Day One Reports Fourth Quarter and Full Year 2023 Financial Results and Corporate Progress

February 26, 2024

PDUFA target action date for tovorafenib NDA in relapsed or progressive pLGG remains set for April 30, 2024

Phase 2 FIREFLY-1 tovorafenib registrational data published in Nature Medicine

Ended 2023 with $366.3 million in cash, cash equivalents and short-term investments providing runway into 2026

BRISBANE, Calif., Feb. 26, 2024 (GLOBE NEWSWIRE) -- Day One Biopharmaceuticals (Nasdaq: DAWN) ("Day One" or the "Company"), a clinical-stage biopharmaceutical company dedicated to developing and commercializing targeted therapies for people of all ages with life-threatening diseases, today announced its fourth quarter and full year 2023 financial results and highlighted recent corporate achievements.

"We have a monumental year ahead of us at Day One with the upcoming PDUFA date for tovorafenib," said Jeremy Bender, Ph.D., chief executive officer of Day One. "Our team is trained and ready to deliver our first expected commercial medicine to children in need of new treatment options. We also continue to advance our Phase 3 front-line trial with tovorafenib and are actively exploring other potential additions to our pipeline for children and adults living with cancer."

Program Highlights

- In October 2023, Day One announced that the U.S. Food and Drug Administration (FDA) accepted its New Drug Application (NDA) for Priority Review of tovorafenib. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of April 30, 2024. The Company anticipates being eligible for a Priority Review Voucher upon potential approval of tovorafenib.
- In November 2023, *Nature Medicine* published the registrational Phase 2 FIREFLY-1 trial results investigating tovorafenib in patients with BRAF-altered, relapsed or progressive pediatric low-grade glioma (pLGG).
- In the fourth quarter of 2023, Day One continued its commercial preparedness for the approval and launch of tovorafenib with the hiring of 18 sales representatives in the U.S.
- 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 in the United States, Canada, Europe, Australia and Asia, with more than 80 sites activated.
- Patient enrollment continues in the Phase 1b/2 substudy (102b) of the FIRELIGHT-1 trial evaluating the combination of tovorafenib with the Company's investigational MEK inhibitor, pimasertib.

Corporate Highlights and Upcoming Milestones

- Elly Barry, MD, has been promoted to Chief Medical Officer where she will lead the execution and expansion of Day One's clinical development programs. Most recently, Dr. Barry was Head of Clinical Development at Day One where she played an integral role in the execution of the Company's clinical programs. Prior to joining the Company in 2021, Dr. Barry was Global Clinical Lead for Pediatric Oncology at Pfizer, as well as Head of Pfizer's Pediatric Oncology Leadership Team where she oversaw multiple oncology clinical programs. She has replaced Raphaël Rousseau, MD, PhD, who has transitioned into a strategic advisory consulting role into the second quarter of 2024.
- Day One welcomed seasoned biotechnology veterans Habib Dable and Dr. William Grossman to its Board of Directors. Both individuals bring deep expertise and leadership in oncology to the Company's Board.
- The recommended Phase 2 dose and schedule in the FIRELIGHT-1 clinical trial is expected in 2H 2024.

Fourth Quarter and Full Year 2023 Financial Highlights

- **Cash Position:** Cash, cash equivalents and short-term investments totaled $366.3 million on December 31, 2023. Based on Day One's current operating plan, management believes it has sufficient capital resources to fund anticipated operations into 2026.
- **R&D Expenses:** Research and development expenses were $37.3 million and $130.5 million for the fourth quarter and full year ended December 31, 2023, respectively, as compared to $26.0 million and $85.6 million for the same periods in 2022. The increase was primarily due to additional employee compensation costs, a milestone payment, as well as clinical trial and manufacturing activities related to Day One's lead product candidate, tovorafenib.
- **G&A Expenses:** General and administrative expenses were $22.2 million and $75.5 million for the fourth quarter and full year ended December 31, 2023, respectively, as compared to $16.7 million and $61.3 million for the same periods in 2022. The increase was primarily due to additional employee compensation costs, an ongoing commercial buildout, and

professional service expenses to support company growth.

