Day One Reports Fourth Quarter and Full Year 2021 Financial Results and Corporate Progress

March 7, 2022

Initial data from pivotal FIREFLY-1 study with DAY101 (tovorafenib) expected in June 2022

Targeted enrollment achieved in pivotal FIREFLY-1 study

Topline results from pivotal FIREFLY-1 study expected in Q1 2023

Current cash provides runway into 2024 and through multiple expected key clinical milestones

SOUTH SAN FRANCISCO, Calif., March 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 its fourth quarter and full year 2021 financial results and highlighted recent corporate achievements.

“Our clinical and corporate achievements in 2021 have set a solid foundation for a potentially transformational next 12 months,” said Jeremy Bender, Ph.D., chief executive officer of Day One. “We expect to report the initial data from our pivotal Phase 2 FIREFLY-1 trial of DAY101 in relapsed pediatric low-grade glioma in June of 2022 followed by topline results in the first quarter of 2023. In addition, we are enrolling patients in our Phase 2 FIRELIGHT-1 monotherapy trial of DAY101 in RAF-altered solid tumors and are preparing to initiate a Phase 1b/2 combination portion of the study with our oral MEK inhibitor, pimasertib. As our clinical development programs continue to advance and expand, we remain well-capitalized to fund our operations into 2024 and we will continue to execute on our mission to provide innovative targeted therapies for people of all ages.”

Program Highlights

- Initial data from FIREFLY-1, a pivotal Phase 2 clinical trial of DAY101 (tovorafenib) in pediatric low-grade glioma (pLGG), is expected in June 2022.
- FIREFLY-1 has reached targeted enrollment across approximately 30 sites globally. Day One anticipates releasing topline results from the 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.
- The first patient has been dosed with a pediatric formulation in the FIREFLY-1 study.
- The Company plans to initiate a pivotal Phase 3 clinical trial (FIREFLY-2) evaluating DAY101 as a first-line therapy in pLGG in the second quarter of 2022.
- Day One is enrolling patients in the Phase 2 FIRELIGHT-1 trial evaluating DAY101 monotherapy in adults with recurrent, progressive, or refractory solid tumors harboring MAPK pathway aberrations, with 8 sites activated. Day One plans to expand FIRELIGHT-1 to include a Phase 1b/2 portion to evaluate DAY101 in combination with pimasertib, the Company’s MEK Inhibitor. The Company expects to initiate the combination portion of the study in March of 2022.

Fourth Quarter and Full Year 2021 Financial Highlights

- **Cash Position:** Cash and cash equivalents totaled $284.3 million on December 31, 2021. 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 $11.2 million and $43.6 million for the fourth quarter and full year ended December 31, 2021, respectively, as compared to $4.2 million and $9.1 million for the same periods in 2020. The increase was primarily due to additional employee compensation costs, milestone payments for licensing agreements, clinical trial, and product development expenses.
- **G&A Expenses:** General and administrative expenses were $10.8 million and $29.2 million for the fourth quarter and full year ended December 31, 2021, respectively, as compared to $2.0 million and $4.7 million for the same periods in 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 $21.9 million for the fourth quarter of 2021 with non-cash stock compensation expense of $5.1 million, compared to $35.6 million for the fourth quarter of 2020 with non-cash stock compensation expense of $0.4 million.

Net loss was $72.8 million for the year ended December 31, 2021, with non-cash stock compensation expense of $13.3 million, compared to $43.8 million for the year ended December 31, 2020, with non-cash stock compensation expense of $0.5 million.

Upcoming Events

- **Cowen 42nd Annual Health Care Conference**
  - Management will participate in a fireside chat today, March 7 at 2:50 p.m. ET. A live and archived audio webcast of the discussion will be available by visiting the Events & Presentations section of the Company's website.

About DAY101 (tovorafenib)
DAY101 (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. 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.

DAY101 has been studied in over 250 patients, and as a monotherapy, previously demonstrated good tolerability and encouraging anti-tumor activity in pediatric and adult populations with specific MAPK pathway-alterations. 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.

DAY101 is being evaluated in a pivotal Phase 2 clinical trial (FIREFLY-1) for the treatment of pediatric low-grade glioma (pLGG). pLGG is the most common form of childhood brain cancer with no approved therapies. Day One has also initiated a Phase 1b/2 study (FIRELIGHT-1) with DAY101 in patients with recurrent or progressive solid tumors with activating RAF alterations and additional studies are planned with 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 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 people of all ages with life-threatening diseases. Day One partners with leading clinicians, families, and scientists to identify, acquire, and develop important emerging targeted treatments. The Company's lead product candidate, DAY101 (tovorafenib), is an investigational, oral, highly-selective type II pan-RAF kinase inhibitor currently 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 kinases 1 and 2 (MEK), which will be evaluated in a Phase 1/2 study (FIRELIGHT-1) in combination with DAY101 (tovorafenib) for adult and adolescent patients with solid tumors with MAPK pathway aberrations. Day One is based in South San Francisco. For more information, please visit https://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.

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

	Year Ended December 31,		
	2021	**2020**	**2019**
Operating expenses:			
Research and development	$ 43,584	$ 9,100	$ 13,899
General and administrative	29,159	4,682	1,006
Total operating expenses	72,743	13,782	14,905
Loss from operations	(72,743)	(13,782)	(14,905)
Interest income (expense), net	4	(30)	(2,077)
Other expense, net	(15)	(31)	(2)
Changes in fair value of derivative tranche liability	—	(30,000)	—
Net loss and comprehensive loss	(72,754)	(43,843)	(16,984)
Net loss attributable to redeemable convertible noncontrolling interests	(2,109)	(3,336)	(4,350)
Exchange of redeemable noncontrolling interest shares – deemed dividend*	(99,994)	—	—
Net loss attributable to common stockholders/members	$ (170,639)	$ (40,507)	$ (12,634)
Net loss per share, basic and diluted	$ (4.62)	$ (7.33)	$ (2.13)
Weighted-average number of common shares used in computing net loss per share, basic and diluted	36,960,569	5,529,519	5,924,640

* The exchange of redeemable non-controlling interest shares for Company common stock was accounted for as a non-cash, deemed dividend. See Note 11 in the form 10-K filed on March 7, 2022, for further information.

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

	December 31, 2021	**December 31, 2020**
Cash and cash equivalents	$ 284,309	$ 43,728
Total assets	289,821	45,661
Total liabilities	8,673	2,200
Accumulated deficit	(127,487)	(56,842)
Total stockholders' equity/members' (deficit)	281,148	(54,205)