Day One Reports Second Quarter 2024 Financial Results and Corporate Progress

July 30, 2024

Achieved $8.2 million in OJEMDA™ (tovorafenib) net product revenues in initial 2 months of launch

Expanded pipeline with DAY301, potential first-in-class Antibody Drug Conjugate (ADC) targeting PTK7

Entered into exclusive licensing agreement with Ipsen to commercialize tovorafenib outside of the U.S. for approximately $111 million upfront in cash and equity investment at a premium

Entered into a definitive agreement for an oversubscribed private placement of its securities for total gross proceeds of approximately $175 million

Company to host conference call and webcast today, July 30, 8:00 a.m. Eastern Time

BRISBANE, Calif., July 30, 2024 (GLOBE NEWSWIRE) -- Day One Biopharmaceuticals, Inc. (Nasdaq: DAWN) ("Day One" or the "Company"), a biopharmaceutical company dedicated to developing and commercializing targeted therapies for people of all ages with life-threatening diseases, today announced its second quarter 2024 financial results and highlighted recent corporate achievements.

"We had an outstanding quarter across all facets of our business," said Jeremy Bender, Ph.D., chief executive officer of Day One. "Demand for OJEMDA led to strong early launch performance following our first approval, and we made significant progress advancing our programs and pipeline, including the addition of DAY301, a potential first-in-class ADC targeting PTK7 that we expect to be in the clinic in the coming months."

Program Highlights

- OJEMDA received U.S. Food and Drug Administration (FDA) accelerated approval in April 2024. It is the first and only FDA approved therapy for the treatment of 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.

- Day One provided updated duration of treatment data from the registrational Phase 2 FIREFLY-1 trial investigating tovorafenib in patients with BRAF-altered, relapsed or progressive pLGG. For the 77 patients enrolled on Arm 1, which was the dataset used to assess OJEMDA's efficacy, the median duration of treatment is now 23.7 months, with some patients being on treatment out to 32 months. Additional analyses will be presented at future medical conferences.

- Day One and Ipsen entered into an exclusive licensing agreement to commercialize tovorafenib outside of the U.S. in July 2024. Under the agreement, Day One will receive approximately $111 million upfront in cash and equity investment at a premium with up to approximately $350 million in additional launch and sales milestone payments as well as tiered double-digit royalties starting in mid-teens percentage on net sales. Ipsen secured commercialization rights to tovorafenib outside of the U.S.

- Day One entered into an exclusive licensing agreement with MabCare Therapeutics for its novel ADC targeting protein-tyrosine kinase 7 (PTK7) in June 2024. The Company expects to dose the first patient in the Phase I portion of the Phase 1/2a clinical trial of DAY301 in the fourth quarter of 2024 or first quarter of 2025.

- Day One presented a poster on tovorafenib demonstrating reversibility of changes in growth velocity observed in the Phase 2 FIREFLY-1 clinical trial at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting. These data were also shared at the 21st International Symposium on Pediatric Neuro-Oncology (ISPNO).

- Day One made the decision to close the pimasertib program in July 2024, including the FIRELIGHT-1 trial evaluating it in combination with tovorafenib. Resources will be redirected to the DAY301 program and results will be shared at a future medical meeting or publication.

- 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 patients in the United States, Canada, Europe, Australia and Asia, with more than 100 sites activated.

Corporate Highlights and Upcoming Milestones

- Day One announced it entered into a definitive agreement for an oversubscribed private placement of its securities for total gross proceeds of approximately $175.0 million in July 2024.

- The Company sold the rare pediatric disease Priority Review Voucher awarded by the FDA upon OJEMDA's approval for total cash proceeds of $108.0 million in May 2024, representing a gain on sale.

- Commercial operations veteran John Stubenrauch joined Day One in July 2024 as Chief Technology Officer. Dr. Stubenrauch, PhD, MBA, was most recently Chief Operating Officer at Nutcracker Therapeutics and brings more than 25 years of experience developing and commercializing medicines, including ADCs, as well as a broad range of product modalities.

