

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): July 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 July 30, 2024, Day One Biopharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 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 June 30, 2024 is attached as Exhibit 99.2 to this report.

**Item 7.01 Regulation FD Disclosure.**

On July 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 June 30, 2024, dated July 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: July 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 Second Quarter 2024 Financial Results and Corporate Progress

*Achieved \$8.2 million in OJEMDA™ (tovorafenib) net product revenues in initial 2 months of launch*

*Expanded pipeline with DAY301, potential first-in-class Antibody Drug Conjugate (ADC) targeting PTK7*

*Entered into exclusive licensing agreement with Ipsen to commercialize tovorafenib outside of the U.S. for approximately \$111 million upfront in cash and equity investment at a premium*

*Entered into a definitive agreement for an oversubscribed private placement of its securities for total gross proceeds of approximately \$175 million*

*Company to host conference call and webcast today, July 30, 8:00 a.m. Eastern Time*

**BRISBANE, Calif., Jul. 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 second quarter 2024 financial results and highlighted recent corporate achievements.

“We had an outstanding quarter across all facets of our business,” said Jeremy Bender, Ph.D., chief executive officer of Day One. “Demand for OJEMDA led to strong early launch performance following our first approval, and we made significant progress advancing our programs and pipeline, including the addition of DAY301, a potential first-in-class ADC targeting PTK7 that we expect to be in the clinic in the coming months.”

### Program Highlights

- OJEMDA received U.S. Food and Drug Administration (FDA) accelerated approval in April 2024. It is the first and only FDA approved therapy for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (pLGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation.
  - Day One provided updated duration of treatment 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 treatment is now 23.7 months, with some patients being on treatment out to 32 months. Additional analyses will be presented at future medical conferences.
  - 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 will receive approximately \$111 million upfront in cash and equity investment at a premium with up to approximately \$350 million in
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additional launch and sales milestone payments as well as tiered double-digit royalties starting in mid-teens percentage on net sales. Ipsen secured commercialization rights to tovorafenib outside of the U.S.

- Day One entered into an exclusive licensing agreement with MabCare Therapeutics for its novel ADC targeting protein-tyrosine kinase 7 (PTK7) in June 2024. The Company expects to dose the first patient in the Phase I portion of the Phase 1/2a clinical trial of DAY301 in the fourth quarter of 2024 or first quarter of 2025.
- Day One presented a poster on tovorafenib demonstrating reversibility of changes in growth velocity observed in the Phase 2 FIREFLY-1 clinical trial at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting. These data were also shared at the 21<sup>st</sup> International Symposium on Pediatric Neuro-Oncology (ISPNO).
- Day One made the decision to close the pimasertib program in July 2024, including the FIRELIGHT-1 trial evaluating it in combination with tovorafenib. Resources will be redirected to the DAY301 program and results will be shared at a future medical meeting or publication.
- 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.

#### Corporate Highlights and Upcoming Milestones

- Day One announced it entered into a definitive agreement for an oversubscribed private placement of its securities for total gross proceeds of approximately \$175.0 million in July 2024.
- The Company sold the rare pediatric disease Priority Review Voucher awarded by the FDA upon OJEMDA's approval for total cash proceeds of \$108.0 million in May 2024, representing a gain on sale.
- Commercial operations veteran John Stubenrauch joined Day One in July 2024 as Chief Technology Officer. Dr. Stubenrauch, PhD, MBA, was most recently Chief Operating Officer at Nutcracker Therapeutics and brings more than 25 years of experience developing and commercializing medicines, including ADCs, as well as a broad range of product modalities.

#### Second Quarter 2024 Financial Highlights

- **Cash Position:** The Company's cash, cash equivalents and short-term investments totaled \$361.9 million as of June 30, 2024.
  - **Product Revenue, Net:** OJEMDA net product revenues were \$8.2 million for the second quarter of 2024, the first partial quarter of the U.S. launch.
  - **R&D Expenses:** Research and development expenses were \$92.1 million for the second quarter of 2024 compared to \$32.2 million for the second quarter of 2023. The increase was primarily due to
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the MabCare Therapeutics license agreement upfront payment of \$55.0 million, increased clinical trial activities related to tovorafenib, and additional employee compensation costs.

- **SG&A Expenses:** Selling, general and administrative expenses were \$30.2 million for the second quarter of 2024 compared to \$17.1 million for the second quarter of 2023. The increase was primarily due to additional employee compensation costs, commercial launch activities, and increased professional service expenses to support company growth.
- **Net Loss:** Net loss totaled \$4.4 million for the second quarter of 2024 with non-cash stock-based compensation expense of \$13.0 million, compared to \$45.9 million for the second quarter of 2023 with non-cash stock-based compensation expense of \$9.5 million.

#### Upcoming Events

- 2024 Webbush PacGrow Healthcare Conference, August 12-14, 2024

#### Conference Call

Day One will host a conference call and webcast today, July 30 at 8:00 a.m. Eastern Time. To access the live conference call by phone, dial 877-704-4453 (domestic) or 201-389-0920 (international), and 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

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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™) and 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 clinical trials, the execution of the Phase 2 and Phase 3 clinical trial for tovorafenib as designed, 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue:				
Product revenue, net	\$ 8,192	\$ —	\$ 8,192	\$ —
Cost and operating expenses:				
Cost of product revenue	707	—	707	—
Research and development	92,106	32,182	132,316	60,010
Selling, general and administrative	30,186	17,072	56,743	35,099
Total cost and operating expenses	122,999	49,254	189,766	95,109
Loss from operations	(114,807)	(49,254)	(181,574)	(95,109)
Non-operating income (expense)				
Gain from sale of priority review voucher	108,000	—	108,000	—
Investment income, net	3,962	3,406	8,327	6,872
Other expense, net	(10)	(15)	(20)	(19)
Total non-operating income, net	111,952	3,391	116,307	6,853
Loss before income taxes	(2,855)	(45,863)	(65,267)	(88,256)
Income tax expense	(1,552)	—	(1,552)	—
Net loss	\$ (4,407)	\$ (45,863)	\$ (66,819)	\$ (88,256)
Net loss per share, basic and diluted	\$ (0.05)	\$ (0.61)	\$ (0.77)	\$ (1.20)
Weighted-average number of common shares used in computing net loss per share, basic and diluted	87,121,310	74,964,878	86,864,545	73,478,567

