Day One Reports Preliminary 2024 OJEMDA™ Net Product Revenue and Highlights 2025 Corporate Priorities

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Preliminary 2024 OJEMDA™ (tovorafenib) net product revenue of approximately $57.2 million (unaudited)

First dose cohort cleared in Phase 1a/b clinical trial of DAY301 (PTK7-targeted ADC)

Ended 2024 with approximately $531.7 million in cash, cash equivalents and short-term investments (unaudited)

Company to present at 43rd Annual J.P. Morgan Healthcare Conference today at 3:45 p.m. Pacific Time (6:45 p.m. Eastern Time)

BRISBANE, Calif., Jan. 13, 2025 (GLOBE NEWSWIRE) -- Day One Biopharmaceuticals (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 preliminary unaudited 2024 OJEMDA net product revenue, cash and investments at year-end and delivered business updates ahead of the company's scheduled presentation today at the 43 rd Annual J.P. Morgan Healthcare Conference at 3 :45 p.m. Pacific Time / 6:45 p.m. Eastern Time. A live webcast of the event will be available at ir.dayonebio.com.

"We started 2025 with tremendous momentum based on our 2024 achievements and are well positioned to further our mission," said Jeremy Bender, Ph.D., chief executive officer of Day One. "Our priorities this year are to drive OJEMDA revenue, to continue investing in programs that leverage our expertise in development and commercialization, and to maintain a strong and durable financial position that allows us to operate independently from capital markets."

Preliminary 2024 Financial Highlights

OJEMDA net product revenues were approximately $29.0 million for the fourth quarter, bringing 2024 full-year revenue to approximately $57.2 million (unaudited).

The Company's cash, cash equivalents and short-term investments totaled approximately $531.7 million as of December 31, 2024 (unaudited), as compared to $366.3 million on December 31, 2023.

2024 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.
    - In December 2024, the Centers for Medicare & Medicaid Services agreed that OJEMDA is approved exclusively for pediatric indications, reducing its Medicaid and 340B minimum rebate percentage from 23.1% to 17.1%.
- Progressed enrollment in the pivotal Phase 3 FIREFLY-2 clinical trial evaluating tovorafenib as a front-line therapy in patients aged 6 months to 25 years with pLGG with more than 100 sites activated in the United States, Canada, Europe, Australia and Asia.
    - The Company expects to complete enrollment of FIREFLY-2 in the first half of 2026.
- Expanded the pipeline with the in-licensing of DAY301 and cleared the first cohort (a single-patient accelerated titration cohort) in the Phase 1a portion of the DAY301 Phase 1a/b clinical trial. DAY301 is a potential first-in-class Antibody Drug Conjugate (ADC) targeting PTK7.
- Entered into an exclusive licensing agreement with Ipsen to commercialize tovorafenib outside of the U.S.

2025 Upcoming Priorities and Milestones

- Continue to grow OJEMDA revenue in relapsed or refractory pLGG.
- Advance the existing pipeline, including the FIREFLY-2 Phase 3 clinical trial with tovorafenib in the front-line setting, and DAY301 in the Phase 1a/b trial.

- Pursue business development opportunities to expand the pipeline.
- Maintain a self-sustaining financial position for investing in durable growth.

The 2024 net product revenues and cash, cash equivalents and short-term investments position included in this release are preliminary and are therefore subject to adjustment. The preliminary net product revenue results are based on management's initial analysis of operations for the year ended December 31, 2024. The Company expects to issue full financial results for the fourth-quarter and full-year 2024 in February 2025.

J.P. Morgan Healthcare Presentation Details

Dr. Jeremy Bender, chief executive officer, will present during the 43rd Annual J.P. Morgan Healthcare Conference on Monday, January 13 at 3:45 p.m. Pacific Time / 6:45 p.m. Eastern Time. A live audio webcast of the presentation will be available by visiting the Events & Presentations section of the Company's website at www.dayonebio.com. An archived replay of the webcast will be available for 30 days following the live presentation.

About Day One Biopharmaceuticals

Day One Biopharmaceuticals is a commercial-stage company focused on advancing first- or best-in-class medicines for childhood and adult diseases with equal intensity. We were founded to address the lack of new therapies resulting from the traditional drug development model, which has left children with cancer and their families waiting too long for new treatments.

At Day One, we aim to identify and develop breakthrough medicines with the goal of improving the outcomes and life trajectories of patients of any age facing serious diseases — starting from Day One. Our "search & development" strategy enables us to find, acquire, and develop potential best-or first-in-class programs with the goal of introducing new medicines that will make a real difference in the treatment of children and adults.

Day One's pipeline includes tovorafenib (OJEMDA™), DAY301 and a VRK1 inhibitor program. The Company is based in Brisbane, California and can be found online at www.dayonebio.com, 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 ability to grow revenue from OJEMDA, plans to develop and commercialize cancer therapies and its pipeline and statements regarding its net produce revenues, cash, cash equivalents and short-term investments. 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.

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