statements other than statements of historical fact contained in this presentation, including information concerning our future financial performance, including the sufficiency of our cash, cash equivalents and short-term investments to fund our operations, business plans and objectives, the anticipated gross proceeds of our private placement offering, timing and success of our commercialization and marketing efforts, timing and success of our planned nonclinical and clinical development activities, the results of any of our strategic collaborations, including the potential achievement of milestones and provision of royalty payments thereunder, timing and results of nonclinical studies and clinical trials, efficacy and safety profiles of our products and product candidates, the ability of OJEMDA™ (tovorafenib) to treat pediatric low-grade glioma (pLGG) or related indications, the potential therapeutic benefits and economic value of our products and product candidates, potential growth opportunities, competitive position, industry environment and potential market opportunities, our ability to protect intellectual property and the impact of global business or macroeconomic conditions, including as a result of inflation, changing interest rates, cybersecurity incidents, potential instability in the global banking system, changes in the U.S. presidential administration, uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto and global regional conflicts, on our business and operations.

Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. These factors, together with those that are described under the heading "Risk Factors" contained in our most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) and other documents we file from time to time with the SEC, may cause our actual results, performance or achievements to differ materially and adversely from those anticipated or implied by our forward-looking statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this presentation, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.



# Cancer Therapies for People of All Ages








## Our Approach

- Develop medicines for genomically-defined cancers
- Establish first-in-class position through rapid registration pathways
- Expand to adolescent and adult populations in parallel and pursue those opportunities with the same commitment we do for children



# Our Pipeline

Product Candidate	Therapeutic Area	Preclinical	Phase 1	Phase 2	Phase 3/ Registrational	Approved	Recent & Anticipated Milestones
<b>Tovorafenib<sup>3</sup></b> Type II RAF Inhibitor  OJEMDA brand name in U.S. <sup>1</sup>  Ex-U.S. Rights: 	BRAF-altered relapsed pLGG						<b>FDA approval</b> April 2024  <b>Ex-U.S. license agreement</b> July 2024
	Frontline RAF- altered pLGG						<b>First patient dosed</b> March 2023
<b>DAY301</b> PTK7 Targeted ADC	Adult and pediatric solid tumors						<b>U.S. IND cleared</b> April 2024  <b>First patient dosed expected</b> 4Q 2024 / 1Q 2025
<b>VRK1 Program</b> VRK1 Inhibitor	Adult and pediatric cancers						<b>In-licensed</b> August 2023

<sup>1</sup> OJEMDA has received accelerated approval by the U.S. Food and Drug Administration. <sup>2</sup> FIREFLY-1 is an open-label, pivotal Phase 2 trial. <sup>3</sup> Ex-U.S. license agreement with Ipsen to commercialize OJEMDA (tovorafenib) outside the U.S. DAY301 is a license agreement with MabCare Therapeutics for exclusive worldwide rights, excluding Greater China, for MTX-13/CB-002, a novel ADC targeting PTK7. pLGG, pediatric low-grade glioma. VRK1 Program is a research collaboration and license agreement with Sprint Bioscience AB for exclusive worldwide rights to a research-stage program targeting VRK1. The safety and efficacy of investigational agents and/or investigational uses of approved products have not been established.







# OJEMDA™ (tovorafenib)

Relapsed or Refractory BRAF-altered pLGG

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# Pediatric Low-Grade Glioma: The Most Common Type Of Brain Tumor In Children

**pLGGs are chronic and relentless**, with patients suffering profound tumor and treatment-associated morbidity that can impact their life trajectory over the long term<sup>1</sup>

## A Serious and Life-Threatening Disease

- For the majority of pLGG patients in the relapsed setting, there is no standard of care and no approved therapies
- Up to 75% of pLGGs have a BRAF alteration<sup>1</sup>, of those ~80% are BRAF fusions and ~20% are BRAF V600 mutations<sup>2-6</sup>
- Despite surgery playing a significant role in treatment, the vast majority of patients still require systemic therapy<sup>7,8</sup>
- Due to high rate of disease recurrence, most patients will undergo multiple lines of systemic therapy over the course of their disease



6 | \*Incidence of BRAF alterations varies across pLGG subtypes. <sup>1</sup>Sievert AJ, Fisher MJ, Pediatric low-grade gliomas. *J Child Neurol.* 2009;24(11):1397-1408. doi:10.1177/0883073809342005. <sup>2</sup>Penman CL et al. *Front Oncol.* 2015;5:54. <sup>3</sup>Cohen AR, *N Engl J Med.* 2020;386(20):1922-1931. <sup>4</sup> Lassaletta A, et al. *J Clin Oncol.* 2017;35(25):2934-2941. <sup>5</sup> Faulkner C, et al. *J Neuropathol Exp Neurol.* 2015;74(9):867-872. <sup>6</sup> Packer RJ, et al. *Neuro Oncol.* 2017;19(6):750-761. <sup>7</sup> Ostrum QT et al., *Neuro Oncol.* 2015; 16(Suppl 10):x1-x36; <sup>8</sup> De Blank P. et al., *Curr Opin Pediatr.* 2019 Feb; 31(1):21-27.

# Conventional Treatments Can Be Disruptive To Childhood And Can Have Significant Long-Term Consequences

## Surgery

- Significant recovery times
- Risks of complications
- Resection may be limited by location of tumor
- Potential for functional deficits based on location of tumor and extent of resection

## Chemotherapy

- Requirement for indwelling catheter and weekly infusions
- Risk of neutropenia, hypersensitivity reactions, nausea and vomiting and peripheral neuropathy

## Radiation

- Risk of secondary malignancy
- Risk of malignant transformation
- Risk of vascular proliferation and stroke
- Neurocognitive impact, depending on location of tumor and radiation field

**Goal of therapy is to control the tumor, minimize the burden of surgery, chemotherapy, and radiation, and reduce the risk of life-long treatment and disease-related effects**



7

Source: 1. Heitzer AM, Raghobar K, Ris MD, et al. Neuropsychological functioning following surgery for pediatric low-grade glioma: a prospective longitudinal study. *J Neurosurg Pediatr.* 2019;1-9. doi:10.3171/2019.9.PEDS19357. 2. Bryant R. Managing side effects of childhood cancer treatment. *J Pediatr Nurs.* 2003;18(2):113-125. doi:10.1053/jpdn.2003.11.3. 3. Zahnreich S, Schmidberger H. Childhood cancer: occurrence, treatment and risk of second primary malignancies. *Cancers (Basel).* 2021;13(11):2607. doi:10.3390/cancers13112607. 4. National Cancer Institute. Fertility issues in girls and women with cancer. <http://www.cancer.gov>. Accessed June 13, 2022. 5. Alessi I, Caroleo A.M., de Palma L, Mastronuzzi A., Pro S., Colafati G.S., Boni A., Della Vecchia N., Velardi M., Evangelisti M., et al. Short and Long-Term Toxicity in Pediatric Cancer Treatment: Central Nervous System Damage. *Cancers.* 2022;14:1540. doi: 10.3390/cancers14061540.

