Day One Reports Third Quarter 2022 Financial Results and Corporate Progress

November 7, 2022

Topline results for full pivotal FIREFLY-1 study population with tovorafenib (DAY101) in relapsed or progressive pediatric low-grade glioma (pLGG) are expected in the first quarter of 2023

Strengthened leadership team with key appointments to senior management team and board of directors

SOUTH SAN FRANCISCO, Calif., Nov. 07, 2022 (GLOBE NEWSWIRE) -- Day One Biopharmaceuticals (Nasdaq: DAWN), a clinical-stage biopharmaceutical company dedicated to developing and commercializing targeted therapies for people of all ages with life-threatening diseases, today announced financial results for the third quarter of 2022 and highlighted recent corporate achievements.

“Day One’s progress in 2022 has been remarkable. We announced positive interim results from our pivotal FIREFLY-1 study with tovorafenib in relapsed or progressive pLGG in patients harboring activating RAF alterations, completed a follow-on public offering, advanced our pivotal Phase 3 FIREFLY-2/LOGGIC trial for frontline pLGG as well as our Phase 2 FIRELIGHT-1 trial for MAPK-altered solid tumors, and recently entered into a CRADA agreement with the NCI to further expand therapeutic research opportunities using tovorafenib,” said Jeremy Bender, Ph.D., chief executive officer of Day One. “With this significant momentum, we believe we are well-positioned to continue to execute on our mission. We look forward to the topline results from the full FIREFLY-1 pivotal study population, expected in the first quarter of 2023, and potential subsequent NDA submission to the FDA. 2023 is poised to be another pivotal year for Day One.”

Program Highlights

- Pivotal FIREFLY-1 trial of tovorafenib in relapsed or progressive pLGG in patients harboring activating RAF alterations continues to progress following positive initial data from the first 25 patients announced in June 2022.
    - Additional interim results from FIREFLY-1 will be presented at the Society for Neuro-Oncology (SNO) annual meeting in November 2022.

- Day One is conducting a pivotal Phase 3 clinical trial (FIREFLY-2/LOGGIC) evaluating tovorafenib as a front-line therapy for patients newly diagnosed with pLGG.
    - The study is a randomized, monotherapy, open-label trial aiming to enroll approximately 400 patients aged 6 months to 25 years across approximately 100 sites globally, including in the United States, Europe and Asia.
    - The primary endpoint will be the ORR based upon Response Assessment for Neuro-Oncology (RANO) criteria as reported by Blinded Independent Central Review.
    - Secondary endpoints will include safety, progression-free survival, overall survival, duration of response, functional outcomes and quality of life measures.

- Patient enrollment continues in the Phase 2 FIRELIGHT-1 trial evaluating tovorafenib as a monotherapy and as a combination with the company’s investigational MEK inhibitor, pimasertib, in adults and adolescents with recurrent, progressive, or refractory solid tumors harboring MAPK pathway aberrations.

- Day One recently entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute's (NCI) Division of Cancer Treatment and Diagnosis, Cancer Therapy Evaluation Program (CTEP) to expand therapeutic research opportunities using tovorafenib.

    - NCI investigators will have the opportunity to study tovorafenib in CTEP-sponsored trials to be conducted by NCI-funded extramural clinical networks in several solid tumor and hematologic cancers.

- The company also recently announced a global collaboration with Foundation Medicine to develop FoundationOne®CDx as a companion diagnostic for tovorafenib.

Corporate Highlights and Upcoming Milestones

- Garry Nicholson was appointed as chairman of Day One’s board of directors. Mr. Nicholson brings more than 30 years of pharmaceutical and biotech oncology experience and previously served as president of Pfizer Oncology where he led its global oncology franchise.

- Day One strengthened its leadership team with the appointment of Adam Dubow as general counsel. Mr. Dubow joins Day One following a 22-year tenure at Bristol Myers Squibb, where he most recently served as chief compliance and ethics

officer and a member of the company's management team.

- Day One anticipates releasing topline results for the full FIREFLY-1 pivotal study population in the first quarter of 2023. If the data are supportive, Day One expects to submit a new drug application (NDA) to the United States Food and Drug Administration (FDA) in the first half of 2023.

- Day One expects to dose the first patient in FIREFLY-2/LOGGIC trial in the fourth quarter of 2022.

Third Quarter 2022 Financial Highlights

- **Cash Position:** Cash, cash equivalents and short-term investments totaled $374.3 million on September 30, 2022. Based on Day One's current operating plan, management believes it has sufficient capital resources to fund anticipated operations into 2025.

- **R&D Expenses:** Research and development expenses were $22.0 million for the third quarter of 2022 compared to $9.8 million for the third quarter of 2021. The increase was primarily due to additional employee compensation costs, clinical trial and pre-commercial manufacturing activities related to Day One's lead product candidate, tovorafenib.

