Day One Reports Third Quarter 2023 Financial Results and Corporate Progress

November 6, 2023

NDA for tovorafenib in relapsed or progressive pLGG accepted for FDA priority review

PDUFA target action date of April 30, 2024

BRISBANE, Calif., Nov. 06, 2023 (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 third quarter 2023 financial results and highlighted recent corporate achievements.

“Day One made significant progress this past quarter towards potentially bringing tovorafenib to children with cancer, most notably with the completion of the tovorafenib rolling submission to the FDA,” said Jeremy Bender, Ph.D., chief executive officer of Day One. “We’re excited the FDA has granted a Priority Review and set a PDUFA date of April 30. Our commercial launch preparation is fully underway, including the hiring of a national sales force.”

Program Highlights

- In September 2023, the Company announced updated FIREFLY-1 data for tovorafenib and completion of the rolling New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) for relapsed or progressive pediatric low-grade glioma (pLGG).
- In October 2023, Day One announced that the FDA accepted its NDA for Priority Review. The Company anticipates being eligible for a Priority Review Voucher upon potential approval of tovorafenib.
- The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of April 30, 2024.
- Day One presented two case reports at the 2023 Connective Tissue Oncology Society Annual Meeting in November 2023, documenting fusion-driven sarcoma case reports from the FIREFLY-1 and FIRELIGHT-1 studies.
- Day One has concluded enrollment in the Phase 2a FIRELIGHT-1 substudy trial of tovorafenib as a monotherapy in patients 12 years and older with relapsed, progressive, or refractory solid tumors harboring MAPK pathway aberrations. Despite observing responses with a generally well-tolerated therapy, a limited duration of response in this relatively rare patient population was observed. Day One will discontinue this monotherapy substudy and re-direct resources to other programs. Results from the substudy will be shared for presentation or publication after the final dataset becomes available.
- 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.
- 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 approximately 70 sites activated.

Corporate Highlights and Upcoming Milestones

- In August 2023, Day One entered into a research collaboration and license agreement with Sprint Biosciences AB for its Vaccinia Related Kinase 1 (VRK1) program, augmenting the Company’s portfolio of targeted therapies in oncology.
- The Company has appointed Adam Dubow, Day One’s current General Counsel, as one of its executive officers under Section 16 of the Securities Exchange Act of 1934, as amended. Mr. Dubow joined Day One in October 2022 and leads the legal and compliance functions.

Third Quarter 2023 Financial Highlights

- **Cash Position:** Cash, cash equivalents and short-term investments totaled $405.5 million on September 30, 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 $33.2 million for the third quarter of 2023 compared to $22.0 million for the third quarter of 2022. The increase was primarily due to additional employee compensation costs, an upfront license 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 $18.3 million for the third quarter of 2023 compared to $17.7 million for the third quarter of 2022. The increase was primarily due to additional employee compensation costs, as well as the ongoing build-out of commercial capabilities.

- **Net Loss:** Net loss totaled $46.2 million for the third quarter of 2023 with non-cash stock compensation expense of $9.6 million, compared to $37.8 million for the third quarter of 2022 with non-cash stock compensation expense of $8.6 million.

Upcoming Events

- Clinical data from the ongoing, open-label, pivotal Phase 2 FIREFLY-1 clinical trial evaluating the investigational agent tovorafenib in relapsed or progressive pLGG will be presented in two plenary presentations at the 2023 Society for Neuro-Oncology Annual Meeting on November 17, 2023.

- Piper Sandler 35th Annual Healthcare Conference, November 28-30, 2023.

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 has been studied in over 325 patients to date and 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 U.S. Food and Drug Administration (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 Twitter.

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, rising interest rates, cybersecurity events, instability in the global banking system, government shutdowns, uncertainty with respect to the federal budget, 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 33,163	$ 22,035	$ 93,173	$ 59,598
General and administrative	18,275	17,664	53,374	44,568
Total operating expenses	51,438	39,699	146,547	104,166
Loss from operations	(51,438)	(39,699)	(146,547)	(104,166)
Investment income, net	5,291	1,895	12,163	2,086
Other (expense) income, net	(3)	9	(22)	8
Net loss attributable to common stockholders	(46,150)	(37,795)	(134,406)	(102,072)
Net loss per share, basic and diluted	$ (0.54)	$ (0.53)	$ (1.73)	$ (1.61)
Weighted-average number of common shares used in computing net loss per share, basic and diluted	85,952,501	71,008,993	77,682,237	63,522,774

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

	September 30, 2023	December 31, 2022
Cash, cash equivalents and short-term investments	$ 405,538	$ 342,269
Total assets	414,179	349,062
Total liabilities	24,552	17,023
Accumulated deficit	(404,074)	(269,668)
Total stockholders' equity	389,627	332,039

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