Day One  
BIOPHARMACEUTICALS

# Overview U.S. Prescribing Information For OJEMDA™ (tovorafenib)

Available in tablet formulation and pediatric-friendly powder for oral suspension

## INDICATION

OJEMDA is indicated for the treatment of pediatric patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma harboring a BRAF fusion or rearrangement, or BRAF V600 mutation

## RECOMMENDED DOSE

380 mg/m<sup>2</sup> administered orally once weekly (not to exceed a dose of 600mg once weekly); OJEMDA can be taken with or without food



For full prescribing information, visit [dayonebio.com](http://dayonebio.com)



8 | This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial.

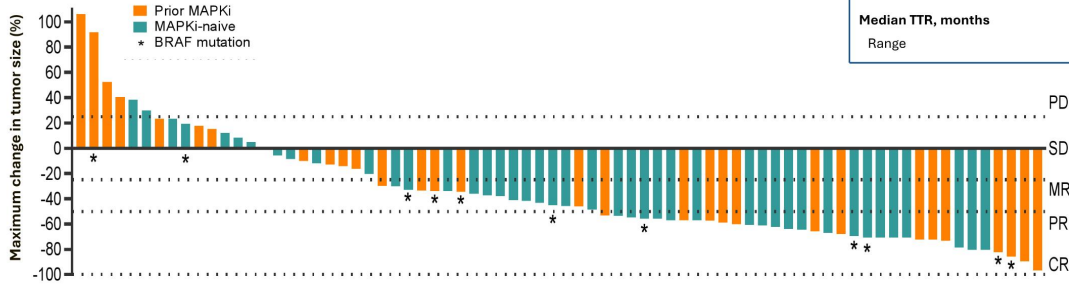
Day One  
BIOPHARMACEUTICALS

# Efficacy Summary From OJEMDA™ (tovorafenib) Prescribing Information



**51%** Overall response rate (RAPNO-LGG) in 76 evaluable patients

Response (IRC)	RAPNO-LGG		
	n	n (%)	95% CI
<b>ORR, n (%)</b>	<b>76</b>	<b>39 (51)</b>	<b>40-63</b>
BRAF fusion or rearrangement	64	33 (52)	39-64
BRAF V600 mutation	12	6 (50)	21-79
Prior MAPKi use	45	22 (49)	31-64
MAPKi-naive	31	17 (55)	36-73
<b>Median DOR, months</b>	<b>39</b>	<b>13.8</b>	<b>11.3-NR<sup>†</sup></b>
<b>Median TTR, months</b>	<b>39</b>	<b>5.3</b>	
Range		1.6-11.2	



June 5, 2023 data cutoff. CI, confidence interval; DOR, duration of response; IRC, independent radiology review committee; LGG, low-grade glioma; NR, not reached; ORR, overall response rate; RAPNO, Response Assessment in Pediatric Neuro-Oncology; TTR, time to response; CR, complete response; PR, partial response; MR, minor response; SD, stable disease; PD, progressive disease. <sup>†</sup> As of the data cutoff, 66% remain on tovorafenib.



# Safety Summary From OJEMDA™ (tovorafenib) Prescribing Information



## Warnings and Precautions

- Hemorrhage
- Skin toxicity, including photosensitivity
- Hepatotoxicity
- Effect on growth
- Embryo-fetal toxicity
- Use in NF1- associated tumors

No boxed warnings or  
contraindications

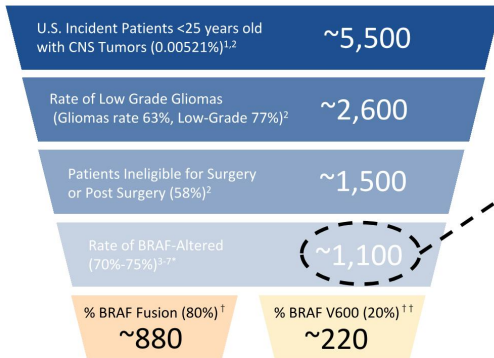
Preferred Term, n (%)	TEAEs (≥ 30% of patients [n=137])	
	Any Grade	Grade ≥3
Any AE	137 (100)	86 (63)
Hair color changes	104 (76)	0
Anemia	81 (59)	15 (11)
Elevated CPK	80 (58)	16 (12)
Fatigue	76 (55)	6 (4)
Vomiting	68 (50)	6 (4)
Hypophosphatemia	64 (47)	0
Headache	61 (45)	2 (1)
Maculo-papular rash	60 (44)	11 (8)
Pyrexia	53 (39)	5 (4)
Dry skin	49 (36)	0
Elevated LDH	48 (35)	0
Increased AST	47 (34)	4 (3)
Constipation	45 (33)	0
Nausea	45 (33)	0
Upper RTI	43 (31)	2 (1)
Dermatitis acneiform	42 (31)	1 (1)
Epistaxis	42 (31)	1 (1)



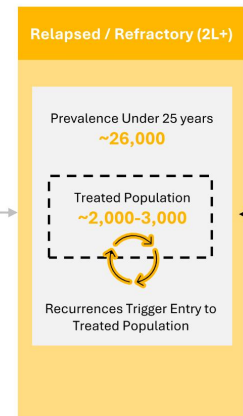
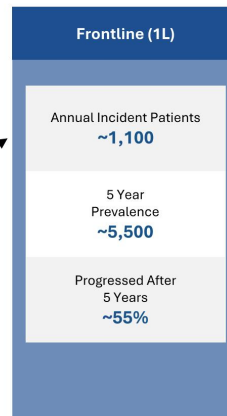
# Addressable U.S. Opportunity of OJEMDA Estimated to be ~2,000-3,000 Patients

Illustrative pLGG Patient Flow<sup>§</sup>

## Incident Therapeutic Build for New pLGG Patients to be Treated in Frontline Setting



1L BRAF-Altered pLGG Patients Eligible for Systemic Therapy



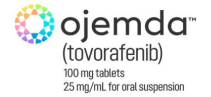
OJEMDA's Addressable Opportunity in the U.S.

Majority of pLGG patients will progress within 5 years



<sup>1</sup> US Census. <sup>2</sup> CBTRUS, Qaddoumi et al 2009, Schreck et al 2019, ClearView Analysis. <sup>3</sup> Penman CL et al. *Front Oncol.* 2015;5:54. <sup>4</sup> Cohen AR., *N Engl J Med.* 2020;386(20):1922-1931. <sup>5</sup> Lassaletta A, et al. *J Clin Oncol.* 2017;35(25):2934-2941. <sup>6</sup> Faulkner C, et al. *J Neuropathol Exp Neurol.* 2015;74(9):867-872. <sup>7</sup> Packer RJ, et al. *Neuro Oncol.* 2017;19(6):750-761. <sup>\*</sup> Incidence of BRAF alterations varies across pLGG subtypes. <sup>†</sup> Predominantly seen in pilocytic astrocytomas. <sup>††</sup> May vary across pLGG subtypes. BRAF, V-Raf murine sarcoma viral oncogene homolog B; MAPK, mitogen-activated protein kinase; pLGG, pediatric low-grade glioma. <sup>§</sup> Estimated annual incidence, estimated prevalence, estimated progression rates, and estimated recurrent/progressive total addressable opportunity are Day One calculations based on publicly available data. The estimated recurrent/progressive total addressable opportunity is based on progression free survival curves modeled from published literature and internal market research conducted by EpidStrategies, A Division of ToxStrategies, Inc. on behalf of Day One.

