Day One Reports Second Quarter 2021 Financial Results and Corporate Progress

August 10, 2021

DAY101 Granted Rare Pediatric Disease Designation from FDA

DAY101 Granted Orphan Designation from European Commission

Dosed the First Patients in Pivotal FIREFLY-1 Clinical Trial of DAY101 in Patients with pLGG

Successfully Completed $184 Million Upsized Initial Public Offering Providing Funding into the Second Half of 2023

SOUTH SAN FRANCISCO, Calif., Aug. 10, 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 second quarter of 2021 and highlighted recent corporate achievements.

“Day One made significant progress across multiple clinical and corporate initiatives during the second quarter of 2021, including dosing the first patients in our ongoing FIREFLY-1 pivotal study of DAY101 in pediatric low-grade glioma,” said Jeremy Bender, Ph.D., chief executive officer of Day One. “The success of our recent IPO reflects a strong commitment from our investors who, like all of us at Day One, recognize the therapeutic potential of DAY101. Entering the second half of 2021, we remain well positioned to advance our pipeline through key data readouts with the goal of fulfilling our mission of developing novel medicines to improve the lives of patients of all ages living with cancer.”

Program Highlights

- The Company announced first patients dosed in the FIREFLY-1 pivotal clinical trial of DAY101 in pediatric low-grade glioma (pLGG). FIREFLY-1 is being conducted in collaboration with the Pacific Pediatric Neuro-Oncology Consortium (PNOC) and is designed to support the regulatory approval of DAY101. Initial data from FIREFLY-1 is expected in the first half of 2022.

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

- The U.S. Food and Drug Administration (FDA) has granted Rare Pediatric Disease Designation to DAY101 for the treatment of low-grade gliomas harboring an activating RAF alteration that disproportionately affects children. If a New Drug Application in the United States for DAY101 is approved, Day One may be eligible to receive a Priority Review Voucher (PRV) from the FDA, which can be redeemed to obtain priority review for any subsequent marketing application or may be sold or transferred.

- The European Commission granted DAY101 Orphan Designation for the treatment of glioma based upon a positive opinion from the European Medicines Agency Committee for Orphan Medicinal Products.

Corporate Highlights

- The Company announced the successful closing of its upsized initial public offering, raising gross proceeds of $184.0 million, bringing total cash, cash equivalents and marketable securities to $310.0 million at the end of June 30, 2021. The company expects its current cash position to fund operations into the second half of 2023 and through key clinical milestones.

- Day One appointed Saira Ramasastry to its Board of Directors. Ms. Ramasastry currently serves as the Managing Partner of Life Sciences Advisory, LLC, and brings more than 20 years of experience to the Board as a life sciences-focused strategic consultant and investment banker.

Second Quarter 2021 Financial Highlights

- **Cash Position:** Cash and cash equivalents and short-term investments totaled $310.0 million at June 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 $9.9 million for the second quarter 2021 and $1.4 million for the second quarter 2020. The increase was primarily due to additional employee compensation costs, clinical trial

expenses, CMC activity and a milestone payment for DAY101.

- **G&A Expenses:** General and administrative expenses were $5.5 million for the second quarter 2021 and $0.9 million for the second quarter 2020. The increase was primarily due to additional employee compensation costs, legal, and professional expenses associated with being a public company.

- **Net Loss:** Net loss totaled $15.5 million and $2.4 million for the second quarter 2021 and 2020, respectively, with non-cash stock compensation expense of $2.5 million and $0.1 million for the second quarter of 2021 and 2020, respectively.

Upcoming Events

- **12th Annual Wedbush PacGrow Healthcare Conference**: Day One's chief executive officer Jeremy Bender will be a participant on the Panel, "Bullseye – Targeted Oncology Part 2". The panel discussion will take place on Wednesday, August 11th at 10:20 am ET. Day One will also be available for one-on-one investor meetings during the conference.

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

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

	Three Months Ended June 30,	
	2021	**2020**
Operating expenses:		
Research and development	$ 9,914	$ 1,437
General and administrative	5,525	872
Total operating expenses	15,439	2,309
Loss from operations	(15,439)	(2,309)
Interest expense	(7)	(10)
Other expense	(27)	-
Changes in fair value of derivative tranches liability	-	(90)
Net loss and comprehensive loss	(15,473)	(2,409)
Net loss attributable to redeemable convertible noncontrolling interests	(1,191)	(649)
Exchange of redeemable noncontrolling interest shares – deemed dividend*	(99,994)	-
Net loss attributable to common share members / common stockholders	$ (114,276)	$ (1,760)
Net loss per share, basic and diluted	$ (5.04)	$ (0.32)
Weighted-average number of common shares used in computing net loss per share, basic and diluted	22,661,889	5,456,203

* The exchange of redeemable non-controlling interest shares for Company common stock was accounted for as a non-cash, deemed dividend. See Note 13 in the form 10-Q filed on August 10, 2021 for further information.

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

	June 30, 2021	**December 31, 2020**
Cash and cash equivalents	$ 309,996	$ 43,728
Total assets	316,537	45,661
Total liabilities	4,774	2,200
Accumulated deficit	(86,308)	(56,842)
Total stockholders' equity /members' (deficit)	311,763	(54,205)

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