Day One Reports Third Quarter 2021 Financial Results and Corporate Progress

November 8, 2021

Enrollment Progresses in the Pivotal Phase 2 FIREFLY-1 Clinical Trial of DAY101 in Patients with pLGG; Initial Data Expected in 1H 2022

Upcoming CTOS Meeting to Highlight Single Agent Activity of Lead Drug Candidate, DAY101, in Spindle Cell Carcinoma Compassionate Use Case

SOUTH SAN FRANCISCO, Calif., Nov. 08, 2021 (GLOBE NEWSWIRE) -- Day One Biopharmaceuticals (Nasdaq: DAWN), a clinical-stage biopharmaceutical company dedicated to developing and commercializing targeted therapies for patients of all ages with genomically defined cancers, today announced financial results for the third quarter of 2021 and highlighted recent corporate achievements.

“We continue to build momentum in our lead program with the granting of Rare Pediatric Disease Designation for DAY101 for the treatment of pediatric low-grade glioma during the third quarter,” said Jeremy Bender, Ph.D., chief executive officer of Day One. “Additionally, with the further strengthening of our leadership team and continued progress with enrollment in our pivotal Phase 2 study, FIREFLY-1, we remain on track to present initial clinical data from this trial in the first half of 2022. We continue to grow our company, advance our development programs, and work to achieve our mission of impacting the lives of all people with cancer, whatever their age, starting from Day One.”

Program Highlights

- FIREFLY-1, a pivotal Phase 2 clinical trial of DAY101 in pediatric low-grade glioma (pLGG), continues active enrollment; initial data are expected in the first half of 2022. The single arm, open-label, global registrational Phase 2 study is anticipated to enroll 60 patients and has activated approximately 25 sites globally.

- Day One will present a poster at the 2021 Connective Tissue Oncology Society (CTOS) Virtual Annual Meeting on November 12, 2021. The poster reviews a compassionate use case of a child with recurrent spindle cell sarcoma harboring a novel SNX8-BRAF gene fusion who had exhausted all treatment options, including a MEK inhibitor, and was treated with DAY101 monotherapy. Following treatment, the patient’s symptoms resolved and there was no evidence of measurable disease at the site of previously visualized tumor, indicating a complete response to treatment with DAY101.

- Day One is also conducting a Phase 2 monotherapy trial of DAY101 in adult patients with recurrent, progressive, or refractory solid tumors harboring MAPK pathway aberrations.

Corporate Highlights

- Day One strengthened its leadership team with appointment of Jaa Roberson as chief people officer. Ms. Roberson will oversee all aspects of Day One’s human resources and talent acquisition efforts as the Company continues to grow.

- The Company recently expanded its board of directors with the appointment of Scott Garland. Mr. Garland is a 30-year veteran of the biopharmaceutical industry with deep commercial and executive leadership experience.

Third Quarter 2021 Financial Highlights

- **Cash Position:** Cash and cash equivalents and short-term investments totaled $297.2 million at September 30, 2021. Based on Day One’s current operating plan, management believes it has sufficient capital resources to fund anticipated operations into the second half of 2023.

- **R&D Expenses:** Research and development expenses were $9.8 million for the third quarter 2021 compared to $2.5 million for the third quarter 2020. The increase was primarily due to additional employee compensation costs, clinical trial expenses, and CMC activity.

- **G&A Expenses:** General and administrative expenses were $9.4 million for the third quarter 2021 compared to $1.0 million for the third quarter 2020. The increase was primarily due to additional employee compensation costs, legal, and professional expenses associated with operating as a public company.

- **Net Loss:** Net loss totaled $19.2 million and $3.8 million for the third quarters of 2021 and 2020, respectively, with non-cash stock compensation expense of $5.1 million and $0.1 million for the third quarters of 2021 and 2020,

respectively.

Upcoming Events

- **Connective Tissue Oncology Society (CTOS) Virtual 2021 Annual Meeting** (November 10-13, 2021) Day One will present the following poster:

  Title: “Activity of Pan-Raf Inhibitor Day101 in a Pediatric Patient with a Recurrent Spindle Cell Sarcoma Harboring a Novel SNX8:BRAF Gene Fusion”
  Presenter: Katherine Offer, MD
  Date: Friday, November 12, 2021
  Time: 2:30 PM - 3:15 PM EST

- **30th Annual Credit Suisse Virtual Healthcare Conference, November 8-11, 2021**
- **33rd Annual Piper Sandler Healthcare Conference, November 29-December 3, 2021**

About DAY101
DAY101 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. Studies have shown DAY101 has high brain distribution and exposure in comparison to other MAPK pathway inhibitors, thus potentially benefiting patients with primary brain tumors or brain metastases of solid tumors. DAY101 is a type II RAF inhibitor found to selectively inhibit both monomeric and dimeric RAF kinase, which may broaden its potential clinical application to treat an array of RAF-altered tumors.