# Product Profile Aligns With What Physicians Are Looking For In A Therapy



<b>Efficacy</b>	Meaningful tumor stabilization or shrinkage may be possible with OJEMDA. In the clinical trial: <ul style="list-style-type: none"><li>• 51% of children experienced tumor shrinkage by at least 25%</li><li>• 82% of children saw their tumors shrink or remain stable</li></ul>
<b>Safety</b>	Generally well-tolerated therapy, with 9 out of 10 patients staying on treatment in the clinical trial  Most common grade 3 / 4 adverse events include: anemia, elevated CPK, maculopapular rash, fatigue & vomiting
<b>Dosing</b>	Once-weekly, taken with or without food conveniently from home can mean fewer daily interruptions

OJEMDA is indicated for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (LGG) harboring a BRAF fusion, rearrangement, or BRAF V600 mutation.

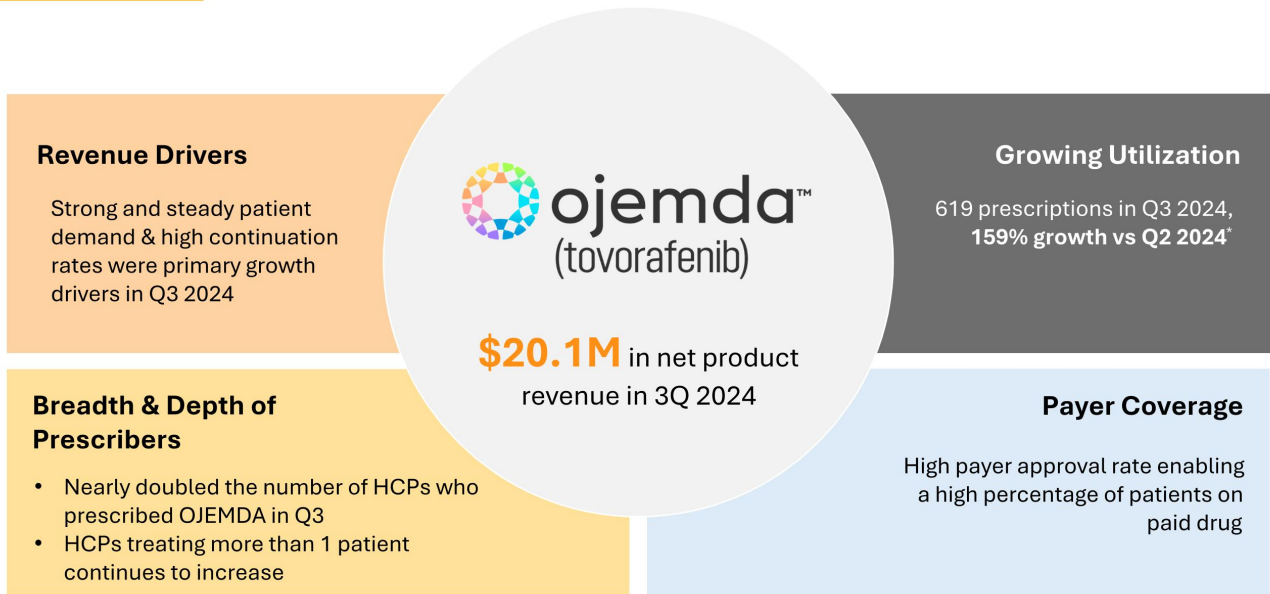


12 | Data from Pivotal Phase 2 FIREFLY-1 trial.



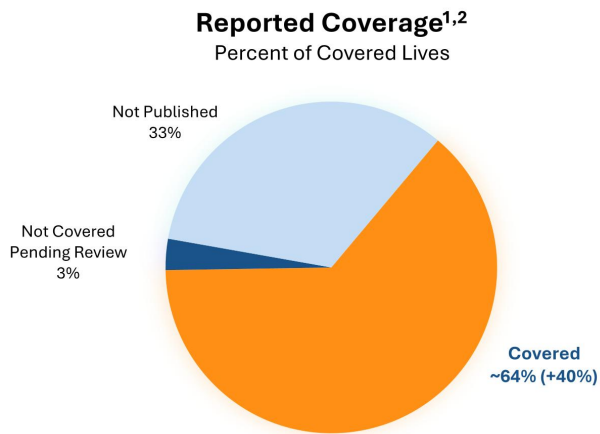


# Strong Q3 Patient Demand Continues to Drive Performance



13 | HCP, Health Care Professional. \* Total prescriptions includes prescriptions for all patients (new & refill, paid & free drug and on-label & off-label patients), prescriptions are approximations based on data available on September 30, 2024.

# Coverage Approval Rates are High Across both Commercial and Medicaid Payers Despite Limited Published Coverage



## Payer Mix

- ~60% commercial patients
- ~40% Medicaid patients

**~80% Patients Approved for Coverage, Despite Lower Reported Coverage<sup>3</sup>**



14 | <sup>1</sup> Breakaway Partners LLC – Breakaway Partners Analytics Platform. Metrics Based on 190.5M Commercial Lives. <sup>2</sup> Artia Solutions - Medicaid Coverage Status Report and Breakaway Partners LLC – Breakaway Partners Analytics Platform. Metrics Based on 73.9M Total Medicaid Lives. <sup>3</sup> Internal prescription data. Data source date 9/30/2024. Coverage comparison data 9/30/2024 vs. 6/30/24.

# Well-Positioned For Commercial Execution And Sustained Growth

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## Continuing Launch Trajectory

**Increase breadth & depth of prescribers**

**Position OJEMDA as the standard of care in 2nd line**

**Establish remaining payer coverage policies**



# FIREFLY-2 / LOGGIC

Pivotal Phase 3 Trial of Tovorafenib in  
Frontline pLGG

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# FIREFLY-2/LOGGIC Pivotal Phase 3 Trial Of Tovorafenib In Frontline pLGG

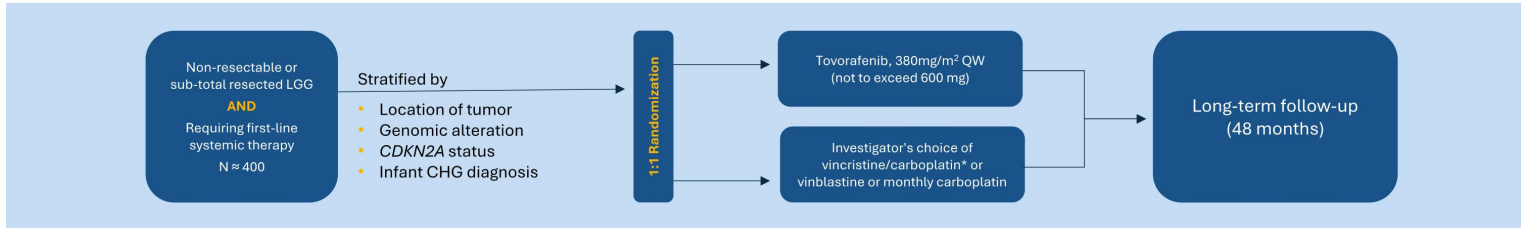


## Trial Design

- Randomized, global, registrational Phase 3 trial of monotherapy tovorafenib vs SoC chemotherapy
- Eligibility: Patients aged 6 months to <25 years with LGG harboring a RAF alteration and requiring first-line systemic therapy
- Tovorafenib available as tablets and pediatric-friendly liquid suspension
- Patients who progress after stopping tovorafenib may be re-challenged
- Patients who progress in the SoC arm during or post-treatment may cross-over to receive tovorafenib