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

	June 30, 2024	December 31, 2023
Cash, cash equivalents and short-term investments	\$ 361,866	\$ 366,347
Total assets	400,437	376,048
Total liabilities	93,706	29,508
Accumulated deficit	(525,404)	(458,585)
Total stockholders' equity	\$ 306,731	\$ 346,540

DAY ONE MEDIA  
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DAY ONE INVESTORS  
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# Second Quarter 2024

## Financial Results and Corporate Progress

July 2024



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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, 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) Commercial Performance

- Lauren Merendino (Chief Commercial Officer)

## Portfolio Expansion & Updates

- Sam Blackman (Co-Founder & Head of R&D)

## Second Quarter 2024 Financial Performance

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

## Q&A Session



# Opening Remarks

Jeremy Bender

*Chief Executive Officer*

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# Executing On Our Priorities As A Commercial-Stage Company

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## OJEMDA Launch

Strong start with \$8.2M in net product revenue in the initial 8 weeks on market

## Commercial Execution

Strong cadence of new patient starts and rapid transition of EAP patients, accompanied by broad reimbursement across payer types has set us on a solid trajectory

## Pipeline Progress

Focused path to value creation, potential first-in-class DAY301 ADC targeting PTK7

## Financial Position

Strong and durable financial position with \$361.9M in cash<sup>1</sup>



**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 June 30, 2024.





# OJEMDA™ (tovorafenib) Commercial Performance

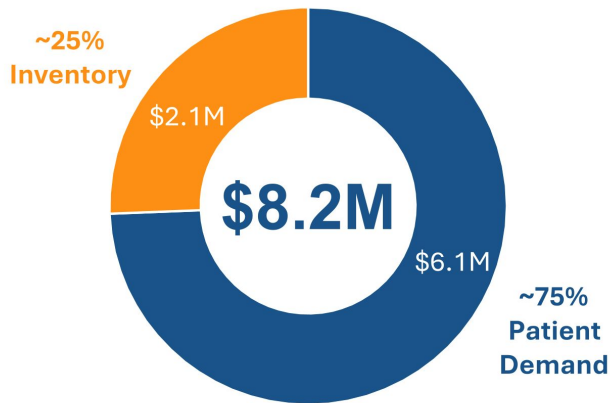
Lauren Merendino

*Chief Commercial Officer*

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# Robust Q2 Performance Driven by Excellent Execution & Strong Patient Demand

## Q2 OJEMDA Net Revenue



## Launch Execution Excellence

### Accelerated Customer Engagement

Live engagements with >90% of ~200 target accounts

### High Pre-Launch Awareness

Awareness pre-launch paved the way for rapid uptake

### Payer Education

Engagement pre & post approval to educate on pLGG enabled early access



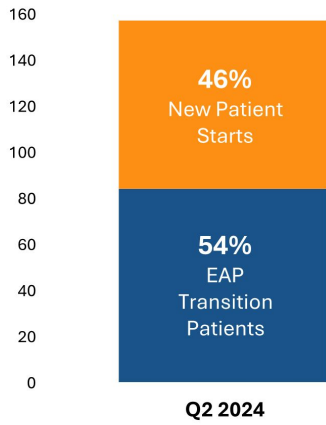
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pLGG, pediatric low-grade glioma



# Patient Demand Driven By Both EAP Transition Patients and New Patient Starts

## 157 Patient Starts on OJEMDA in Q2 2024\*



Strong new patient starts ramp, demonstrating underlying demand



Rapid transition of patients on Early Access Program (EAP) to commercial drug



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\* Includes US patients on paid drug and commercial free drug programs. Does not include patients not yet transitioned from EAP.



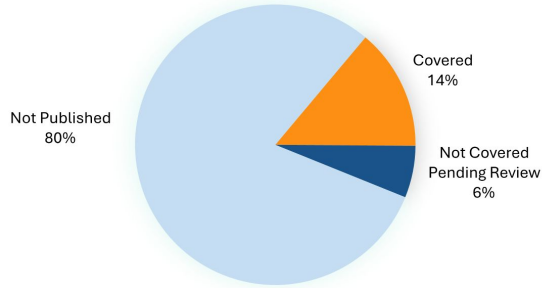
# Despite Limited Published Coverage To Date, Coverage Approval Rates are High Across both Commercial and Medicaid Payers

59% Commercial Patients

Payer Mix

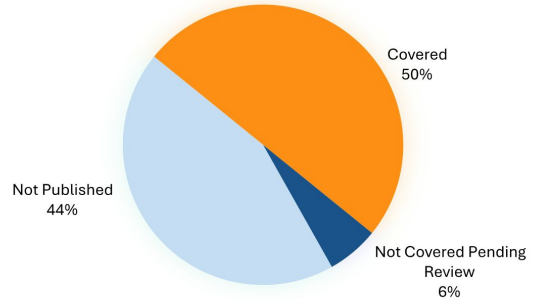
38% Medicaid Patients

**Commercial Reported Coverage<sup>1</sup>**  
Percent of Covered Lives



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

**Medicaid Reported Coverage<sup>2</sup>**  
Percent of Covered Lives



**>70% 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 Commercial Execution And Sustained Growth

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## Continuing Launch Trajectory

**Increase breadth & depth of prescribers**

**Establish OJEMDA in the 2nd line**

**Solidify payer coverage policies**



# Portfolio Expansion and Updates

Sam Blackman

*Co-Founder & Head of R&D*

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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 Potential 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



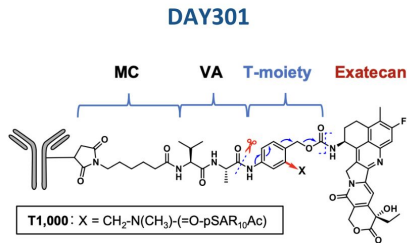
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<sup>1</sup> Cho BC, et al. Ann Oncol. (34; Suppl 2): S460-S461, 2023.



