

**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): April 13, 2022

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.)

395 Oyster Point Blvd., Suite 217
South San Francisco, California
(Address of principal executive offices)

94080
(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 7.01 Regulation FD Disclosure.

On April 13, 2022, Day One Biopharmaceuticals, Inc. (the "Company") updated its corporate presentation.

A copy of the updated corporate presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K. The corporate presentation is also available on the Company's website in the Events & Presentations section at www.dayonebio.com.

The information in this item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended ("Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Corporate Presentation .
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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

DAY ONE BIOPHARMACEUTICALS, INC.

Date: April 13, 2022

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



Day One

BIOPHARMACEUTICALS

Targeted Therapies for People of All Ages

April 2022





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, business plans and objectives, timing and success of our planned nonclinical and clinical development activities, timing and results of nonclinical studies and clinical trials, efficacy and safety profile of our product candidates, our ability to obtain regulatory approval, the potential therapeutic benefits and economic value of our product candidates, potential growth opportunities, competitive position, industry environment and potential market opportunities, and the impact of the COVID-19 pandemic 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 Annual Report on Form 10-K 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.



- Develop medicines for genomically-defined cancers
- Goal is to establish first-in-class position through rapid pediatric registration
- Expand to adult populations in parallel

- Deep expertise in oncology, pediatric, and rare disease development, registration, and commercialization
- Extensive network in the global pediatric oncology community
- Proven track record of success in building biopharma companies

- Potential to be first-in-class oral, CNS-penetrant pan-RAFi
- Potentially the first approval in a market with no standard of care
- Monotherapy CRs and PRs in pediatric low-grade glioma (pLGG)
- Breakthrough Therapy Designation, Rare Pediatric Disease Designation

- Two clinical-stage MEKi assets, in-licensed for combination trial
- Projected cash runway into 2024
- Capital through pivotal data in pLGG and early adult solid tumor Phase 1b data



Regulatory and reimbursement tailwinds

- Lack of approved products create potential first-in-class opportunities
- Pricing flexibility for important new therapies
- Supportive and engaged advocacy and investigator community desiring better treatment options

Rapid clinical development

- Early engagement with global regulatory authorities
- Small trials and clear endpoints that permit rapid development to clinical proof-of-concept and potential approval

Enriched responder populations informed by underlying biology

- Many pediatric tumors are genetically simple and genomically stable
- Genetic alterations are often oncogenic

A Senior Team with Deep Experience Developing and Commercializing Products in Pediatric and Adult Oncology Markets



Jeremy Bender, PhD, MBA
Chief Executive Officer
VP of Corporate Development at Gilead; COO Tizona Therapeutics; CBO Sutro Biopharma; founding Board member of VaxCyt



Samuel Blackman, MD, PhD
Chief Medical Officer & Founder
Pediatric Heme/Onc and Neuro-Onc; Oncology Clinical Development at Mavupharma, Silverback, Juno, Seattle Genetics, GSK



Charles York II, MBA
Chief Operating and Financial Officer
CFO and Head of Corporate Development at Aegle; Consulting CFO at Bridgepoint Consulting; PricewaterhouseCoopers



Lisa Bowers
Chief Commercial Officer
CEO of Rhia Ventures, COO of The Tara Health Foundation, VP of the North American Supply Chain and Commercial Leader at Genentech



Mike Preigh, PhD
Chief Technical Officer
Head of CMC at Array for 10+ years. Brought >20 drug candidates to IND & clinical development



Davy Chiodin, PharmD
Chief Development Officer
VP Regulatory Science, Acerta/AZ; Global Regulatory Leader, Pediatric Oncology, Roche/Genentech



Jaa Roberson
Chief People Officer
Head of Human Resources at Bellucum Pharmaceuticals; Human Resources Roles at AstraZeneca, Roche/Genentech

Our Pipeline



Product Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Milestones
Tovorafenib (DAY101) Type II Pan-RAF Inhibitor ✓ FDA Breakthrough Therapy Designation ✓ FDA Rare Pediatric Disease Designation (PRV Eligible) ✓ FDA Orphan Drug Designation ✓ EC Orphan Designation	Relapsed pLGG	FIREFLY-1 ¹ (pivotal) 				Target enrollment achieved: March 2022 Initial data: June 2022 Topline data: 1Q 2023
	Frontline pLGG	FIREFLY-2 (planned) 				Phase 3 initiation: 2Q 2022
	RAF-altered solid tumors ² (monotherapy)	FIRELIGHT-1* 				First patient dosed: November 2021
Pimasertib MEK 1/2 Inhibitor	MAPK-altered solid tumors ³ (Combo w/DAY101)	FIRELIGHT-1* 				Phase 1b/2 initiated: March 2022

¹Pivotal Phase 2 trial expected to support registration

²DAY101 adult monotherapy Phase 1 dose escalation and expansion trial previously completed