## Endpoints

- **Primary endpoint: ORR based on RAPNO-LGG criteria, assessed by blinded independent central review**
  - **The ORR primary analysis is expected to occur ~12 months after the last patient randomized**
- Key secondary endpoints: PFS and DoR by RAPNO-LGG criteria
- Other secondary endpoints: changes in neurological and visual function, safety, and tolerability
- Key exploratory objectives: QoL and health utilization measures



\* COG or SIOPe-LGG regimen. Abbreviations: CHG, chiasmatic, hypothalamic glioma; DoR, duration of response; LGG, low-grade glioma; ORR, objective response rate; QoL, quality of life; QW, once weekly; SoC, standard of care.



# DAY301

PTK7 Targeted Antibody Drug Conjugate (ADC)

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# DAY301: Next Generation ADC Targeting PTK7

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## PTK7: Clinically-Validated ADC Target

Anti-tumor activity of anti-PTK7 ADC demonstrated in Phase 1b trial of Pfizer / Abbvie's cofetuzumab pelidotin<sup>1</sup>

## DAY301: Potential First-in-Class Asset

Novel ADC active in preclinical models, designed to maximize therapeutic window

## Substantial Development and Commercial Opportunities for DAY301

High PTK7 expression in multiple adult and pediatric tumor histologies

U.S. IND Cleared – Target First Patient Dosed in Q4 2024 / Q1 2025



19 | <sup>1</sup> Cho BC, et al. Ann Oncol. (34; Suppl 2): S460-S461, 2023.



## PTK7: A Clinically-Validated ADC Target

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### Potential opportunity for a next-generation PTK7 ADC with improved therapeutic index

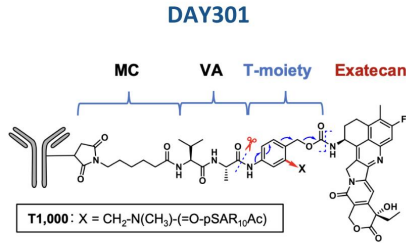
- Clinical results for cofetuzumab pelidotin<sup>1</sup> demonstrated proof of concept for PTK7-targeted ADCs
- Cofetuzumab pelidotin activity seen in multiple tumor types:
  - Ovarian (Pt-resistant): ORR 27% (n=63)
  - TNBC: ORR 21% (n=29)
  - NSCLC: ORR 19% (n=31)
  - mDOR: 4.2-5.7m for Ovarian (Pt-resistant)/TNBC/NSCLC
  - mPFS: 1.5-2.9m for Ovarian (Pt-resistant)/TNBC/NSCLC
- Aur0101 program limited by toxicity, resulting in reduced dose intensity and duration
- A next generation product with optimized properties and a better therapeutic index may achieve greater clinical efficacy





# DAY301: Potential First-In-Class Asset

DAY301 has been designed to maximize therapeutic index and overcome limitations of prior programs

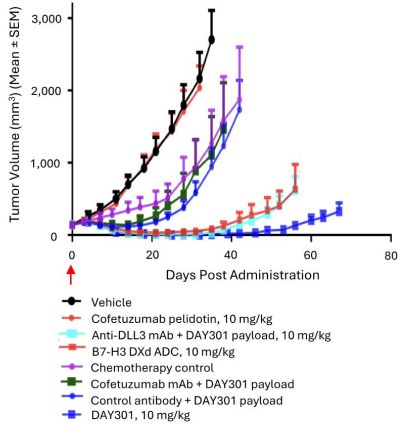


- Tumor regression at tolerable doses seen in multiple preclinical models
- Higher HNSTD in cyno toxicology studies; payload with known safety profile
- High cell permeability / bystander effect; low efflux (not a P-gp substrate)
- Novel, highly hydrophilic, cleavable linker
- Moderate-to-high affinity antibody with favorable stability and developability profile
- Drug-antibody-ratio (DAR) of 8, shown to be effective for other ADCs in solid tumors
- IP: Composition of Matter patent term expected 2044, once issued

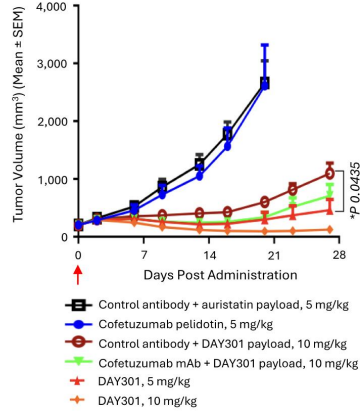
# DAY301: First-in-Class Potential

Improved tumor regression activity demonstrated for DAY301 vs. benchmarks in multiple preclinical models

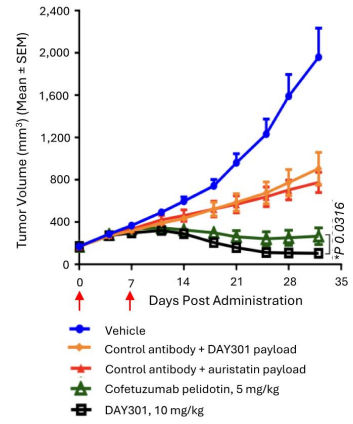
**PDX 362797 SCLC**  
H-score 210



**PDX 362310 TNBC**  
H-score 255



**PDX LD1-200615 HNSCC**  
H-score 120



↑ Indicates when drug was administered

## DAY301: Encouraging Development And Commercial Opportunities

Indication	PTK7 Expression ( $\geq 1+$ )	U.S. Patient Population Cases/deaths	ORR at Relapse	Median OS at Relapse
Endometrial	100% <sup>2</sup>	67,880/13,250 <sup>3</sup>	39% <sup>7</sup>	9 months <sup>7</sup>
Esophageal SCC	76% <sup>1</sup>	22,370/16,130 <sup>3</sup>	5% <sup>4</sup>	3 months <sup>4</sup>
Gastric	35% <sup>2</sup>	26,890/10,880 <sup>3</sup>	12% <sup>14</sup>	6-14 months <sup>15</sup>
Head & Neck SCC	75% <sup>1</sup>	54,540/11,580 <sup>3</sup>	32% <sup>5</sup>	7.8 months <sup>5</sup>
NSCLC	50% <sup>2</sup>	199,393/106,310 <sup>3</sup>	45-60% <sup>8</sup>	7-12 months <sup>9</sup>
Ovarian (platinum resistant)	30% <sup>2</sup> (95%)*	19,710/13,270 <sup>3</sup>	20-35% <sup>3</sup>	17.2 months <sup>6</sup>
Small Cell Lung	50% <sup>2</sup>	35,187/18,760 <sup>3</sup>	10-40% <sup>10</sup>	9-12 months <sup>11</sup>
TNBC	70% <sup>2</sup>	310,720/42,250 <sup>3</sup>	5-35% <sup>12</sup>	28 months <sup>13</sup>
Potential pediatric indications include: neuroblastoma, rhabdomyosarcoma and osteosarcoma				