- **G&A Expenses:** General and administrative expenses were $17.7 million for the third quarter of 2022 compared to $9.4 million for the third quarter of 2021. 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 $37.8 million for the third quarter of 2022 compared to $19.2 million for the third quarter of 2021 with non-cash stock compensation expense of $8.6 million and $5.1 million for the third quarters of 2022 and 2021, respectively.

Upcoming Events

- Society for Neuro-Oncology (SNO) annual meeting, November 16-20, 2022
- 34th Annual Piper Sandler Healthcare Conference, November 29–December 1, 2022

Inducement Grants
In connection with Mr. Dubow's appointment as general counsel, the compensation committee of the company's board of directors granted Mr. Dubow 47,400 restricted stock units (RSUs) and 309,000 options to purchase shares of the company's common stock on October 31, 2022 pursuant to the terms of the Company's 2022 Equity Inducement Plan. The grants of the RSUs and options were approved by the compensation committee as inducements to Mr. Dubow commencing employment with Day One, in accordance with Nasdaq Marketplace Rule 5635(c)(4). The RSUs vest as to 25% on the first anniversary of the first Quarterly Vesting Date (as defined below), and 1/12th of the remaining RSUs will vest quarterly thereafter, on each applicable quarterly vesting date. For purposes of this announcement, "Quarterly Vesting Date" means February 15, May 15, August 15 or November 15. Each RSU is subject to the terms and conditions of the 2022 Equity Inducement Plan and restricted stock unit agreement covering the grant. The options have an exercise price per share equal to the closing selling price as reported on the Nasdaq Stock Market for the grant date. 1/4th of the options vest and become exercisable on the one-year anniversary of the grant date, and 1/48th of the options vest and become exercisable on a monthly basis thereafter, in each case, so long as the employee remains employed by Day One through the applicable vesting date. The options have a ten-year term and are subject to the terms and conditions of the 2022 Equity Inducement Plan and stock option agreement covering the grant.

About Tovorafenib
Tovorafenib is an investigational, oral, brain-penetrant, highly selective type II pan-RAF kinase inhibitor designed to target a key enzyme in the MAPK signaling pathway, which is being investigated in primary brain tumors and solid tumors harboring activating RAF alterations. Tovorafenib has been studied in over 325 patients to date. Currently tovorafenib is under evaluation in a pivotal Phase 2 clinical trial (FIREFLY-1) among pediatric, adolescent and young adult patients with relapsed or progressive pediatric low-grade glioma (pLGG), which is an area of considerable unmet need with no approved therapies for the majority of patients. Day One has also initiated a pivotal Phase 3 study (FIREFLY-2/LOGGIC) in newly-diagnosed patients with pLGG. Beyond pLGG, tovorafenib is being evaluated alone or 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 (EC) for the treatment of glioma.

About Pimasertib
Pimasertib is an investigational, oral, highly selective, small molecule inhibitor of mitogen-activated protein kinases 1 and 2 (MEK-1/-2) within the MAPK signaling pathway. Pimasertib has been dosed in over 850 patients to date for various tumor types. Preclinical data indicates that the combination of a MEK inhibitor, such as pimasertib, and a type II RAF inhibitor, such as tovorafenib, has synergistic anti-tumor activity.

Day One is conducting a Phase 1b/2 study (FIRELIGHT-1) to evaluate the safety, tolerability, and preliminary efficacy of combining pimasertib with tovorafenib in adolescent and adult patients (≥12 years of age) with recurrent, progressive, or refractory solid tumors with MAPK pathway aberrations.

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 "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 (DAY101), is an investigational, oral, brain-penetrant, highly-selective type II pan-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 South San Francisco. 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 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 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 the COVID-19 pandemic, inflation and rising interest rates 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 and Comprehensive Loss
(unaudited)
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 22,035	$ 9,849	$ 59,598	$ 32,395
General and administrative	17,664	9,392	44,568	18,373
Total operating expenses	39,699	19,241	104,166	50,768
Loss from operations	(39,699)	(19,241)	(104,166)	(50,768)
Interest income (expense), net	1,895	(6)	2,086	(19)
Other income (expense), net	9	7	8	(29)
Net loss	(37,795)	(19,240)	(102,072)	(50,816)
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	$ (37,795)	$ (19,240)	$ (102,072)	$ (148,701)
Net loss per share, basic and diluted	$ (0.53)	$ (0.33)	$ (1.61)	$ (4.98)
Weighted-average number of common shares used in computing net loss per share, basic and diluted	71,008,993	57,514,218	63,522,774	29,859,883

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

	September 30, 2022	December 31, 2021
Cash, cash equivalents, and short-term investments	$ 374,341	$ 284,309
Total assets	381,861	289,821
Total liabilities	18,785	8,673
Accumulated deficit	(229,559)	(127,487)
Total stockholders' equity	363,076	281,148

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