Day One Reports First Quarter 2024 Financial Results and Corporate Progress

May 6, 2024

OJEMDA™ (tovorafenib) launch underway following U.S. FDA accelerated approval for relapsed or refractory BRAF-altered Pediatric Low-Grade Glioma (pLGG)

First prescriptions received in the U.S.

BRISBANE, Calif., May 06, 2024 (GLOBE NEWSWIRE) -- Day One Biopharmaceuticals (Nasdaq: DAWN) ("Day One" or the "Company"), a commercial-stage biopharmaceutical company dedicated to developing and commercializing targeted therapies for people of all ages with life-threatening diseases, today announced its first quarter 2024 financial results and highlighted recent corporate achievements.

"We are excited that OJEMDA is now approved and available here in the U.S., and we are grateful to the members of the pediatric brain tumor community whose support of the program has been invaluable," said Jeremy Bender, Ph.D., chief executive officer of Day One. "Our team is focused on executing our U.S. launch, on advancing our other programs, and on exploring opportunities to expand our pipeline."

Program Highlights

- In April 2024, the Company received U.S. Food and Drug Administration (FDA) accelerated approval of OJEMDA (tovorafenib), the first and only FDA approved therapy for the treatment of pediatric patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (pLGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation.

- With OJEMDA now available and the first prescriptions written, patients have begun enrolling in EveryDay Support From Day One™, a comprehensive program that offers personalized services for OJEMDA patients and their care teams, including insurance coverage support, financial assistance options and educational resources throughout the treatment journey.

- The pivotal Phase 3 FIREFLY-2/LOGGIC clinical trial evaluating tovorafenib as a front-line therapy in patients aged 6 months to 25 years with pLGG continues to enroll in the United States, Canada, Europe, Australia and Asia, with more than 90 sites activated.

- Patient enrollment continues in the Phase 1b/2 substudy (102b) of the FIRELIGHT-1 trial evaluating the combination of tovorafenib with the Company's investigational MEK inhibitor, pimasertib.

Corporate Highlights and Upcoming Milestones

- The Company received a rare pediatric disease priority review voucher from the FDA upon OJEMDA's approval.

- Results from the FIRELIGHT-1 Phase 1b and next steps are expected in the second half of 2024.

First Quarter 2024 Financial Highlights

- **Cash Position:** Cash, cash equivalents and short-term investments totaled $317.9 million on March 31, 2024. Based on Day One's current operating plan, management believes it has sufficient capital resources to fund anticipated operations into 2026.

- **R&D Expenses:** Research and development expenses were $40.2 million for the first quarter of 2024 compared to $27.8 million for the first quarter of 2023. The increase was primarily due to additional employee compensation costs, a payment for the buyback of priority review voucher obligation, and increased clinical trial and manufacturing activities related to Day One's lead product, OJEMDA.

- **G&A Expenses:** General and administrative expenses were $26.6 million for the first quarter of 2024 compared to $18.0 million for the first quarter of 2023. The increase was primarily due to additional employee compensation costs, ongoing commercial buildout, and increased professional service expenses to support company growth.

- **Net Loss:** Net loss totaled $62.4 million for the first quarter of 2024 with non-cash stock compensation expense of $12.6 million, compared to $42.4 million for the first quarter of 2023 with non-cash stock compensation expense of $9.4 million.

Upcoming Events

- 2024 American Society of Clinical Oncology (ASCO) Annual Meeting, May 31-June 4, 2024
  - Abstract #10036 titled “Type II RAF inhibitor tovorafenib in relapsed/refractory pediatric low-grade glioma (pLGG): Reversible decreases in growth velocity in the phase 2 FIREFLY-1 trial” will be presented in a poster session on Saturday, June 1 from 1:30-4:30 pm CDT in Hall A

- Goldman Sachs 45th Annual Global Healthcare Conference, June 10-13, 2024

- 21st International Symposium on Pediatric Neuro-Oncology (ISPNO), June 28-29, 2024

About OJEMDA™
OJEMDA (tovorafenib) is a Type II RAF kinase inhibitor of mutant BRAF V600, wild-type BRAF, and wild-type CRAF kinases.

OJEMDA is indicated for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (LGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Tovorafenib is under evaluation as a therapy for patients with pLGG requiring front-line treatment (Phase 3 FIREFLY-2/LOGGIC). It is also being studied in combination with the MEK inhibitor pimasertib for adolescent and adult patient populations with recurrent or progressive solid tumors with MAPK pathway alterations (FIRELIGHT-1).

Tovorafenib was granted Breakthrough Therapy and Rare Pediatric Disease designations by the FDA for the treatment of patients with pLGG harboring an activating RAF alteration, and it was evaluated by the FDA under priority review. Tovorafenib has also received Orphan Drug designation from the FDA for the treatment of malignant glioma and from the European Commission for the treatment of glioma.

For more information, please visit www.ojemda.com.

About Day One Biopharmaceuticals
Day One Biopharmaceuticals is a commercial-stage biopharmaceutical company that believes when it comes to pediatric cancer, we can do better. The Company was founded to address a critical unmet need: the dire lack of therapeutic development in pediatric cancer. Inspired by “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 targeted cancer treatments. The Company’s pipeline includes tovorafenib (OJEMDA™) and pimasertib.

Day One is based in Brisbane, California. For more information, please visit www.dayonebio.com or find the Company on LinkedIn or X.

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 and commercialize cancer therapies, expectations from current clinical trials, the execution of the Phase 2 and Phase 3 clinical trial for tovorafenib as designed, any expectations about safety, efficacy, timing and ability to complete clinical trials, release data results and to obtain regulatory approvals for tovorafenib and other candidates in development, and the ability of tovorafenib 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 and retain regulatory approval for or commercialize any product candidate, Day One’s ability to protect intellectual property, the potential impact of global business or macroeconomic conditions, including as a result of inflation, rising interest rates, instability in the global banking system, geopolitical conflicts 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.

Day One Biopharmaceuticals, Inc.
Condensed Statements of Operations
(unaudited)
(in thousands, except shares)

	Three Months Ended March 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 40,210	$ 27,828
General and administrative	26,557	18,027
Total operating expenses	66,767	45,855
Loss from operations	(66,767)	(45,855)
Investment income, net	4,365	3,466
Other expense, net	(10)	(4)
Net loss attributable to common stockholders	(62,412)	(42,393)
Net loss per share, basic and diluted	$ (0.72)	$ (0.59)
Weighted-average number of common shares used in computing net loss per share, basic and diluted	86,679,282	71,972,888

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

	March 31, 2024	**December 31, 2023**
Cash, cash equivalents and short-term investments	$ 317,944	$ 366,347
Total assets	326,645	376,048
Total liabilities	29,839	29,508
Accumulated deficit	(520,997)	(458,585)
Total stockholders' equity	296,806	346,540

DAY ONE MEDIA
Laura Cooper, Head of Communications
media@dayonebio.com

DAY ONE INVESTORS
LifeSci Advisors, PJ Kelleher
pkelleher@lifesciadvisors.com