# 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 to 2044, once issued

# DAY301-001: Initial Phase 1/2a Clinical Trial Design

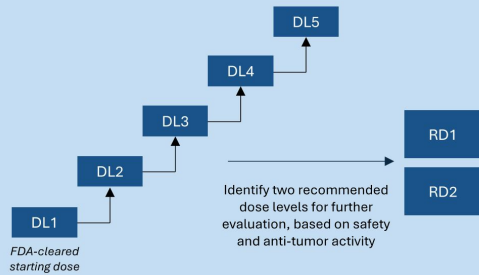
## Key Design Elements

- 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/2a
- Final dose optimization scheme and approval path pending discussions with FDA at end of dose escalation

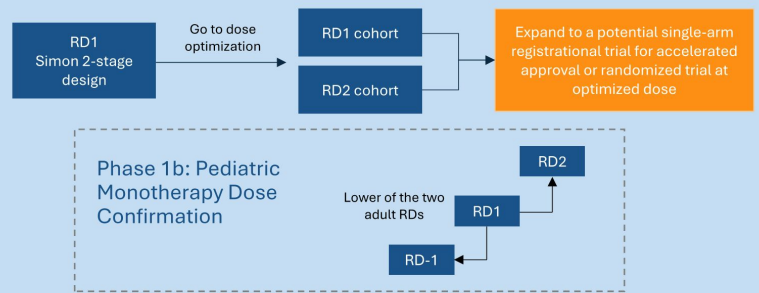
## Adult & Pediatric Development

- 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 2a: Monotherapy Dose Expansion and Optimization



# Our Pipeline

Product Candidate	Therapeutic Area	Preclinical	Phase 1	Phase 2	Phase 3/ Registrational	Approved
<b>Tovorafenib</b> Type II RAF Inhibitor  OJEMDA brand name in U.S. <sup>1</sup>  Ex-U.S. Rights <sup>2</sup> : 	BRAF-altered Relapsed pLGG					
	Frontline RAF-altered pLGG					
<b>DAY301</b> PTK7 Targeted ADC	Adult and pediatric solid tumors					
<b>VRK1 Program</b> VRK1 Inhibitor	Adult and pediatric cancers					

pLGG, pediatric low-grade glioma. <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> 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. 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.



# Second Quarter 2024 Financial Performance

Charles York

*Chief Operating Officer and Chief Financial Officer*

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## Second Quarter 2024 Financial Results

Financial Summary (\$ in millions)	Three Months Ended 6/30/24	Three Months Ended 6/30/23	Six Months Ended 6/30/24	Six Months Ended 6/30/23
<b>OJEMDA Net Revenue</b>	<b>\$8.2</b>	<b>\$--</b>	<b>\$8.2</b>	<b>\$--</b>
Cost of Sales	0.7	--	0.7	--
Research and Development Expense <sup>1</sup>	92.1	32.2	132.3	60.0
Selling, General and Administrative Expense <sup>2</sup>	30.2	17.1	56.8	35.1
<b>Total Cost and Operating Expenses</b>	<b>123.0</b>	<b>49.3</b>	<b>189.8</b>	<b>95.1</b>
Other Income <sup>3</sup>	111.9	3.4	116.3	6.8
Income Tax Expense	1.5	--	1.5	--
<b>Net Loss</b>	<b>\$4.4</b>	<b>\$45.9</b>	<b>\$66.8</b>	<b>\$88.3</b>
			6/30/24	6/30/23
Cash, cash equivalents and short-term investments			\$361.9	\$442.9

17 | All financial information is unaudited. <sup>1</sup> Includes stock-based compensation expense of \$4.7 million and \$9.4 million for the three and six months ended 6/30/24, and \$3.4 million and \$6.8 million for the three and six months ended 6/30/23, respectively. <sup>2</sup> Includes stock-based compensation expense of \$8.3 million and \$16.3 million for the three and six months ended 6/30/24, and \$6.1 million and \$12.1 million for the three and six months ended 6/30/23, respectively. <sup>3</sup> Includes sale of Priority Review Voucher of \$108.0 million for the three and six months ended 6/30/24

**Thank You**



# Day One Biopharmaceuticals

Targeted Therapies for People of All Ages

July 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, 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.

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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>FIREFLY-1 (pivotal Phase 2)<sup>2</sup></b>  	<b>FDA approval</b> April 2024  <b>Ex-U.S. license agreement</b> July 2024
	Frontline RAF- altered pLGG						<b>FIREFLY-2 (pivotal Phase 3)</b>	<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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# OJEMDA Now Approved In The U.S.

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OJEMDA is the **first and only FDA Approved therapy** for the treatment of 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



6

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.





# 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



<sup>1</sup>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**



8

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.

# 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)



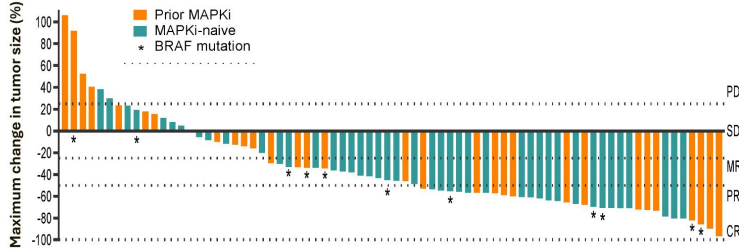
9 | This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial.