# DAY301-001: Initial Phase 1a/b Clinical Trial Design

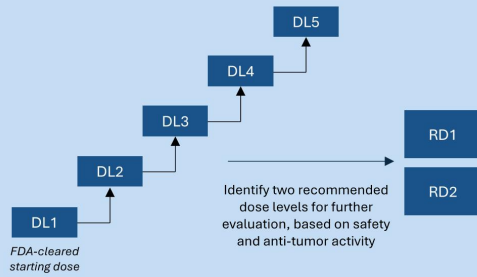
## Key Design Elements

- BOIN design for efficiency of dose escalation
- Backfill active dose levels to generate additional safety data
- Enroll tumor types with known high PTK7 expression
- Advance two recommended dose levels to Phase 1b
- Final dose optimization scheme and approval path pending discussions with FDA at end of dose escalation

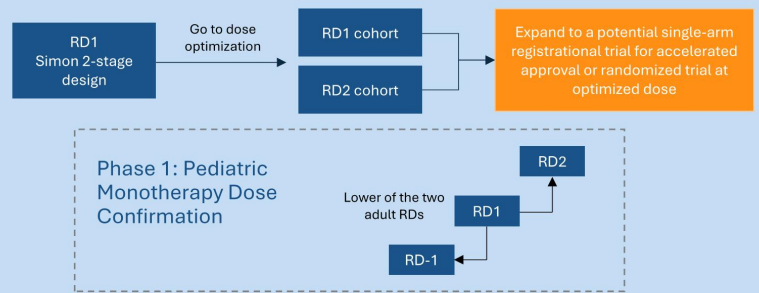
## Adult & Pediatric Development

- Potential adult indications include platinum resistant ovarian cancer, squamous NSCLC, esophageal SCC, HNSCC, endometrial, and/or SCLC
  - Patients to be selected based on PTK7 expression clinical trial assay
- Pediatric dose confirmation and efficacy assessment to begin near/at the end of adult dose escalation
  - Initial target indications include neuroblastoma, osteosarcoma, rhabdomyosarcoma

### Phase 1a: Monotherapy Dose Escalation



### Phase 1b: Monotherapy Dose Expansion and Optimization



# Summary

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## Third Quarter 2024 Financial Results

Financial Summary (\$ in millions)	Three Months Ended 9/30/24	Three Months Ended 9/30/23	Nine Months Ended 9/30/24	Nine Months Ended 9/30/23
OJEMDA Net Revenue	20.1	--	28.3	--
License Revenue	73.7	--	73.7	--
<b>Total Revenue</b>	<b>\$93.8</b>	<b>\$--</b>	<b>\$101.1</b>	<b>\$--</b>
Cost of Product Revenue	1.6	--	2.3	--
Research and Development Expense <sup>1</sup>	33.6	33.2	165.9	93.2
Selling, General and Administrative Expense <sup>2</sup>	29.0	18.3	85.7	53.4
<b>Total Cost and Operating Expenses</b>	<b>\$64.1</b>	<b>\$51.4</b>	<b>\$253.9</b>	<b>\$146.5</b>
Non-operating Income <sup>3</sup>	6.5	5.3	122.8	12.1
Income Tax Benefit (Expense)	0.9	--	(0.7)	--
<b>Net Income (Loss)</b>	<b>\$37.0</b>	<b>(\$46.2)</b>	<b>(\$29.8)</b>	<b>(\$134.4)</b>

	9/30/24	9/30/23
Cash, cash equivalents and short-term investments	\$558.4	\$405.5

26 | All financial information is unaudited. <sup>1</sup> Includes stock-based compensation expense of \$3.8 million and \$13.2 million for the three and nine months ended 9/30/24, and \$3.3 million and \$10.1 million for the three and nine months ended 9/30/23, respectively. <sup>2</sup> Includes stock-based compensation expense of \$7.8 million and \$24.0 million for the three and nine months ended 9/30/24, and \$6.3 million and \$18.4 million for the three and nine months ended 9/30/23, respectively. <sup>3</sup> Includes sale of Priority Review Voucher of \$108.0 million for the nine months ended 9/30/24.

# Priorities as a Commercial-Stage Company

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## Launch OJEMDA™ (tovorafenib)

- Expand awareness amongst physicians and establish broad coverage to enable patient access
- Establish OJEMDA as the standard of care for relapsed or refractory pLGG harboring a BRAF alteration
- Provide a positive and supportive experience when initiating OJEMDA therapy for patients and families

## Advance Portfolio

- FIREFLY-2: Study tovorafenib as a frontline therapy for treatment-naive patients with pLGG
- Develop DAY301, ADC targeting PTK7 in pediatric and adult solid tumors
- Advance early stage VRK1 program to clinical development

## Expand Pipeline

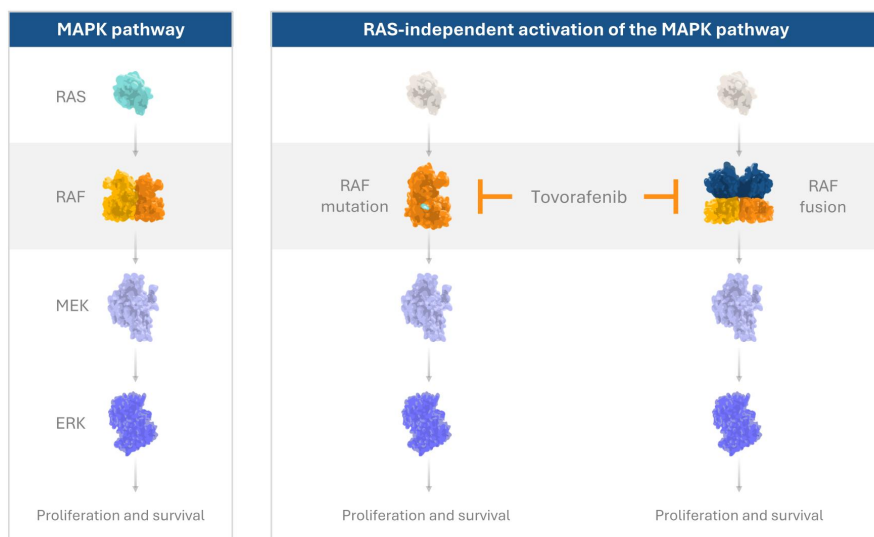
- Grow Day One into a leading, biopharmaceutical company that is the partner of choice for oncology drug development
- Explore selective partnerships as a source of capital and risk sharing
- Further invest in business development activities to expand our multiple asset portfolio for both children and adults

# Appendix





## Tovorafenib Inhibits Both BRAF Fusions And BRAF V600 Mutations



Tovorafenib is an investigational, oral, selective, CNS-penetrant, type II RAF inhibitor that was designed to inhibit both monomeric and dimeric RAF kinase

- Activity in tumors driven by both RAF fusions and BRAF V600E mutations
- Tablet and pediatric-friendly liquid suspension
- Once weekly dosing

Currently approved type I BRAF inhibitors are indicated for use in patients with tumors bearing BRAF V600 mutations