³Pimasertib Phase 1 dose escalation and expansion trial previously completed

^{*}Includes patients ≥12 years of age

pLGG = pediatric low-grade glioma

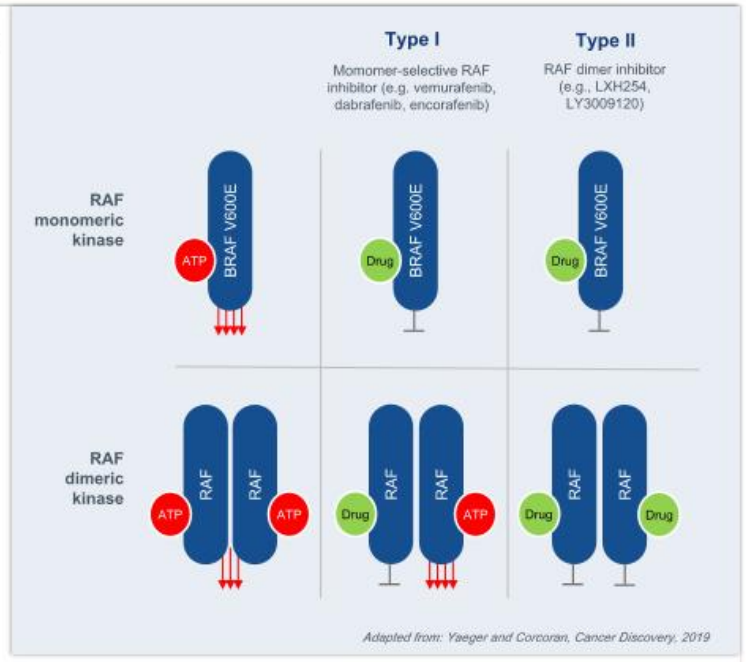


Tovorafenib (DAY101)
Type II Pan-RAF Inhibitor

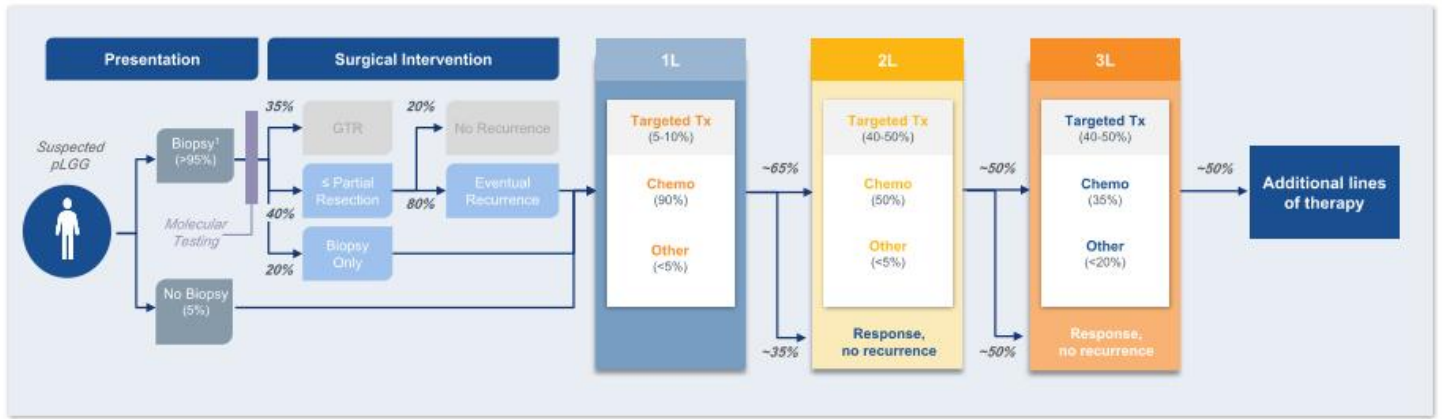
Tovorafenib (DAY101): Monotherapy Approach is Focused on RAF Fusions While Our Combination Strategy Addresses a Broad Set of MAPK Alterations



- Tovorafenib (DAY101) is a type II RAF inhibitor that selectively **inhibits both monomeric** and **dimeric** RAF kinase
- Approved BRAF products (*e.g.* vemurafenib, encorafenib) are type I RAF inhibitors that **only inhibit** RAF monomers and are therefore limited to use in BRAF V600E-altered tumors
 - Type I inhibitors can also cause paradoxical activation of the MAPK pathway, which could potentially lead to increased tumor growth
- Tovorafenib's **inhibition of both** RAF monomers and dimers makes it a unique monotherapy approach for patients with tumors driven by RAF wild-type fusions, and a bespoke therapy for pediatric low-grade gliomas
 - Unlike type I RAF inhibitors, tovorafenib **does not cause** paradoxical activation in RAF wild-type cells
- Tovorafenib (DAY101), in combination with MEK inhibitors, may act synergistically to inhibit tumors driven by other MAPK alterations and broadens its potential clinical applications



The Current pLGG Treatment Paradigm Reflects the Unrelenting Nature of this Chronic Brain Tumor