Day One  
BIOPHARMACEUTICALS

# Efficacy Summary From OJEMDA™ (tovorafenib) Prescribing Information



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



RAPNO-LGG			
Response (IRC)	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

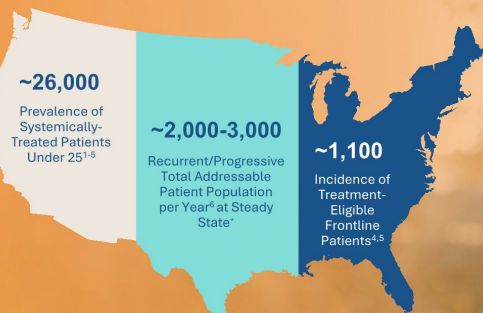
- Hemorrhage
- Skin toxicity, including photosensitivity
- Hepatotoxicity
- Effect on growth
- Embryo-fetal toxicity
- Use in NF1- associated tumors

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)



# Estimated *BRAF*-Altered pLGG Patient Population In The U.S.



Up to 75% of pLGG cases are *BRAF*-altered<sup>7-14</sup>

*Incidence of BRAF alterations varies across pLGG subtypes*



of these cases have **BRAF fusion, primarily KIAA1549-BRAF<sup>7</sup>**



of these cases have **BRAF point mutations, primarily BRAF V600<sup>11</sup>**



<sup>1</sup> Selt F, van Tilburg CM, Bison B, et al. Response to trametinib treatment in progressive pediatric low-grade glioma patients. *J Neurooncol.* 2020;149(3):499-510. doi:10.1007/s11060-020-03640-3<sup>2</sup> Ryall S, Tabori U, Hawkins C. Pediatric low-grade glioma in the era of molecular diagnostics. *Acta Neuropathol Commun.* 2020;8(1):30. doi:10.1186/s40478-020-00902-z.<sup>3</sup> SEER US complete prevalence counts of patients aged under 25 with Brain and Other Nervous Systems tumors as of January 1, 2017. <sup>4</sup> CBTRUS, Qaddoumi et al 2009, Schreck et al 2019, ClearView Analysis. <sup>5</sup> US Census. Estimated annual incidence, estimated prevalence, and estimated recurrent/progressive total addressable patient population are Day One calculations based on publicly available data. <sup>6</sup> Source: Internal market research conducted by EpiQStrategies, A Division of ToxStrategies, Inc. on behalf of Day One. <sup>7</sup> Ryall S, et al. *Acta Neuropathol Commun.* 2020;8(1):30. <sup>8</sup> Behling F, et al. *Cancers (Basel).* 2019;11(6):794. <sup>9</sup> Penman CL, et al. *Front Oncol.* 2015;5:54. <sup>10</sup> Packer RJ, et al. *Neuro Oncol.* 2017;19(6):750-761. <sup>11</sup> Cohen AR, et al. *N Engl J Med.* 2022;386(20):1922-1931. <sup>12</sup> Ryall S, et al. *J Neuropathol Exp Neurol.* 2017;76(7):562-570. <sup>13</sup> Lassaletta A, et al. *J Clin Oncol.* 2017;35(25):2934-2941. <sup>14</sup> Faulkner C, et al. *J Neuropathol Exp Neurol.* 2015;74(9):867-872. <sup>15</sup> The estimated addressable pool of recurrent or progressive pLGG patients is based on progression free survival curves modeled from published literature. <sup>16</sup> Predominantly seen in pilocytic astrocytomas. <sup>17</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.

# What Physicians & Caregivers Are Looking For In A Therapy

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## What HCP's are Seeking

Effective in stopping or shrinking tumors  
Manageable safety profile  
Minimal disruption to child's life



*"The goal is not interfering with the child's life."*  
– Ped Onc, Chicago Ad Board

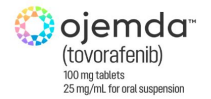
## What Caregivers are Seeking

Live as normal of a childhood as possible  
Minimal impact from the disease  
Minimal disruption to child's life



*"Our time with our kids is precious and not guaranteed, so the less time with meds and doctors the better."*  
– Caregiver for a child under 5 yrs