- Type I BRAF inhibitors cause paradoxical MAPK activation in the setting of wild-type RAF, increasing the risk of tumor growth in BRAF fusion-driven

# Pivotal Phase 2 Trial Of Monotherapy Tovorafenib In Relapsed Or Progressive pLGG (FIREFLY-1)

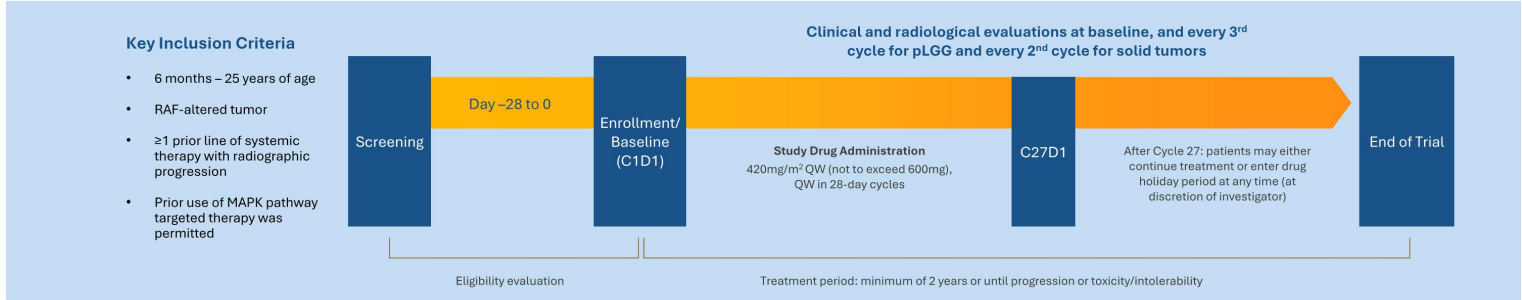


## Trial Design

- Three arm, open-label, global registrational phase 2 trial
- **Pivotal Arm 1 (recurrent/progressive pLGG, n=77): harboring a KIAA1549-BRAF fusion or BRAF V600E mutation**
- Arm 2 (expanded access recurrent/progressive LGG, n=60): harboring an activating RAF alteration
- Arm 3 (extracranial solid tumors): harboring an activating RAF fusion

## Endpoints (Pivotal Arm 1)

- **Primary endpoint: ORR based on RANO-HGG<sup>1</sup>, assessed by blinded independent central review**
- Secondary endpoints: ORR by RAPNO-LGG<sup>2</sup> assessed by blinded independent central review; PFS, DoR; TTR, CBR; safety
- Exploratory analyses: ORR and CBR by RANO-LGG<sup>3</sup> assessed by blinded independent central review



30 | June 5, 2023 data cutoff. <sup>1</sup>Wen PY, et al. *J Clin Oncol.* 2010;28(11):1963-1972. <sup>2</sup>Fangusaro J, et al. *Lancet Oncol.* 2020;21(6):e305–316. <sup>3</sup>van den Bent MJ, et al. *Lancet Oncol.* 2011;12(6):583-593. Abbreviations: CBR, clinical benefit rate; IRC, independent review committee; C, cycle; D, day; LGG, low-grade glioma; ORR, objective response rate; PFS, progression-free survival; DoR, duration of response; QW, once weekly; TTR, time to response; RANO, Response Assessment in Neuro-Oncology; RAPNO, Response Assessment in Pediatric Neuro-Oncology; MAPK, mitogen-activated protein kinase. For more information, please refer to NCT04775485





# Data from Pivotal Phase 2 FIREFLY-1 Trial

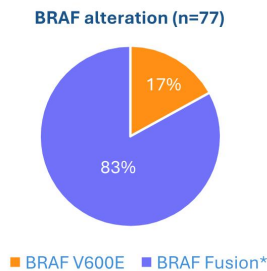
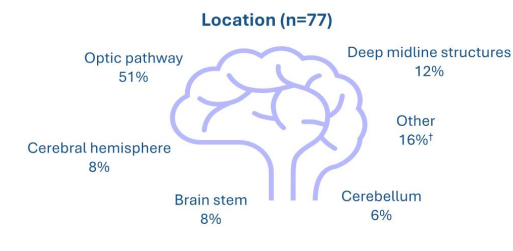
June 5, 2023 data cutoff

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# FIREFLY-1 Baseline Patient Characteristics



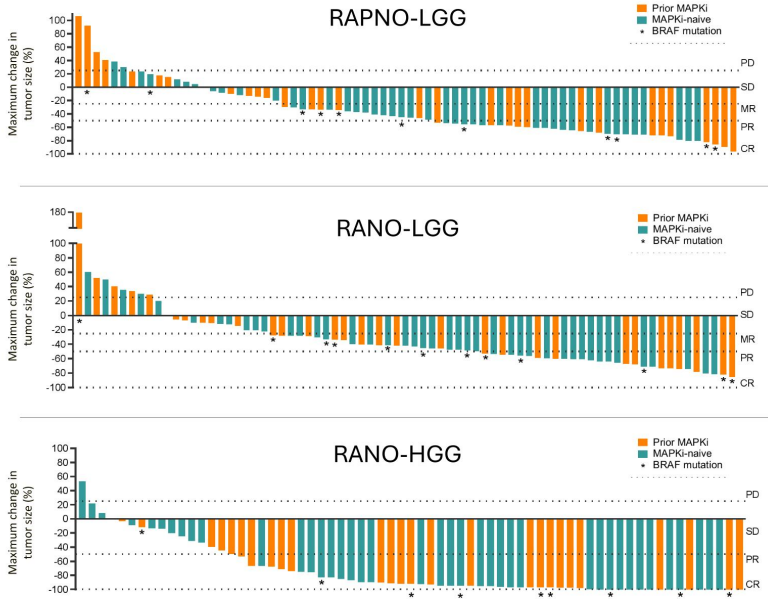
Characteristic	Arm 1 (n=77)
Median age, years (range)	8 (2-21)
Sex, n (%)	
Male	40 (52)
Female	37 (48)
Race, n (%)	
White	41 (53)
Asian	5 (6)
Black	2 (3)
Multiple	3 (4)
Other	6 (8)
Not specified	20 (26)
Number of lines of prior systemic therapy	
Median (range)	3 (1-9)
1, n (%)	17 (22)
2, n (%)	21 (27)
≥3, n (%)	39 (51)
Prior MAPK pathway targeted therapy, n (%)	
Prior MEK inhibitor	43 (56)
Prior BRAF inhibitor	8* (10)
Prior BRAF and MEK inhibitors†	5 (7)
Any MAPK inhibitor	46 (60)



32 | June 5, 2023 data cutoff. \*Includes 6 patients with BRAF duplication and 2 with BRAF rearrangement per fluorescence in situ hybridization or in situ hybridization. †Includes tumors that were extending into multiple regions of the brain, leptomeningeal disease, and/or spinal disease. ‡The 5 patients that had previously received both a MEK inhibitor and also a BRAF inhibitor are recorded in both the “Prior MEK inhibitor” and “Prior BRAF inhibitor” groups. MAPK, mitogen-activated protein kinase.