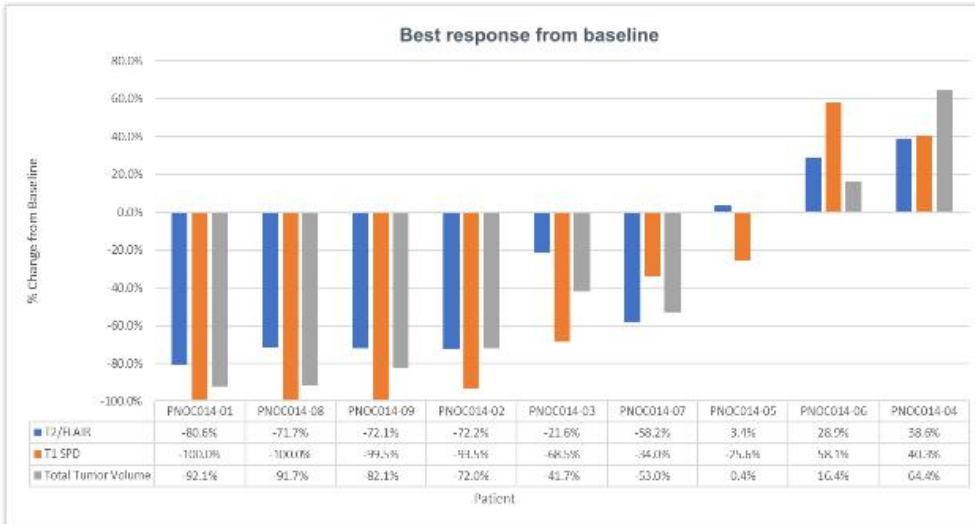
Because many pLGGs undergo senescence when patients reach their 20s, the goal of therapy is to **maximize tumor control** while **minimizing treatment-associated toxicities** from surgery, chemotherapy, and radiation. As a result, a large number of pLGG patients will undergo **multiple lines of systemic therapy** over the course of their disease.

PNOC014 Study Results Demonstrated Responses or Stable Disease in Majority of pLGG Patients Treated with Tovorafenib (DAY101)



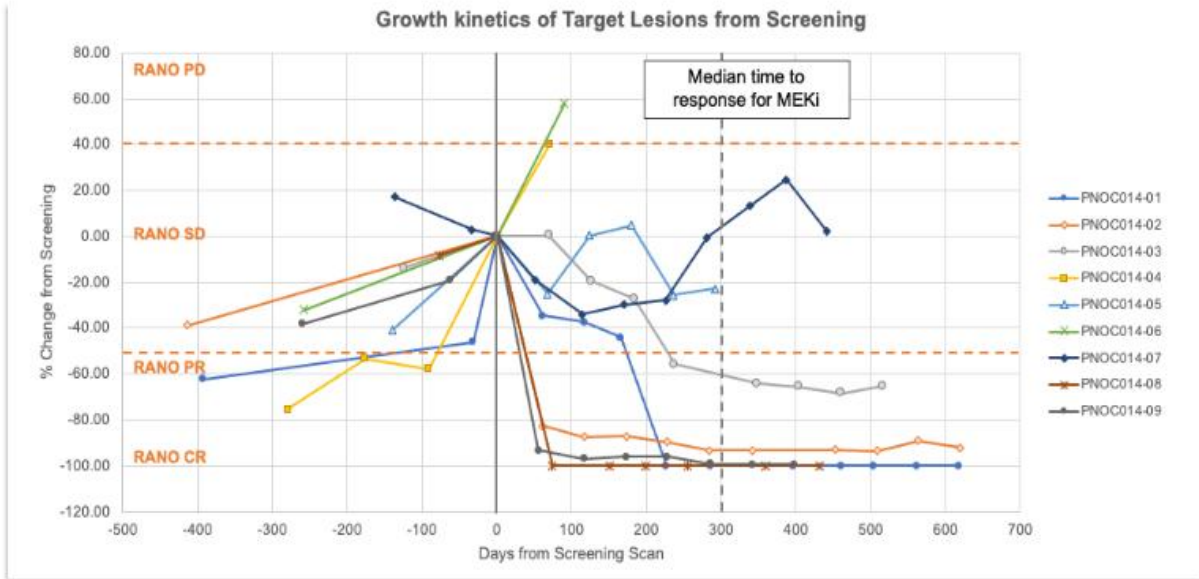
- Tovorafenib (DAY101) studied as once-weekly **monotherapy** in a Phase 1 dose escalation trial in relapsed pediatric glioma patients conducted by the Dana-Farber Cancer Institute and the Pacific Pediatric Neuro-Oncology Consortium (PNOC)
- Of the eight patients with RAF fusions (7 BRAF, 1 CRAF), **two patients** achieved a **complete response** by Response Assessment for Neuro-Oncology (RANO), **three** had a **partial** response, and **two** achieved prolonged **stable** disease
- Median time to achieve a response was **10.5 weeks**, with most common side effects being skin rash and hair color changes. Most patients treated up to **two years** at 420 mg/m²/week
- US FDA has **granted DAY101 Breakthrough Therapy designation** for the treatment of pediatric patients with advanced low-grade glioma harboring RAF alteration and **Orphan Drug Designation** for the treatment of malignant glioma





- RANO: Response assessment for neuro-oncology (FDA standard)
- Volumetric image analysis (exploratory)
- RAPNO: Response assessment for pediatric neuro-oncology (exploratory)

Multiple Rapid, Deep and Durable Responses Observed following Initiation of Tovorafenib (DAY101) Treatment of pLGG Patients in PNOC014