# 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.

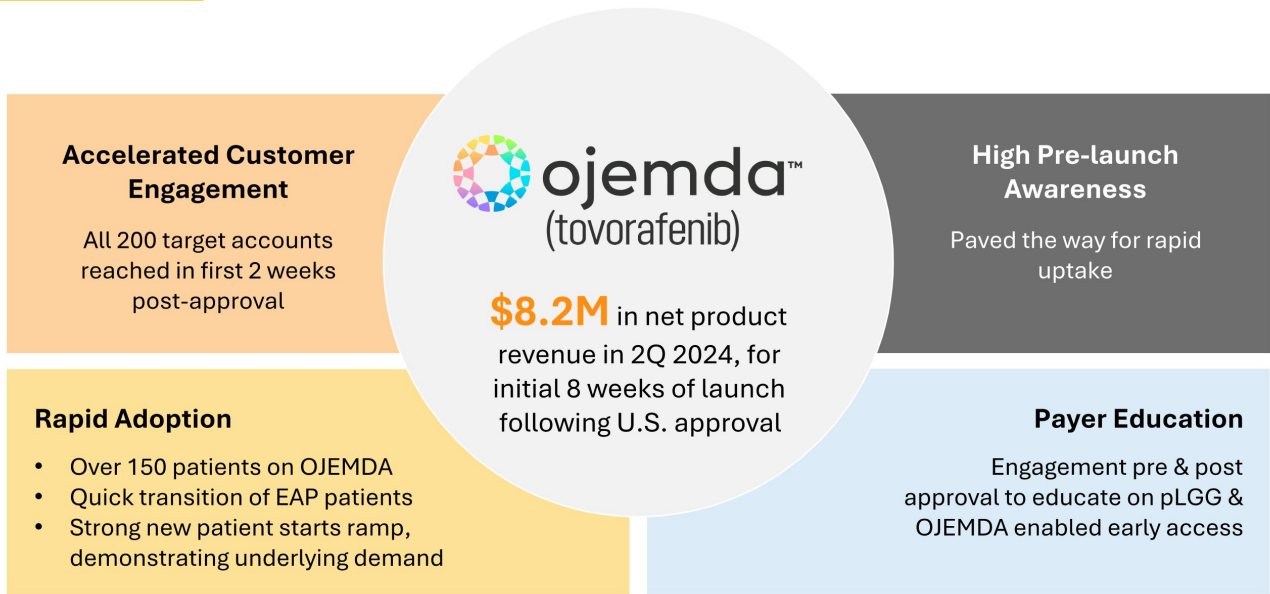


14 | Data from Pivotal Phase 2 FIREFLY-1 trial.





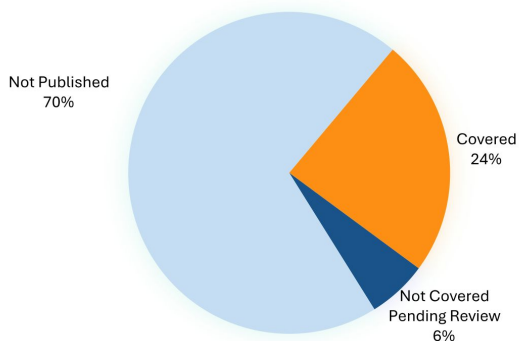
# Robust Q2 Performance Driven by Successful Execution & Strong Patient Demand



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

## Reported Coverage<sup>1</sup>

Percent of Covered Lives



**>80% Patients Approved for Coverage, Despite Lower Reported Coverage<sup>2</sup>**

### Payer Mix

59% commercial patients  
38% Medicaid patients

### Patients Approved for Coverage, Despite Lower Reported Coverage<sup>2</sup>

>80% commercial patients  
>70% Medicaid patients

### Quick Start Program

Provides free drug to patients awaiting payer approval  
>60% transition to paid drug after one shipment

# Patient Support Program Supporting Access

# EveryDay Support.

FROM DAY ONE



# Well-Positioned For Commercial Execution And Sustained Growth

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## Continuing Launch Trajectory

**Increase breadth & depth of Prescribers**

**Establish OJEMDA in the 2nd line**

**Solidify 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

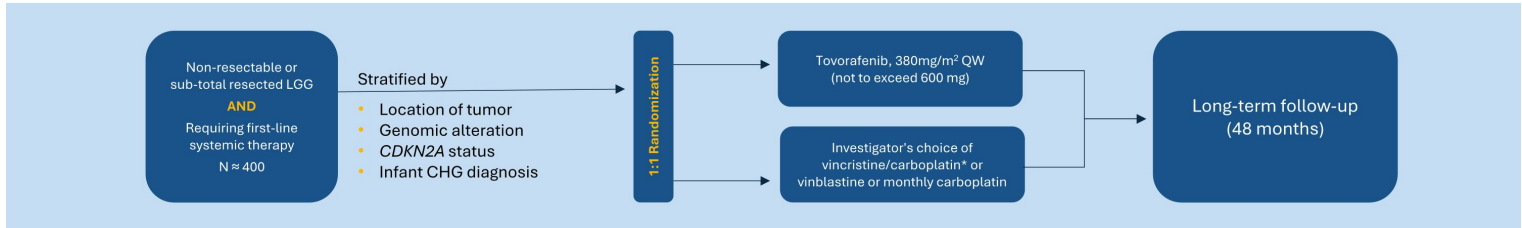


## Trial Design

- 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



20 | \* 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



22

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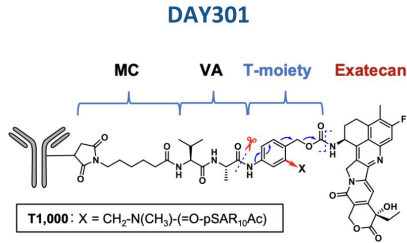
### Potential opportunity for a next-generation PTK7 ADC with improved therapeutic index

- 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
- MMAE 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

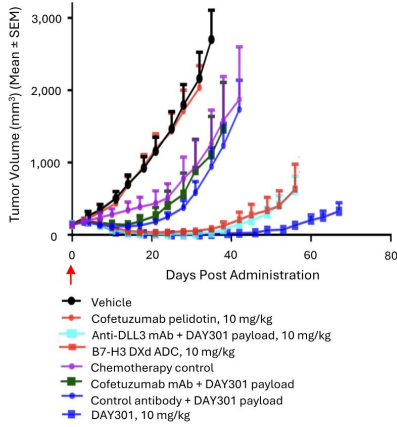


- Tumor regression at tolerable doses seen in multiple preclinical models
- Higher HNSTD in cyno toxicology studies; payload with known safety profile
- High cell permeability / bystander effect; low efflux (not a P-gp substrate)
- Novel, highly hydrophilic, cleavable linker
- Moderate-to-high affinity 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