# Tumor Response To Tovorafenib Using RAPNO-LGG, RANO-LGG and RANO-HGG

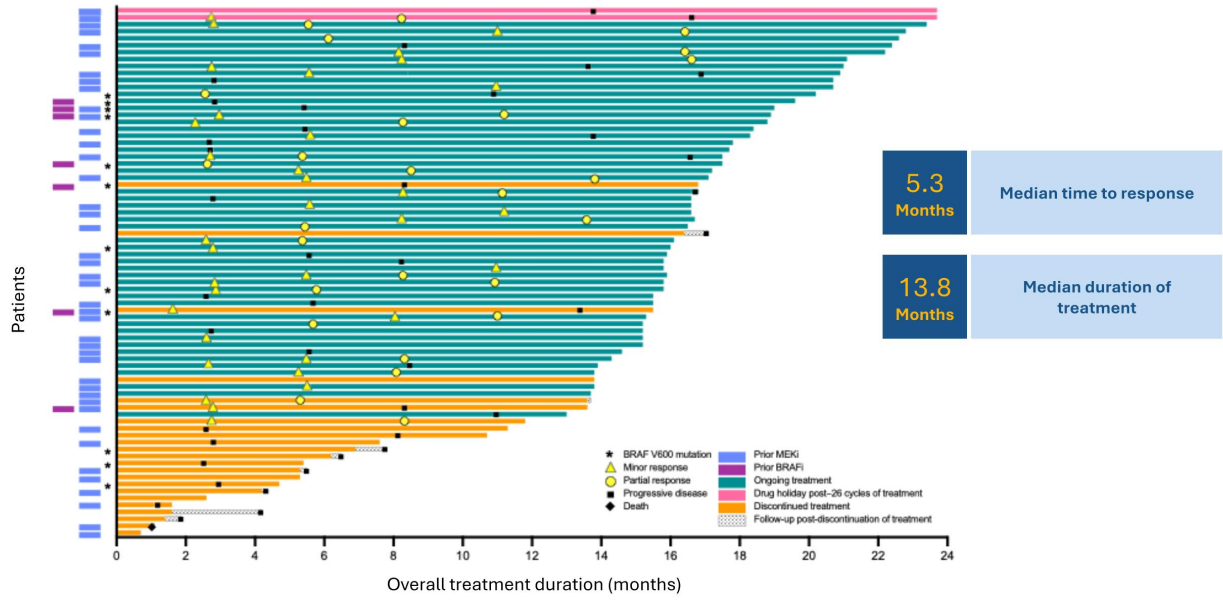


Response (IRC)	RAPNO-LGG n=76	RANO-LGG N=76	RANO-HGG N=69
<b>ORR,* n (%)</b>	<b>39 (51)</b>	<b>40 (53)</b>	<b>46 (67)</b>
95% CI	40-63	41-64	54-78
<b>CBR,* n (%)</b>			
SD of any length of time	62 (82)	63 (83)	64 (93)
SD ≥12 months	43 (57)	46 (61)	54 (78)
<b>BOR,* n (%)</b>			
CR	0	0	12 (17)
PR	28 (37)	20 (26)	34 (49)
MR	11 (14)	20 (26)	n/a
SD	23 (30)	23 (30)	18 (26)
SD <12 months	19 (25)	17 (22)	10 (14)
SD ≥12 months	4 (5)	6 (8)	8 (12)
PD	13 (17)	11 (14)	4 (6)
NE	1 (1)	2 (3)	1 (1)
<b>Median DOR, months</b>	<b>13.8</b>	<b>14.4</b>	<b>16.6</b>
95% CI	11.3-NR	11.0-NR	11.6-NR
<b>Median TTR, months</b>	<b>5.3</b>	<b>5.5</b>	<b>3.0</b>
Range	1.6-11.2	1.6-11.3	2.6-16.6

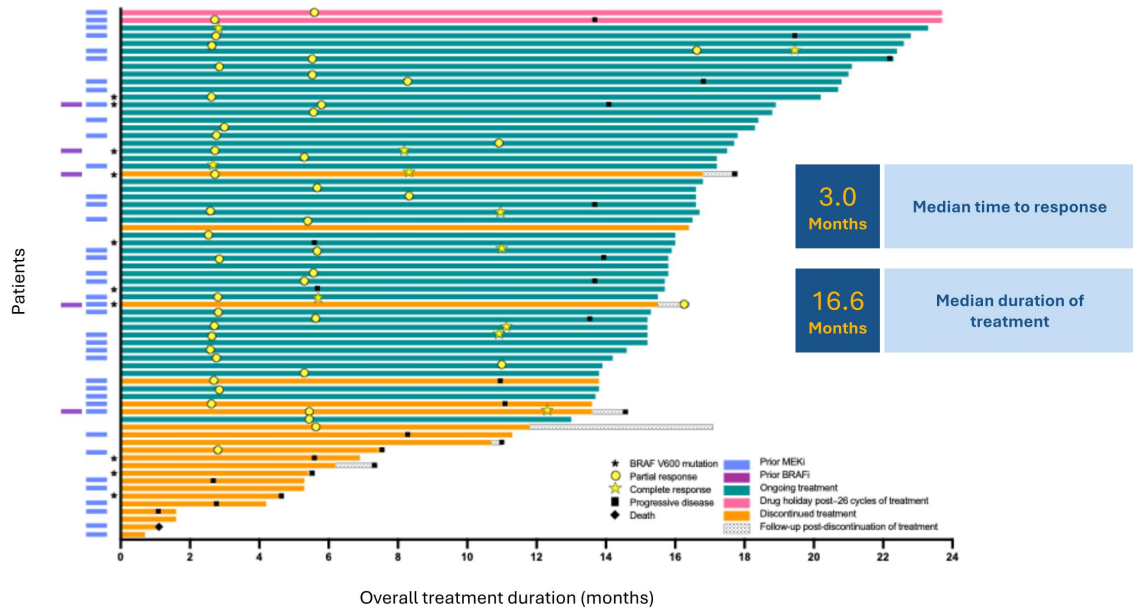
33 June 5, 2023 data cutoff. BOR, best overall response; CBR, clinical benefit rate; CI, confidence interval; CR, complete response; DOR, duration of response; HGG, high-grade glioma; IRC, independent radiology review committee; LGG, low-grade glioma; MR, minor response; n/a, not applicable; NE, not evaluable; NR, not reached; ORR, overall response rate; PD, progressive disease; PR, partial response; RANO, Response Assessment in Neuro-Oncology; RAPNO, Response Assessment in Pediatric Neuro-Oncology; SD, stable disease; TTR, time to response. \* ORR, CBR and BOR for RAPNO-LGG and RANO-LGG included MRs.