Drug-related Adverse Events Observed for Tovorafenib (DAY101) in PNOC014 Showed Favorable Safety and Tolerability Profile in pLGG



DAY101 AE summary

- Most common toxicity: skin
- AEs reversible and all manageable
- Single, reversible Grade 3 event
- No Grade 4 AEs
- No dose reductions (vs. 40% of patients on selumetinib monotherapy required dose reductions)

Drug-related AEs for Tovorafenib (DAY101)

Toxicities	Grade 1-2	Grade 3	Grade 4
Anemia	6 (67%)		
Hypophosphatemia	4 (44%)		
Fatigue	5 (55%)		
Rash	8 (89%)		
Achromotrichia	7 (78%)		
Pruritis	6 (67%)		
Photosensitivity	1 (11%)		
Nevus	7 (78%)		
Alopecia	3 (34%)		
Epistaxis	2 (22%)		
Dry skin	3 (34%)		
Myalgias/arthralgias	3 (34%)		
Anorexia	2 (22%)		
Cheilitis	3 (34%)		
Hypermagnesemia	1 (11%)		
Bleeding gums	1 (11%)		
Increased AST	4 (44%)		
Nausea/vomiting	3 (33%)		
CPK elevation		1 (11%)	
Weight loss	2 (22%)		

Drug-related AEs for selumetinib

Toxicities	Grade 1-2	Grade 3	Grade 4
Increased ALT	20 (40%)	1 (2%)	
CPK elevation	34 (68%)	5 (10%)	
Diarrhea	27 (54%)	2 (4%)	
Decreased ejection fraction	19 (38%)	1 (2%)	
Gastric haemorrhage		1 (2%)	
Headache	14 (28%)	1 (2%)	
Decreased lymphocyte count	19 (38%)		1 (2%)
Neutropenia	14 (28%)	3 (6%)	
Paronychia	19 (38%)	3 (6%)	
Rash (acneiform)	29 (58%)	2 (4%)	
Rash (maculopapular)	26 (52%)	5 (10%)	
Skin infection	7 (14%)	1 (2%)	
Tooth infection		1 (2%)	
Weight gain	5 (10%)	1 (2%)	
Vomiting	22 (44%)		
Nausea	21 (42%)		
Increased AST	25 (50%)		
Anemia	28 (56%)		
Pruritis	10 (20%)		
Dyspnea	30 (60%)		



Date of DAY101 data cutoff: 02 JAN 2020; Wright K et al. Neuro Oncology Abstract CTNI-19, 2020; Fangusaro J et al. Lancet Oncol 2019



Trial Design

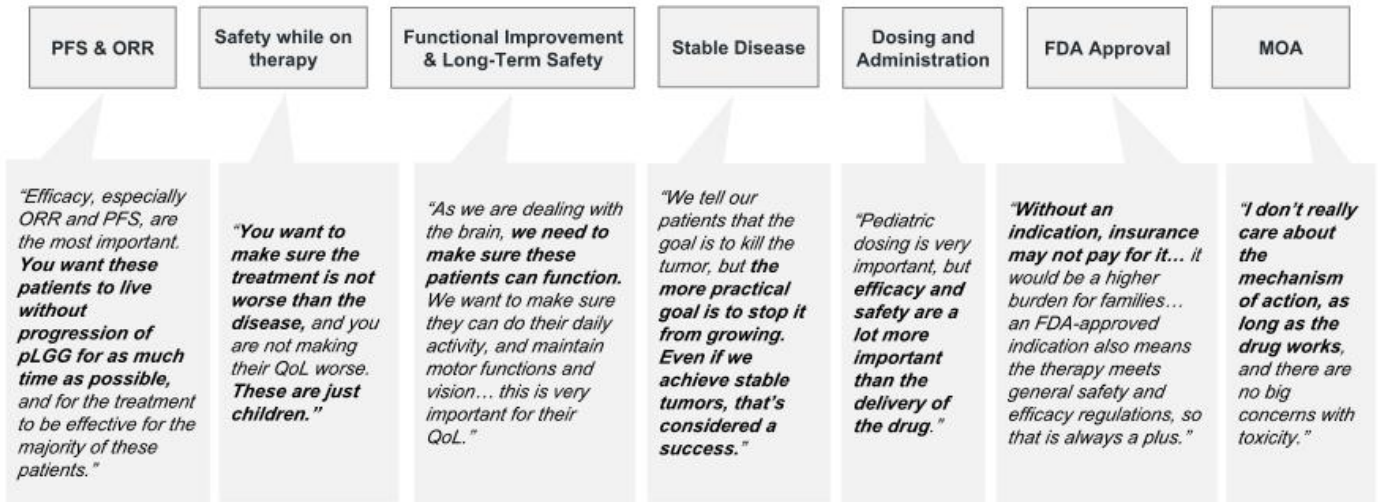
- Single arm, open-label, global registrational phase 2 study
- n = 60 patients (approximately)
- Eligibility: Patients aged 6 months – 25 years with LGG harboring a KIAA1549:BRAF wild-type fusion or BRAF V600 mutation

Endpoints

- Primary endpoint: ORR based on RANO criteria, assessed by independent review
- Secondary endpoints: ORR by RAPNO criteria; EFS; safety



Key Product Attributes for pLGG Prescribers When Choosing a New Therapy



Incidence and Prevalence of BRAF-altered pLGG in the U.S.