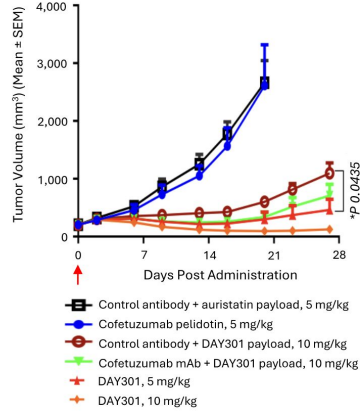
# DAY301: First-in-Class Potential

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

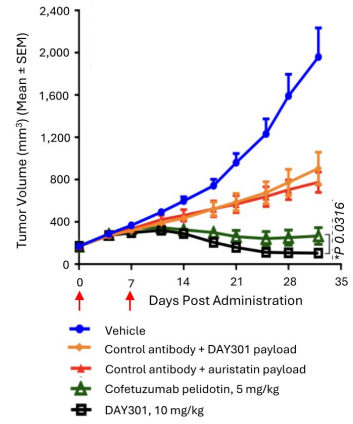
**PDX 362797 SCLC**  
H-score 210



**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 1/2a Clinical Trial Design

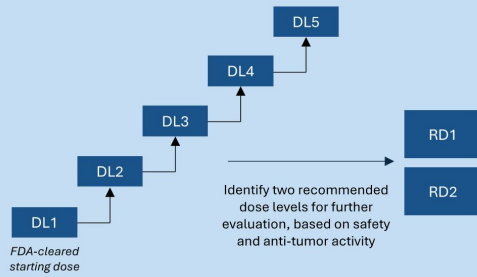
## Key Design Elements

- 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/2a
- 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

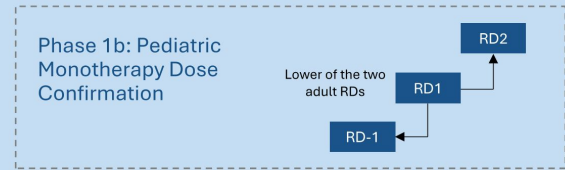
### Phase 1a: Monotherapy Dose Escalation



### Phase 2a: Monotherapy Dose Expansion and Optimization



### Phase 1b: Pediatric Monotherapy Dose Confirmation



# Summary

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## Second Quarter 2024 Financial Results

Financial Summary (\$ in millions)	Three Months Ended 6/30/24	Three Months Ended 6/30/23	Six Months Ended 6/30/24	Six Months Ended 6/30/23
<b>OJEMDA Net Revenue</b>	<b>\$8.2</b>	<b>\$--</b>	<b>\$8.2</b>	<b>\$--</b>
Cost of Sales	0.7	--	0.7	--
Research and Development Expense <sup>1</sup>	92.1	32.2	132.3	60.0
Selling, General and Administrative Expense <sup>2</sup>	30.2	17.1	56.8	35.1
<b>Total Cost and Operating Expenses</b>	<b>123.0</b>	<b>49.3</b>	<b>189.8</b>	<b>95.1</b>
Other Income <sup>3</sup>	111.9	3.4	116.3	6.8
Income Tax Expense	1.5	--	1.5	--
<b>Net Loss</b>	<b>\$4.4</b>	<b>\$45.9</b>	<b>\$66.8</b>	<b>\$88.3</b>
			6/30/24	6/30/23
Cash, cash equivalents and short-term investments			\$361.9	\$442.9

29 | All financial information is unaudited. <sup>1</sup> Includes stock-based compensation expense of \$4.7 million and \$9.4 million for the three and six months ended 6/30/24, and \$3.4 million and \$6.8 million for the three and six months ended 6/30/23, respectively. <sup>2</sup> Includes stock-based compensation expense of \$8.3 million and \$16.3 million for the three and six months ended 6/30/24, and \$6.1 million and \$12.1 million for the three and six months ended 6/30/23, respectively. <sup>3</sup> Includes sale of Priority Review Voucher of \$108.0 million for the three and six months ended 6/30/24

# 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

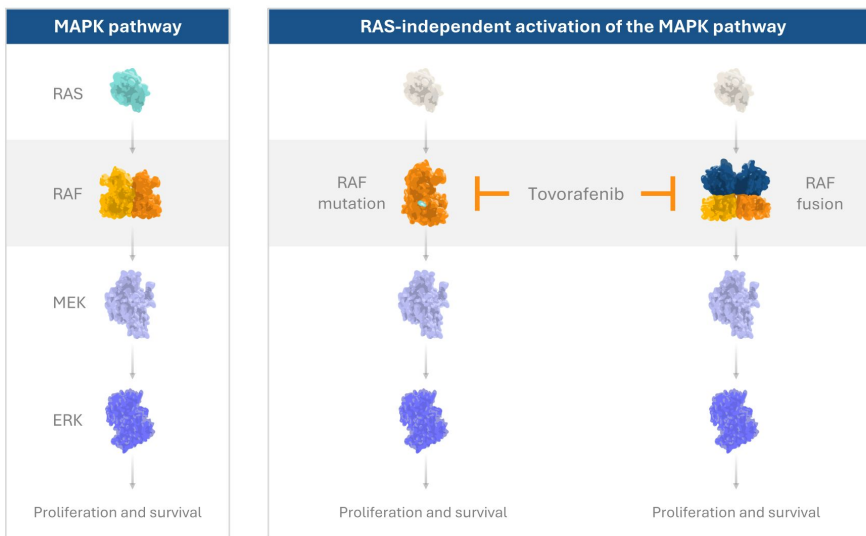
- Grow Day One into a leading, biopharmaceutical company that is the partner of choice for oncology drug development
- Explore selective partnerships as a source of capital and risk sharing
- Further invest in business development activities to expand our multiple asset portfolio for both children and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

