Day One Reports First Quarter 2022 Financial Results and Provides Business Update

May 12, 2022

Initial data from pivotal FIREFLY-1 study with tovorafenib (DAY101) in relapsed pediatric low-grade glioma (pLGG) expected in June 2022

Company plans to initiate pivotal Phase 3 FIREFLY-2 clinical trial evaluating tovorafenib as a first-line therapy in pLGG in the second quarter of 2022

Initiated Phase 1b/2 combination study with tovorafenib and pimasertib in RAF-altered solid tumors

SOUTH SAN FRANCISCO, Calif., May 12, 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 first quarter of 2022 and highlighted recent corporate achievements.

“We continue to make excellent progress across our clinical programs and look forward to reporting initial data from our pivotal Phase 2 FIREFLY-1 trial in relapsed pLGG next month,” said Jeremy Bender, Ph.D., chief executive officer of Day One. “These initial data will provide preliminary insights into the potential of tovorafenib to transform patient care for the most common childhood brain cancer, which currently has no approved therapies. Beyond FIREFLY-1, we are preparing to initiate a pivotal Phase 3 study, FIREFLY-2, for the first-line treatment of pLGG patients and recently initiated the combination portion of our Phase 2 FIRELIGHT-1 study with tovorafenib and our investigational oral MEK inhibitor, pimasertib. As our clinical programs advance, we continue to accelerate planning for our first potential regulatory submission for tovorafenib in 2023 and execute on our business strategy to make an impact for patients of all ages with life threatening diseases.”

Program Highlights

- Initial data from FIREFLY-1, a pivotal Phase 2 clinical trial of tovorafenib in relapsed pLGG, is expected in June 2022.
- Day One anticipates releasing topline results from the fully-enrolled pivotal study in the first quarter of 2023. Pending positive results from FIREFLY-1, Day One anticipates filing a new drug application (NDA) with the U.S. Food and Drug Administration (FDA) in 2023.
- Day One has expanded the FIREFLY-1 study to include two additional study arms:
    - An expanded access arm that enables treatment for eligible patients once the primary cohort has completed enrollment; and
    - An advanced solid tumor arm to evaluate the preliminary efficacy of tovorafenib in patients aged 6 months to 25 years with a relapsed or progressive extracranial solid tumors with activating RAF fusion.
- Day One plans to initiate a pivotal Phase 3 clinical trial (FIREFLY-2) evaluating tovorafenib as a front-line therapy in pLGG in the second quarter of 2022.
- Day One is enrolling patients in the Phase 2 FIRELIGHT-1 trial evaluating tovorafenib monotherapy in adults with recurrent, progressive, or refractory solid tumors harboring MAPK pathway aberrations. Day One recently expanded FIRELIGHT-1 to include a Phase 1b/2 portion to evaluate tovorafenib in combination with pimasertib, Day One’s investigational MEK inhibitor.

First Quarter 2022 Financial Highlights

- **Cash Position:** Cash and cash equivalents totaled $262.7 million on March 31, 2022. Based on Day One’s current operating plan, management believes it has sufficient capital resources to fund anticipated operations into 2024.
- **R&D Expenses:** Research and development expenses were $15.0 million for the first quarter of 2022 compared to $12.6 million for the first quarter of 2021. The increase was primarily due to additional employee compensation costs, clinical trial and product development expenses which were offset by a decrease in milestone payments for licensing agreements.
- **G&A Expenses:** General and administrative expenses were $12.7 million for the first quarter of 2022 compared to $3.5 million for the first quarter of 2021. The increase was primarily due to additional employee compensation costs, initial commercial buildout, and professional expenses to support company growth.
- **Net Loss:** Net loss totaled $27.7 million for the first quarter of 2022 compared to $16.1 million for the first quarter of 2021

with non-cash stock compensation expense of $6.2 million and $0.5 million for the first quarters of 2022 and 2021, respectively.

Upcoming Events

- **2022 American Society of Clinical Oncology (ASCO) Annual Meeting**
  - A trial-in-progress poster on Day One's FIREFLY-1 pivotal study, abstract number TPS10062, will be presented at the ASCO Annual Meeting on Monday, June 6, 2022, from 8 to 11 a.m. CST.

- **The 20th International Symposium on Pediatric Neuro-Oncology (ISPNO) Annual Meeting**
  - An educational exhibit on Day One's pipeline will be displayed at Booth #F.05, at ISPNO's Annual Meeting, which is being held June 12-15, 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 or brain metastases of solid tumors. Tovorafenib has been studied in over 250 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 pediatric low-grade glioma (pLGG), which is an area of considerable unmet need with no approved therapies. Tovorafenib is also 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 developing targeted therapies for patients of all ages with life-threatening diseases. 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 is 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 clinical trial for DAY101 as designed, any expectations about safety, efficacy, timing and ability to complete clinical trials 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 March 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 15,003	$ 12,632
General and administrative	12,745	3,454
Total operating expenses	27,748	16,086
Loss from operations	(27,748)	(16,086)
Interest income (expense), net	2	(7)
Other expense, net	(1)	(8)
Net loss and comprehensive loss	(27,747)	(16,101)
Net loss attributable to redeemable convertible noncontrolling interests	—	(919)
Net loss attributable to common stockholders/members	$ (27,747)	$ (15,182)
Net loss per share, basic and diluted	$ (0.48)	$ (2.58)
Weighted-average number of common shares used in computing net loss per share, basic and diluted	58,382,444	5,892,145

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

	March 31, 2022	**December 31, 2021**
Cash and cash equivalents	$ 262,731	$ 284,309
Total assets	267,779	289,821
Total liabilities	8,176	8,673
Accumulated deficit	(155,234)	(127,487)
Total stockholders' equity	259,603	281,148