	2020 Estimated Incidence Under 25	2017 Estimated SEER Prevalence Under 25
US Population ¹	~105,000,000	NA
Rate of CNS Tumors (0.00521%) ²	~5,500	~130,000 ³
Gliomas (63%) ²	~3,500	~82,000
Low Grade (77%) ²	~2,600	~63,000
Has Received Drug Tx (58%) ²	~1,500	~36,000
BRAF Mutated (70%) ²	~1,100	~26,000

	<p>~1,100 Estimated Annual Incidence</p>
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<p>~26,000 Estimated Prevalence (SEER)</p>



¹US Census; ²CBTRUS, Qaddoumi et al 2009, Schreck et al 2019, ClearView Analysis; ³SEER US complete prevalence counts of patients aged under 25 with Brain and Other Nervous Systems tumors as of January 1, 2017.

Estimated annual incidence and estimated prevalence (SEER) are Day One calculations based on publicly available data.

Our Pipeline



Product Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Anticipated Milestones
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¹Pivotal Phase 2 trial expected to support registration

²DAY101 adult monotherapy Phase 1 dose escalation and expansion trial previously completed

³Pimasertib Phase 1 dose escalation and expansion trial previously completed

^{*}Includes patients ≥12 years of age

pLGG = pediatric low-grade glioma

Tovorafenib (DAY101) is Active as a Monotherapy in Patients with RAF-altered Adult Solid Tumors and Has Shown Strong Synergy Preclinically in Combination



Clinical activity demonstrated in relapsed melanoma patients; preclinical activity demonstrated in RAF fusions, BRAF non-V600 mutations, and BRAF V600 mutations

- >225 adult patient exposures
- Responses in BRAF V600E mutant tumors similar to type I BRAF inhibitors
- Responses in relapsed BRAF and NRAS-mutant melanoma, suggesting tovorafenib (DAY101) may be active in tumors currently unaddressed by approved Type I BRAF inhibitors



Differentiated safety profile for tovorafenib (DAY101) vs. existing BRAF and MEK inhibitors

- Less frequent and less severe acneiform rash
- No observed ophthalmologic liabilities (RVO/CSR)
- No observed CV liabilities (changes in LVEF)
- No type I BRAF SAEs: SCCs/KAs, pyrexia, arthralgia



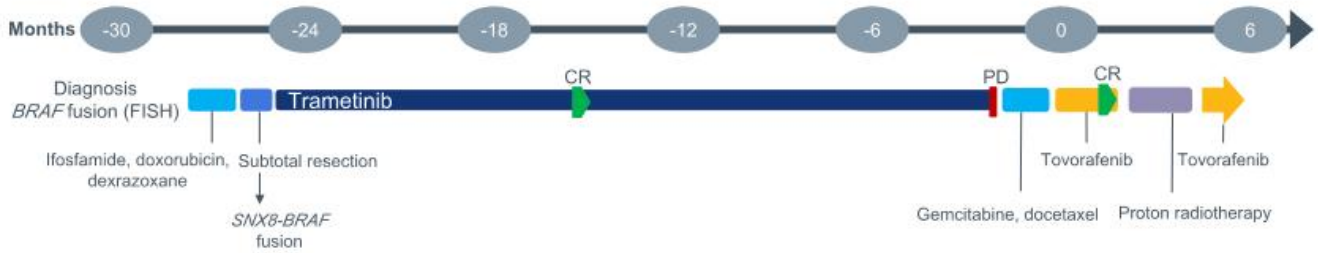
We **initiated** an adult solid tumor **study** to further evaluate monotherapy tovorafenib (DAY101) in patients with RAF altered tumors for which there are no currently approved therapies

- Same study will include combination cohorts of tovorafenib (DAY101) + pimasertib
- First patient dosed in Phase 2 monotherapy study in November 2021

