Day One Reports Second Quarter 2022 Financial Results and Corporate Progress

August 4, 2022

Reported positive initial data from ongoing pivotal FIREFLY-1 study with tovorafenib (DAY101) in relapsed pediatric low-grade glioma (pLGG); topline results for full pivotal study population expected in the first quarter of 2023

Expanded development of tovorafenib with initiation of pivotal Phase 3 FIREFLY-2/LOGGIC clinical trial evaluating tovorafenib as a front-line therapy in pLGG

Completed $172.5 million upsized public offering providing funding into 2025

SOUTH SAN FRANCISCO, Calif., Aug. 04, 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 second quarter of 2022 and highlighted recent corporate achievements.

“Day One continues to deliver on our mission. During this past quarter we announced positive initial data from the ongoing pivotal FIREFLY-1 study with tovorafenib in relapsed pLGG and raised $172.5 million in a follow-on public offering, which will fund the company into 2025,” said Jeremy Bender, Ph.D., chief executive officer of Day One. “We look forward to the topline results from the full FIREFLY-1 pivotal study population in the first quarter of 2023. We are also excited to have recently expanded the development of tovorafenib into newly-diagnosed pLGG patients (FIREFLY-2/LOGGIC), and we continue to enroll patients in our Phase 2 FIRELIGHT-1 trial evaluating tovorafenib both as a monotherapy and in combination with pimasertib in adolescent and adult patients with solid tumors harboring MAPK alterations.”

Program Highlights

- Announced positive initial data from the pivotal FIREFLY-1 trial of tovorafenib in relapsed pLGG. Initial data from the first 25 patients enrolled in the trial showed:
    - 64% overall response rate (ORR) and 91% CBR (partial response/unconfirmed partial response + stable disease) in the 22 RANO-evaluable patients
        - 14 partial responses (13 confirmed responses and 1 unconfirmed response)
        - 6 patients with stable disease
    - All patients with stable disease (n=6) were noted to have tumor shrinkage, ranging between 19% and 43%
    - Responses were observed in patients with both BRAF fusions and BRAF V600E mutations who received prior MAPK-targeted therapy
    - The median-time-to-response was 2.8 months
    - A heavily-pretreated population, with a median of 3 prior lines of therapy (range: 1-9)
    - All patients who responded remain on therapy (n=14) and no patients have discontinued treatment due to treatment-related adverse events
  - Initial safety data indicated monotherapy tovorafenib to be generally well-tolerated
    - The majority of adverse events (AEs) were grade 1 or 2 in nature; the most common (≥25% any grade) treatment related AEs were increase in blood creatine phosphokinase, rash, and hair color changes
    - Treatment-related AEs of grade 3 or greater occurred in nine patients (36%)

- Day One has initiated 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 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

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

Corporate Highlights and Upcoming Milestones

- In June 2022, Day One announced the successful closing of an upsized public offering, raising gross proceeds of $172.5

million, which extends the Company's cash runway into 2025.

- 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 third quarter of 2022.

Second Quarter 2022 Financial Highlights

- **Cash Position:** Cash, cash equivalents and short-term investments totaled $394.9 million on June 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 $22.6 million for the second quarter of 2022 compared to $9.9 million for the second 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 $14.2 million for the second quarter of 2022 compared to $5.5 million for the second quarter of 2021. The increase was primarily due to additional employee compensation costs, initial commercial buildout, and professional service expenses to support company growth.

- **Net Loss:** Net loss totaled $36.5 million for the second quarter of 2022 compared to $15.5 million for the second quarter of 2021 with non-cash stock compensation expense of $5.6 million and $2.5 million for the second quarters of 2022 and 2021, respectively.

Upcoming Events

- 2022 Wedbush PacGrow Healthcare Virtual Conference
  - Management will participate in a panel discussion on Tuesday, August 9, 2022 at 10:55 a.m. ET. A live and archived audio webcast of the discussion will be available for 30 days by visiting the Events & Presentations section of the Company's website.
- Morgan Stanley 20th Annual Global Healthcare Conference, September 12-14, 2022

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 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 DAY101 as designed, any expectations about safety, efficacy, timing and ability to complete clinical trials, release data results and to obtain regulatory approvals for DAY101 and other candidates in development, and the ability of DAY101 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 the COVID-19 pandemic 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.
Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(In thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 22,560	$ 9,914	$ 37,563	$ 22,547
General and administrative	14,159	5,525	26,904	8,990
Total operating expenses	36,719	15,439	64,467	31,537
Loss from operations	(36,719)	(15,439)	(64,467)	(31,537)
Interest income (expense), net	189	(7)	191	(14)
Other expense, net	—	(27)	(1)	(24)
Net loss	(36,530)	(15,473)	(64,277)	(31,575)
Net loss attributable to redeemable convertible noncontrolling interest	—	(1,191)	—	(2,109)
Exchange of redeemable noncontrolling interest shares – deemed dividend	—	(99,994)	—	(99,994)
Net loss attributable to common stockholders/members	$ (36,530)	$ (114,276)	$ (64,277)	$ (129,460)
Net loss per share, basic and diluted	$ (0.60)	$ (5.04)	$ (1.08)	$ (10.81)
Weighted-average number of common shares used in computing net loss per share, basic and diluted	60,760,527	22,661,889	59,586,529	11,976,577

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

	June 30, 2022	December 31, 2021
Cash, cash equivalents, and short-term investments	$ 394,864	$ 284,309
Total assets	404,047	289,821

Total liabilities	13,416	8,673
Accumulated deficit	(191,764)	(127,487)
Total stockholders’ equity	390,631	281,148