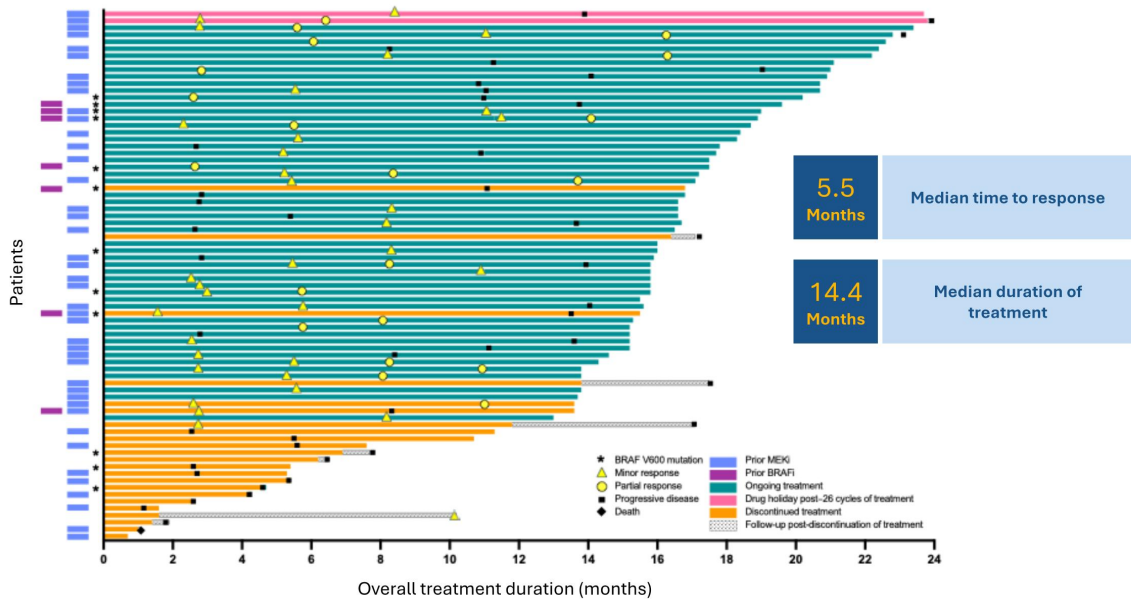
# Duration Of Tovorafenib Therapy For All Patients With RAPNO-LGG Evaluable Lesions



# Duration Of Tovorafenib Therapy For All Patients With RANO-HGG Evaluable Lesions



# Duration Of Tovorafenib Therapy For All Patients With RANO-LGG Evaluable Lesions





# Tumor Response To Tovorafenib Across Three Assessment Criteria Were Consistent Across BRAF Fusion And Mutation Patients, and Patients With Prior MAPK Treatment



Response (IRC)	RAPNO-LGG <sup>2</sup>		RANO-LGG <sup>3,4</sup>		RANO-HGG <sup>1</sup>	
	n		n		n	
<b>ORR,* n (%)</b>	<b>76</b>	<b>39 (51)</b>	<b>76</b>	<b>40 (53)</b>	<b>69</b>	<b>46 (67)</b>
BRAF fusion	64	33 (52)	64	33 (52)	59	41 (69)
BRAF mutation	12	6 (50)	12	7 (58)	10	5 (50)
Prior MAPKi	45	22 (49)	45	23 (51)	41	29 (71)
MAPKi-naive	31	17 (55)	31	17 (55)	28	17 (61)
<b>CBR,* n (%) (SD of any length of time)</b>	<b>76</b>	<b>62 (82)</b>	<b>76</b>	<b>63 (83)</b>	<b>69</b>	<b>64 (93)</b>
BRAF fusion	64	53 (83)	64	53 (83)	59	55 (93)
BRAF mutation	12	9 (75)	12	10 (83)	10	9 (90)
Prior MAPKi	45	38 (84)	45	38 (84)	41	37 (90)
MAPKi-naive	31	24 (77)	31	25 (81)	28	27 (96)
<b>CBR,* n (%) (SD ≥12 months)</b>	<b>76</b>	<b>43 (57)</b>	<b>76</b>	<b>46 (61)</b>	<b>69</b>	<b>54 (78)</b>
BRAF fusion	64	37 (58)	64	39 (61)	59	49 (83)
BRAF mutation	12	6 (50)	12	7 (58)	10	5 (50)
Prior MAPKi	45	25 (56)	45	26 (58)	41	33 (80)
MAPKi-naive	31	18 (58)	31	20 (65)	28	21 (75)
<b>Median DOR, months (95% CI)**</b>	<b>39</b>	<b>13.8 (11.3-NR)</b>	<b>40</b>	<b>14.4 (11.0-NR)</b>	<b>46</b>	<b>16.6 (11.6-NR)</b>
BRAF fusion	33	13.8 (11.3-NR)	33	16.3 (11.0-NR)	41	16.8 (11.6-NR)
BRAF mutation	6	NR (8.4-NR)	7	12.0 (8.4-NR)	5	15.1 (8.3-NR)
Prior MAPKi	22	13.8 (11.3-NR)	23	12.0 (8.5-NR)	29	15.1 (9.0-16.8)
MAPKi-naive	17	NR (8.4-NR)	17	16.3 (8.4-NR)	17	NR (11.6-NR)

37 | June 5, 2023 data cutoff. <sup>1</sup> Fangusaro J, et al. *Lancet Oncol.* 2020;21(6):e305-316. <sup>2</sup> Fangusaro J, et al. *Lancet Oncol.* 2020;21(6):e305-316. <sup>3</sup> van den Bent MJ, et al. *Lancet Oncol.* 2011;12(6):583-593. <sup>4</sup> Wen PY, et al. *J. Clin Oncol.* 2017;35(21):2439-2449. \* ORR, CBR for RAPNO-LGG and RANO-LGG included MRs. \*\* the 95% CI were calculated using Kaplan-Meier method.



# Tovorafenib Safety Data (n=137)



Preferred Term, n (%)	TEAEs		TRAEs	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Any AE	137 (100)	86 (63)	134 (98)	58 (42)
Hair color changes	104 (76)	0	104 (76)	0
Anemia	81 (59)	15 (11)	67 (49)	14 (10)
Elevated CPK	80 (58)	16 (12)	77 (56)	16 (12)
Fatigue	76 (55)	6 (4)	60 (44)	6 (4)
Vomiting	68 (50)	6 (4)	28 (20)	3 (2)
Hypophosphatemia	64 (47)	0	48 (35)	0
Headache	61 (45)	2 (1)	29 (21)	0
Maculo-papular rash	60 (44)	11 (8)	56 (41)	11 (8)
Pyrexia	53 (39)	5 (4)	17 (12)	1 (1)
Dry skin	49 (36)	0	45 (33)	0
Elevated LDH	48 (35)	0	42 (31)	0
Increased AST	47 (34)	4 (3)	41 (30)	4 (3)
Constipation	45 (33)	0	31 (23)	0
Nausea	45 (33)	0	25 (18)	0
Upper RTI	43 (31)	2 (1)	2 (1)	0
Dermatitis acneiform	42 (31)	1 (1)	41 (30)	1 (1)
Epistaxis	42 (31)	1 (1)	27 (20)	0
Decreased appetite	39 (28)	5 (4)	28 (20)	4 (3)
Paronychia	36 (26)	2 (1)	32 (23)	2 (1)
Pruritus	35 (26)	1 (1)	32 (23)	1 (1)
COVID-19	34 (25)	0	0	0

- The most common reasons for discontinuation were tumor hemorrhage (3 patients) and decrease in growth velocity (2 patients)
- 33 patients (24%) had TRAEs leading to dose reduction; 50 patients (37%) had TRAEs leading to dose interruption
- Median duration of dose interruption was 2 weeks
- 9 patients (7%) had TRAEs leading to discontinuation