Activity of Tovorafenib (DAY101) in *SNX8:BRAF* Fusion Spindle Cell Sarcoma

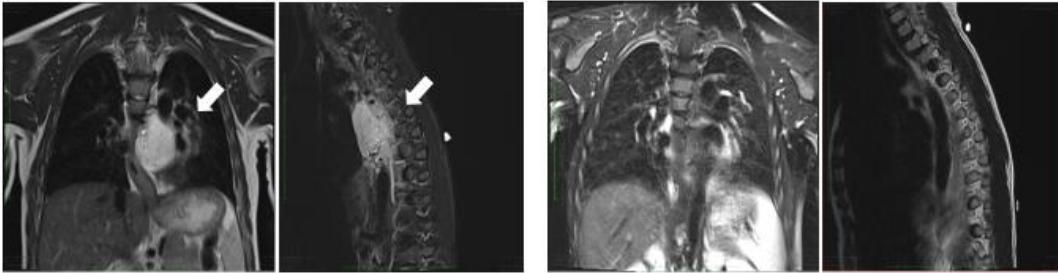


A male child with spindle cell sarcoma, 5-years of age at diagnosis



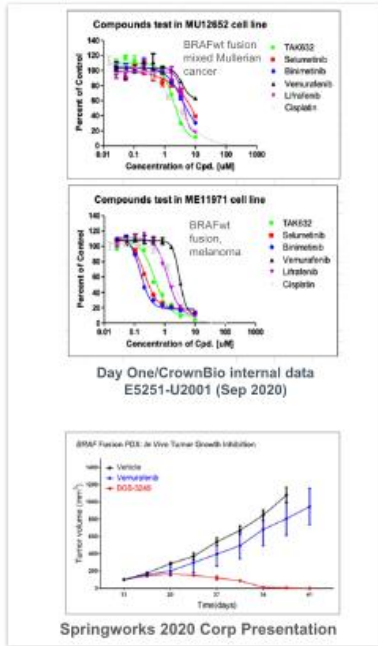
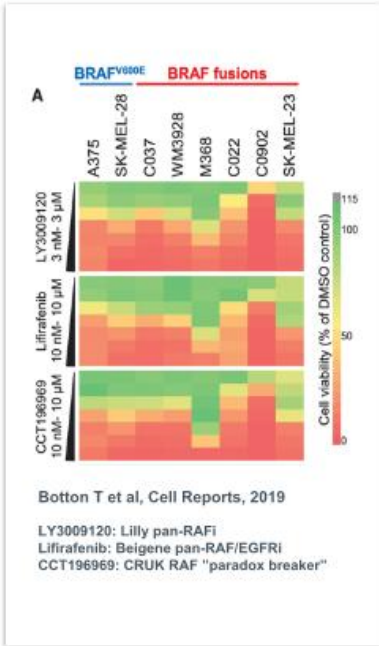
Baseline

After 2 cycles of tovorafenib

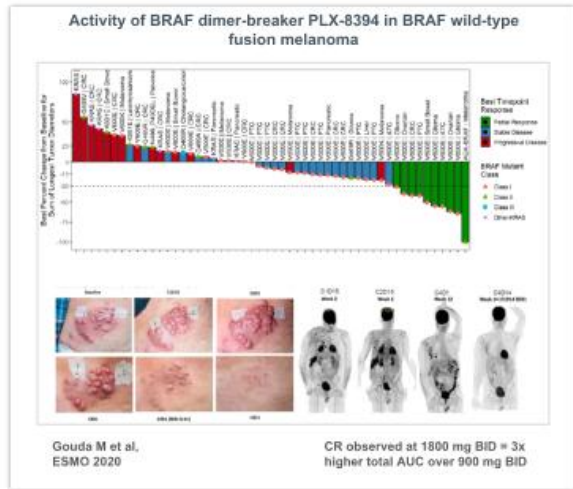


- After the first dose of tovorafenib (DAY101), the patient experienced grade 2 rash, which resolved in a day following a dose of diphenhydramine
- Radiotherapy-related adverse events included hyperpigmentation overlying the spine on the upper back with no skin breaks, and mild dysphagia

Next-generation RAF Inhibitors are Unique in Their Ability to Address Adult Cancers Associated with RAF Wild-type Fusions



Only tovorafenib (DAY101) has demonstrated *monotherapy clinical activity* in KIAA1549:BRAF and SRGAP3:CRAF wild-type fusions in pLGG



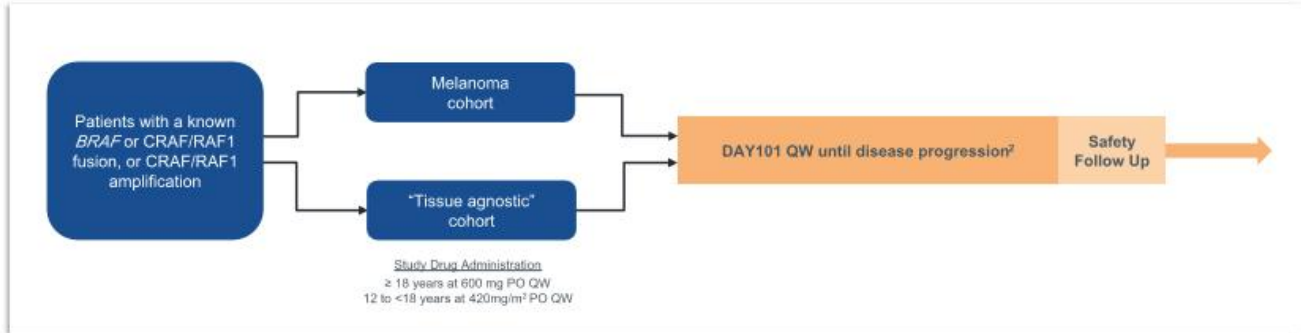


Trial Design¹

- Single arm, open-label, global phase 1b/2a study
- n = 40 patients (approximately)
- Eligibility: Patients aged 12 years and older with non-hematologic tumor with an activating BRAF fusion, CRAF/RAF1 fusion, or CRAF/RAF1 amplification