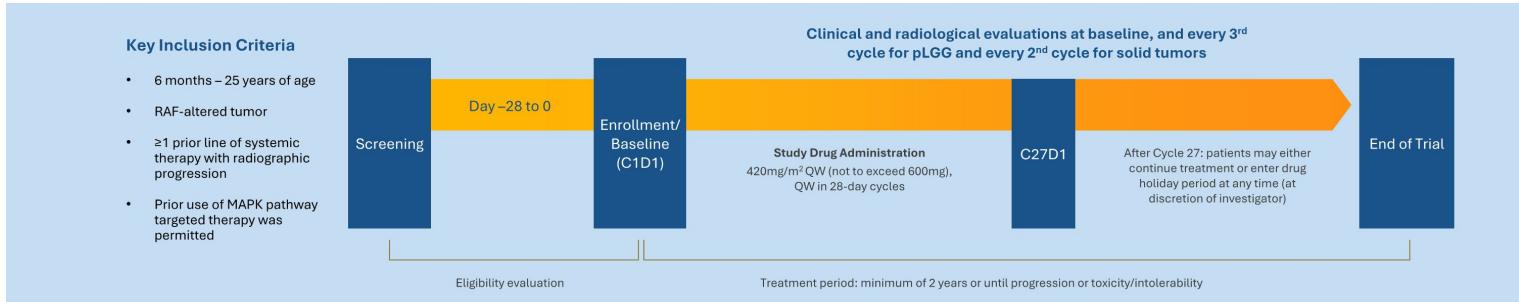


## Trial Design

- 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



33 | 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

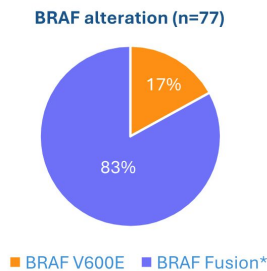
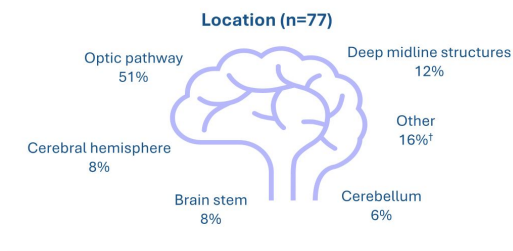
June 5, 2023 data cutoff

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# FIREFLY-1 Baseline Patient Characteristics



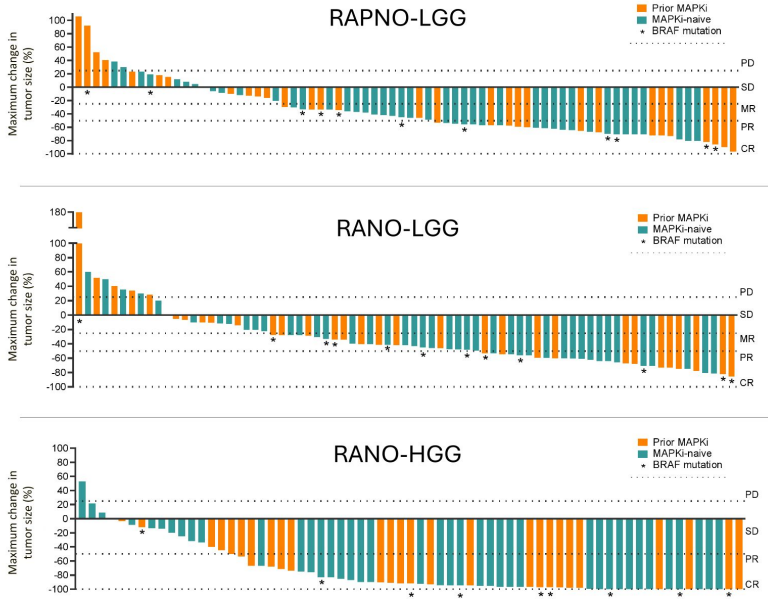
Characteristic	Arm 1 (n=77)
Median age, years (range)	8 (2-21)
Sex, n (%)	
Male	40 (52)
Female	37 (48)
Race, n (%)	
White	41 (53)
Asian	5 (6)
Black	2 (3)
Multiple	3 (4)
Other	6 (8)
Not specified	20 (26)
Number of lines of prior systemic therapy	
Median (range)	3 (1-9)
1, n (%)	17 (22)
2, n (%)	21 (27)
≥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)



35 | 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.