Second Quarter 2024 Financial Highlights

- **Cash Position:** The Company's cash, cash equivalents and short-term investments totaled $361.9 million as of June 30, 2024.

- **Product Revenue, Net:** OJEMDA net product revenues were $8.2 million for the second quarter of 2024, the first partial quarter of the U.S. launch.

- **R&D Expenses:** Research and development expenses were $92.1 million for the second quarter of 2024 compared to $32.2 million for the second quarter of 2023. The increase was primarily due to the MabCare Therapeutics license agreement upfront payment of $55.0 million, increased clinical trial activities related to tovorafenib, and additional employee compensation costs.

- **SG&A Expenses:** Selling, general and administrative expenses were $30.2 million for the second quarter of 2024 compared to $17.1 million for the second quarter of 2023. The increase was primarily due to additional employee compensation costs, commercial launch activities, and increased professional service expenses to support company growth.

- **Net Loss:** Net loss totaled $4.4 million for the second quarter of 2024 with non-cash stock-based compensation expense of $13.0 million, compared to $45.9 million for the second quarter of 2023 with non-cash stock-based compensation expense of $9.5 million.

Upcoming Events

- 2024 Wedbush PacGrow Healthcare Conference, August 12-14, 2024

Conference Call

Day One will host a conference call and webcast today, July 30 at 8:00 a.m. Eastern Time. To access the live conference call by phone, dial 877-704-4453 (domestic) or 201-389-0920 (international), and provide the access code 13745150. Live audio webcast will be accessible from the Day One Investors & Media page. To ensure a timely connection to the webcast, it is recommended that participants register at least 15 minutes prior to the scheduled start time. An archived version of the webcast will be available for replay on the Events & Presentations section of the Day One Investors & Media page for 30 days following the event.

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 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 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 DAY301 and a VRK1 inhibitor program.

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

Day One uses its Investor Relations website (ir.dayonebio.com), its X handle (x.com/DayOneBio), and LinkedIn Home Page (linkedin.com/company/dayonebio) as a means of disseminating or providing notification of, among other things, news or announcements regarding its business or financial performance, investor events, press releases, and earnings releases, and as a means of disclosing material nonpublic information and for complying with its disclosure obligations under Regulation FD.

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
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue:				
Product revenue, net	$ 8,192	$ —	$ 8,192	$ —
Cost and operating expenses:				
Cost of product revenue	707	—	707	—
Research and development	92,106	32,182	132,316	60,010
Selling, general and administrative	30,186	17,072	56,743	35,099
Total cost and operating expenses	122,999	49,254	189,766	95,109
Loss from operations	(114,807)	(49,254)	(181,574)	(95,109)
Non-operating income (expense)				
Gain from sale of priority review voucher	108,000	—	108,000	—
Investment income, net	3,962	3,406	8,327	6,872
Other expense, net	(10)	(15)	(20)	(19)
Total non-operating income, net	111,952	3,391	116,307	6,853
Loss before income taxes	(2,855)	(45,863)	(65,267)	(88,256)
Income tax expense	(1,552)	—	(1,552)	—
Net loss	$ (4,407)	$ (45,863)	$ (66,819)	$ (88,256)
Net loss per share, basic and diluted	$ (0.05)	$ (0.61)	$ (0.77)	$ (1.20)
Weighted-average number of common shares used in computing net loss per share, basic and diluted	87,121,310	74,964,878	86,864,545	73,478,567

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

	June 30, 2024	December 31, 2023
Cash, cash equivalents and short-term investments	$ 361,866	$ 366,347
Total assets	400,437	376,048
Total liabilities	93,706	29,508
Accumulated deficit	(525,404)	(458,585)
Total stockholders' equity	$ 306,731	$ 346,540

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