Endpoints

- Primary endpoint: ORR by RECIST version 1.1 for non-CNS solid tumors and RANO criteria for any CNS tumors
- Secondary endpoints: safety and additional efficacy parameters



Abbreviations: ORR, objective response rate; QW, once weekly; PO, by mouth; BRAF, B-Raf proto-oncogene.
¹Umbrella master study – DAY101-102 (main protocol) DAY101 and MAPK pathway aberration, Sub-study 1 monotherapy (DAY101-102a), Sub-study 2 MEK combo (DAY101-102b), ²DAY101 QW until disease progression, intolerable toxicity, withdrawal of consent, or death

Strong Scientific Rationale for Combining Tovorafenib (DAY101) with Additional MAPK Pathway Inhibitors



	BRAF non-V600	BRAF or CRAF WT fusion	KRAS or NRAS mutant	NF1 LOF
Signaling pathways	<p>Proliferation, survival</p>	<p>Proliferation, survival</p>	<p>Proliferation, survival</p>	<p>Proliferation, survival</p>
Potential combinations	Type II RAFi + MEKi or SHP2i	Type II RAFi + MEKi	Type II RAFi + KRAS-G12Ci or MEKi or SHP2i	Type II RAFi + SHP2i
Rationale	<ul style="list-style-type: none"> Non V600 BRAF dimers are effectively inhibited by type II, but not type I, RAFi 	<ul style="list-style-type: none"> BRAF fusion dimers are effectively inhibited by type II, but not type I RAFi 	<ul style="list-style-type: none"> Targeting multiple nodes of MAPK pathway will drive deeper and more durable response 	<ul style="list-style-type: none"> Targeting multiple pathways will drive deeper response

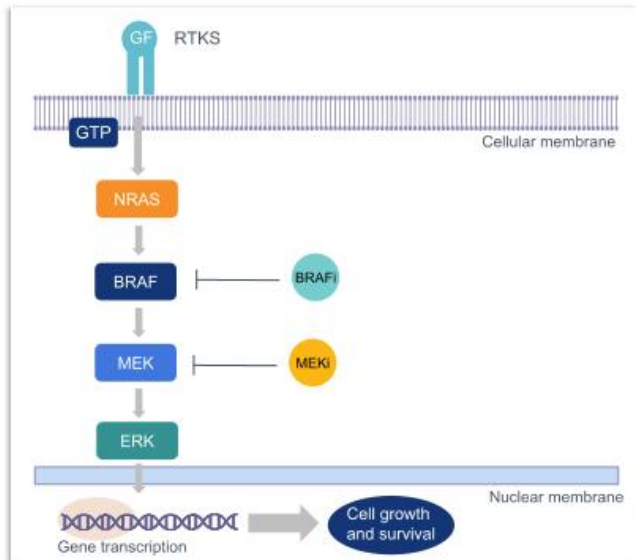


Pimasertib
MEK1/2 Inhibitor

Pimasertib: Allosteric MEK1/2 Inhibitor with Demonstrated Activity in MAPK-driven Solid Tumors



- Pimasertib is an orally-bioavailable, selective, non-competitive MEK1/2 inhibitor in-licensed from Merck KGaA in February 2021
- Extensive non-clinical and clinical development work through Phase 2, including a solid tumor trial in Japan and combinations with other MOAs
- Main AEs typical for all in-class allosteric MEK inhibitors (GI, CPK elevation, skin rash, visual disturbances)
- Nearly three-fold higher CNS penetration than other MEKi inhibitors (trametinib or selumetinib)
- Pimasertib showed monotherapy clinical activity, including an improvement in median PFS versus dacarbazine in NRAS mutant melanoma
- Combination with tovorafenib (DAY101) and other targeted therapies may unlock the full value of pimasertib in advanced solid tumors

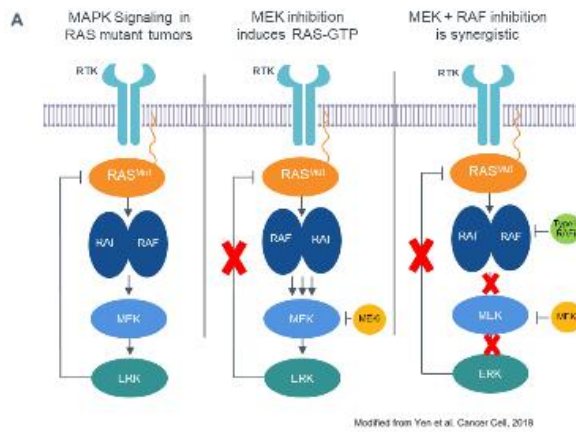


Source: Hepner, Salgues, Anjos, et al. 2017.