DAY101 has been studied in over 250 patients, and as a monotherapy demonstrated good tolerability and encouraging anti-tumor activity in pediatric and adult populations with specific MAPK pathway-alterations. In November 2020, Day One announced preliminary results from PNOC014, an ongoing Phase 1 Pacific Pediatric Neuro-Oncology Consortium (PNOC) network study with DAY101 sponsored by the Dana-Farber Cancer Institute. Preliminary results demonstrated that of the eight relapsed pLGG patients in the study with RAF fusions, two patients achieved a complete response by Response Assessment for Neuro-Oncology (RANO), three had a partial response, two achieved prolonged stable disease, and one experienced progressive disease. DAY101 also demonstrated a tolerable safety profile with the most common side effects being skin rash and hair color changes.

DAY101 has been granted Breakthrough Therapy designation by the U.S. Food and Drug Administration (FDA) for the treatment of patients with pLGG harboring an activating RAF alteration who require systemic therapy and who have either progressed following prior treatment or who have no satisfactory alternative treatment options. The FDA has also granted Rare Pediatric Disease Designation to DAY101 for the treatment of low-grade gliomas harboring an activating RAF alteration that disproportionately affects children. In addition, DAY101 has received Orphan Drug designation from the FDA for the treatment of malignant glioma and orphan designation from the European Commission for the treatment of glioma.

Day One is conducting a pivotal Phase 2 trial (FIREFLY-1) of DAY101 in pediatric, adolescent and young adult patients with pLGG. Day One also plans to study DAY101 alone or in combination with other agents that target key signaling nodes in the MAPK pathway, such as the Company’s MEK inhibitor pimasertib, in patient populations where various RAS and RAF alterations are believed to play an important role in driving disease.

About Day One Biopharmaceuticals
Day One Biopharmaceuticals is a clinical-stage biopharmaceutical company dedicated to developing and commercializing targeted therapies for patients of all ages with genomically defined cancers. Day One was founded to address a critical unmet need: children with cancer are being left behind in a cancer drug development revolution. Our name was inspired by the “The Day One Talk” [1] that physicians have with patients and their families about an initial cancer diagnosis and treatment plan. We aim 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, DAY101, is an oral, highly-selective type II pan-RAF kinase inhibitor, and is being evaluated in a pivotal Phase 2 clinical trial (FIREFLY-1) in pediatric, adolescent and young adult patients with recurrent or progressive low-grade glioma (pLGG). The Company’s pipeline also includes the investigational agent pimasertib, a clinical-stage, oral, small molecule found to selectively inhibit mitogen-activated protein kinase kinases 1 and 2 (MEK). Through Day One and its collaborators, cancer drug development comes of age. Day One is based in South San Francisco. For more information, please visit www.dayonebio.com.

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.

[1]Jennifer W. Mack and Holcombe E. Grier; Journal of Clinical Oncology 2004 22:3, 563-566

Contacts:

Media:
1AB
Dan Budwick
dan@1abmedia.com

Investors:
LifeSci Advisors
Hans Vitzthum
hans@lifesciadvisors.com

Day One Biopharmaceuticals, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(In thousands)

	Three Months Ended September 30,	
	2021	**2020**
Operating expenses:		
Research and development	$ 9,849	$ 2,537
General and administrative	9,392	1,024
Total operating expenses	19,241	3,561
Loss from operations	(19,241)	(3,561)
Interest expense	(6)	(9)
Other expense	7	(1)
Changes in fair value of derivative tranches liability	-	(271)
Net loss and comprehensive loss	(19,240)	(3,842)
Net loss attributable to redeemable convertible noncontrolling interests	-	(1,018)
Net loss attributable to common share members / common stockholders	$ (19,240)	$ (2,824)
Net loss per share, basic and diluted	$ (0.33)	$ (0.50)
Weighted-average number of common shares used in computing net loss per share, basic and diluted	57,514,218	5,601,511

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

	September 30, 2021	December 31, 2020
Cash and cash equivalents	$ 297,160	$ 43,728
Total assets	303,783	45,661
Total liabilities	6,111	2,200
Accumulated deficit	(105,547)	(56,842)
Total stockholders'/members' equity (deficit)	297,672	(54,205)