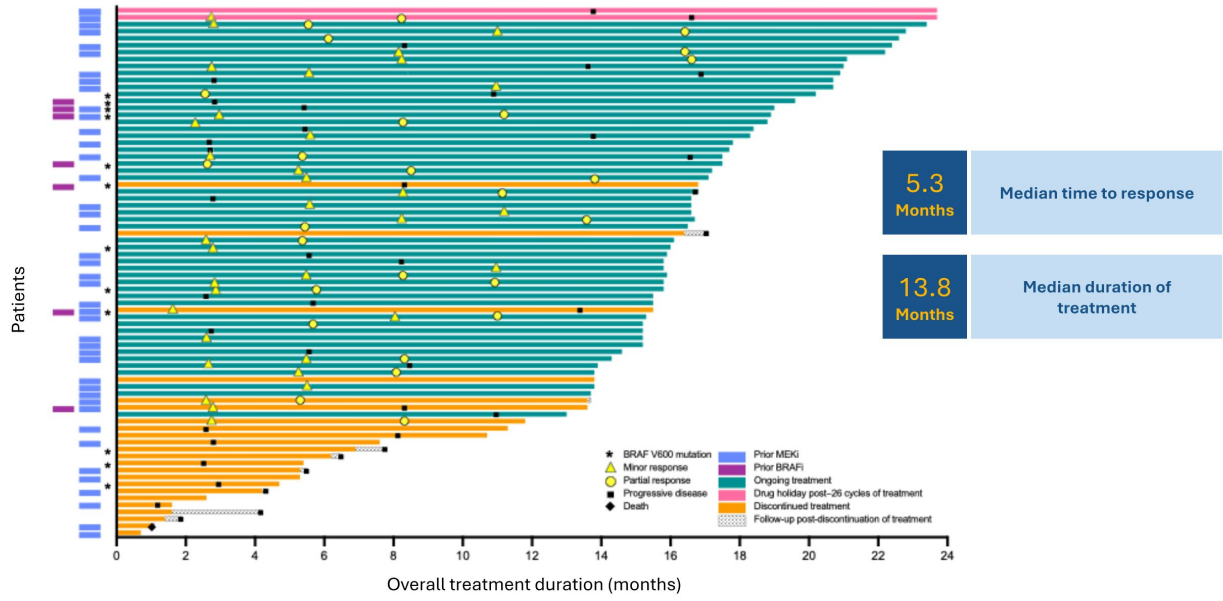


# Tumor Response To Tovorafenib Using RAPNO-LGG, RANO-LGG and RANO-HGG

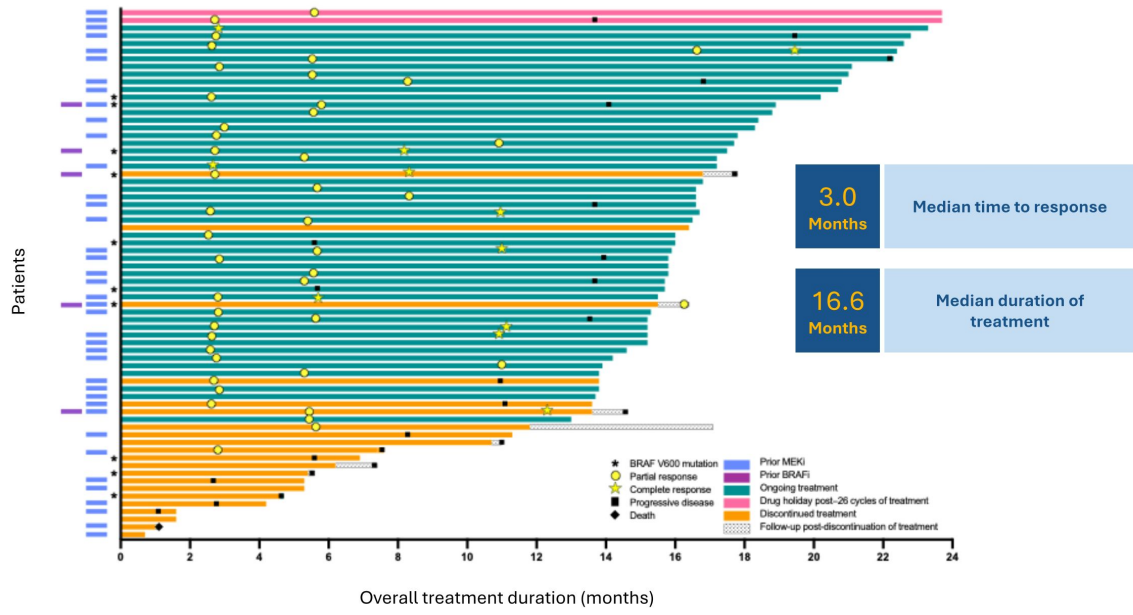


Response (IRC)	RAPNO-LGG n=76	RANO-LGG N=76	RANO-HGG N=69
<b>ORR,* n (%)</b>	<b>39 (51)</b>	<b>40 (53)</b>	<b>46 (67)</b>
95% CI	40-63	41-64	54-78
<b>CBR,* n (%)</b>			
SD of any length of time	62 (82)	63 (83)	64 (93)
SD ≥12 months	43 (57)	46 (61)	54 (78)
<b>BOR,* n (%)</b>			
CR	0	0	12 (17)
PR	28 (37)	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

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

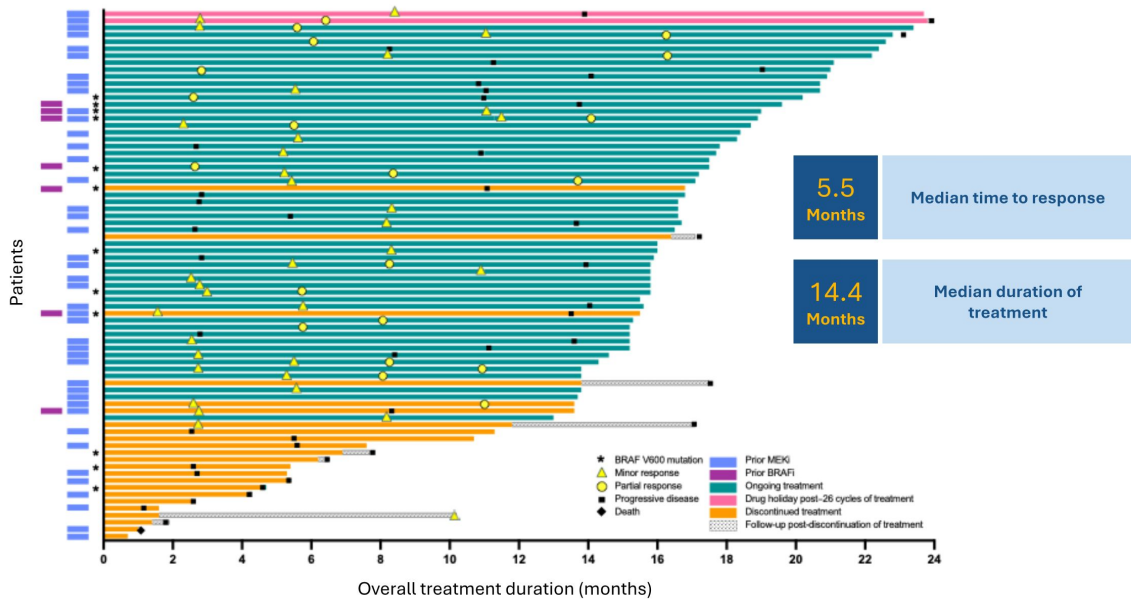


# Duration Of Tovorafenib Therapy For All Patients With RANO-HGG Evaluable Lesions





# 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)

40 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