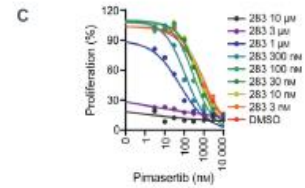
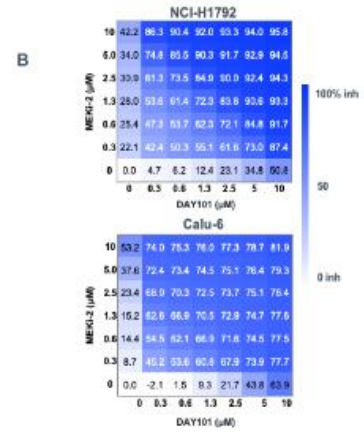
Vertical MAPK Pathway Inhibition with Tovorafenib (DAY101) and Pimasertib Unlocks Potential Synergy for Adult Solid Tumors



- The MAPK pathway normally has multiple feedback loops that negatively regulate upstream (RAS/RAF) activation to ensure optimal signaling
- Monotherapy MEK inhibition disables these feedback loops and induces RAS signaling as well as RAF dimerization and activation
- Combination therapy with a MEK inhibitor and type II RAF inhibitor is synergistic in KRASmut and BRAFmut tumor models



A. Mechanistic model for vertical MAPK pathway inhibition (modified from Yen et al. Cancer Cell, 2018).
 B. DAY101 + MEK inhibitor is synergistic in KRAS G12C and Q61 mutant tumor cell models (Day One internal data).
 C. Sensitivity of KRAS Q61 mutant cells to pimasertib is enhanced when cells are treated with the type II RAF inhibitor BGB-283 (Yuan et al., Mol Onc 2020)



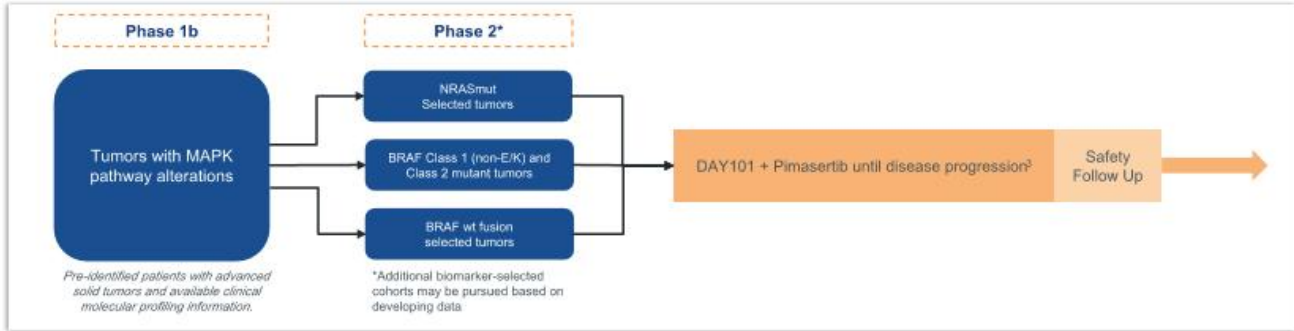


Trial Design¹

- Combination dose escalation, global phase 1b/2 study²
- Phase 1b, BOIN (adaptive), n = 10/cohort (approximately)
- Phase 2, Simon 2-stage, n = 25/cohort (approximately)
- Eligibility: Patients aged 12 years and older, dose escalation will be performed in advanced solid tumor patients with any MAPK alteration. Expansion cohorts will focus on indications with a potential path to accelerated approval

Endpoints

- Phase 1b: PK, PD and Safety, MTD/RP2D
- Phase 2: Efficacy (ORR, DOR)





Summary



- Cash and cash equivalents as of December 31, 2021: \$284.3 million (no debt)
- IPO in May 2021: \$184 million in gross proceeds, includes full exercise of underwriters' option
- 62.0 million shares of common stock outstanding

\$ Millions	Three Months Ended 12/31/21	Twelve Months Ended 12/30/21
R&D Expense	\$11.2	\$43.6
G&A Expense	\$10.8	\$29.2
Net Loss	\$21.9	\$72.8

Projected cash runway
into 2024

FIREFLY-1: Pivotal Phase 2 clinical trial of tovorafenib (DAY101)

- Initial clinical data expected in June 2022
- Target enrollment achieved; full topline results expected in 1Q 2023
- Anticipated NDA filing in 2023, if data from FIREFLY-1 are supportive

FIRELIGHT-1: Tovorafenib (DAY101) and pimasertib combination

- Trial initiated in March 2022



Key Highlights

Tovorafenib (DAY101)¹

FIREFLY-1 (Relapsed pLGG)

- First patient dosed in Pivotal FIREFLY-1 trial: May 2021
- Target enrollment achieved: March 2022
- Breakthrough Therapy Designation & Rare Pediatric Disease Designation

FIFELIGHT-1 (RAF-altered solid tumors - monotherapy)

- First patient dosed in phase 2 monotherapy trial: November 2021

Intellectual Property

- Composition of matter to mid-2030s with PTE, potential exclusivity to late 2030s / early 2040s via broad patent portfolio

Pimasertib¹

FIFELIGHT-1 (MAPK-altered solid tumors – Combo w/Tovorafenib)

- Initiated combination dose escalation, global phase 1b/2 trial: March 2022

2022 Outlook

Tovorafenib (DAY101)

FIREFLY-1 (Relapsed pLGG)

- Initial data expected: June 2022
- Topline data expected: 1Q 2023

FIREFLY-2 (Frontline pLGG)

- Phase 3 trial initiation: 2Q 2022

Day One

BIOPHARMACEUTICALS



Thank you