- **Net Loss:** Net loss totaled $54.5 million for the fourth quarter of 2023 with non-cash stock compensation expense of $10.8 million, compared to $40.1 million for the fourth quarter of 2022 with non-cash stock compensation expense of $6.8 million. Net loss was $188.9 million for the year ended December 31, 2023, with non-cash stock compensation expense of $39.3 million, compared to $142.2 million for the year ended December 31, 2022, with non-cash stock compensation expense of $27.2 million.

Upcoming Events

- **44th Annual TD Cowen Health Care Conference**
  - Management will participate in a fireside chat on Tuesday, March 5 at 9:50 a.m. ET. A live and archived audio webcast of the discussion will be available by visiting the Events & Presentations section of the Company's website.

About Tovorafenib

Tovorafenib is an investigational, oral, brain-penetrant, highly selective type II RAF kinase inhibitor designed to target a key enzyme in the MAPK signaling pathway, which is being investigated in primary brain tumors or brain metastases of solid tumors. Tovorafenib is currently under evaluation in two pivotal clinical trials for pLGG. Tovorafenib is also being evaluated as a combination therapy for adolescent and adult patient populations with recurrent or progressive solid tumors with MAPK pathway aberrations (FIRELIGHT-1).

Tovorafenib has been granted Breakthrough Therapy and Rare Pediatric Disease designations by the FDA for the treatment of patients with pLGG harboring an activating RAF alteration. 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.

About Day One Biopharmaceuticals

Day One Biopharmaceuticals is a clinical-stage biopharmaceutical company that believes when it comes to pediatric cancer, we can do better. We put kids first and are developing targeted therapies that deliver to their needs. Day One was founded to address a critical unmet need: the dire lack of therapeutic development in pediatric cancer. The Company's name was inspired by "The Day One Talk" that physicians have with patients and their families about an initial cancer diagnosis and treatment plan. Day One aims to re-envision cancer drug development and redefine what's possible for all people living with cancer—regardless of age—starting from Day One.

Day One partners with leading clinical oncologists, families, and scientists to identify, acquire, and develop important emerging cancer treatments. The Company's lead product candidate, tovorafenib, is an investigational, oral, brain-penetrant, highly selective type II RAF kinase inhibitor. The Company's pipeline also includes pimasertib, an investigational, oral, highly selective small molecule inhibitor of mitogen -activated protein kinases 1 and 2 (MEK-1/-2). Day One is based in Brisbane, California. For more information, please visit www.dayonebio.com or find the Company on LinkedIn or X.

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 cancer therapies, expectations from current clinical trials, the execution of the Phase 2 and Phase 3 clinical trials for tovorafenib as designed, any expectations about safety, efficacy, timing and ability to complete clinical trials, release data results, the ability of Day One to obtain regulatory approvals for and to commercialize 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 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, changing interest rates, 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 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.

Day One Biopharmaceuticals, Inc.
Consolidated Statements of Operations
(unaudited)
(in thousands, except shares)

	Year Ended December 31,		
	2023	**2022**	**2021**
Operating expenses:			
Research and development	$ 130,521	$ 85,618	$ 43,584

General and administrative	75,543	61,291	29,159
Total operating expenses	206,064	146,909	72,743
Loss from operations	(206,064)	(146,909)	(72,743)
Investment income, net	17,187	4,746	4
Other expense, net	(40)	(18)	(15)
Net loss	(188,917)	(142,181)	(72,754)
Net loss attributable to redeemable convertible noncontrolling interest	—	—	(2,109)
Exchange of redeemable noncontrolling interest shares – deemed dividend	—	—	(99,994)
Net loss attributable to common stockholders/members	$ (188,917)	$ (142,181)	$ (170,639)
Net loss per share, basic and diluted	$ (2.37)	$ (2.17)	$ (4.62)
Weighted-average number of common shares used in computing net loss per share, basic and diluted	79,773,004	65,466,773	36,960,569

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

	December 31, 2023	December 31, 2022
Cash, cash equivalents and short-term investments	$ 366,347	$ 342,269
Total assets	376,048	349,062
Total liabilities	29,508	17,023
Accumulated deficit	(458,585)	(269,668)
Total stockholders' equity	346,540	332,039

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