# Day One Reports First Quarter 2023 Financial Results and Corporate Progress

May 1, 2023

*FIREFLY-1 clinical abstract selected for oral presentation at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting*

*Leadership team strengthened with executive appointments in clinical development and commercialization*

*Pre-New Drug Application (NDA) meeting held April 19, 2023 with U.S. Food and Drug Administration (FDA) for tovorafenib (DAY101) for relapsed or progressive pediatric low-grade glioma (pLGG)*

*Company to host conference call on June 4th at 6:00 PM CT*

BRISBANE, Calif., May 01, 2023 (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 first quarter 2023 financial results and highlighted recent corporate achievements.

"We are excited about our upcoming milestones, including the opportunity to share new clinical data from the FIREFLY-1 trial in an oral presentation at ASCO," said Jeremy Bender, Ph.D., chief executive officer of Day One. "We are also thrilled to announce the appointment of two industry veterans to Day One's executive leadership team. Lauren Merendino will join as Chief Commercial Officer and Dr. Raphaël Rousseau will join as Chief Medical Officer. Paired with the promotion of our co-founder Dr. Samuel Blackman to Head of Research and Development, these key appointments will help shape our future and contribute to long-term value creation for the company."

**Program Highlights**

- On April 26, 2023, Day One announced new clinical data from the ongoing, open-label, pivotal Phase 2 FIREFLY-1 trial evaluating the investigational agent tovorafenib in relapsed or progressive pLGG will be presented on June 4, 2023, as an oral presentation at the 2023 ASCO Annual Meeting. An ASCO abstract scheduled for release on May 25, 2023 will include topline data from FIREFLY-1 as of September 28, 2022, while new detailed clinical data will be highlighted at the June 4, 2023 oral presentation.

- Two additional posters will be presented on June 5, 2023 in the ASCO Pediatric Oncology session. These include a trial-in-progress poster for the FIREFLY-2 study and a poster describing a healthcare resource utilization study conducted for pLGG patients.

- On April 19, 2023, Day One held a pre-NDA meeting with the FDA for tovorafenib for the treatment of patients with relapsed or progressive pLGG. The company remains in position to initiate the submission of the NDA as early as the second quarter of 2023.

- On April 20, 2023, Day One presented a poster titled "Clinical Activity of the Type II pan-RAF Inhibitor Tovorafenib in BRAF-fusion Melanoma" at the 19th European Association of Dermato-Oncology (EADO) Congress demonstrating initial antitumor activity in relapsed/refractory adult BRAF-fusion in the ongoing FIRELIGHT-1 study (NCT04985604).

- In March 2023, Day One dosed the first patient in its pivotal Phase 3 FIREFLY-2/LOGGIC clinical trial evaluating tovorafenib as a frontline therapy for patients newly diagnosed with pLGG.

- Patient enrollment continues in the Phase 1b/2 FIRELIGHT-1 trials evaluating tovorafenib as a monotherapy and as a combination with the company's investigational MEK inhibitor, pimasertib, in adults and adolescents with relapsed, progressive, or refractory solid tumors harboring MAPK pathway aberrations.

**Corporate Highlights and Upcoming Milestones**

- Samuel C. Blackman, MD, PhD, co-founder and former Chief Medical Officer (CMO), has been promoted to Head of Research and Development. In this role, he will lead the direction of Day One's overall scientific research and development strategy. Dr. Blackman co-founded Day One and has served as CMO since November 2018. Under his leadership, the company has advanced its lead product candidate tovorafenib into a Phase 2 registrational trial in relapsed or progressive pLGG, a Phase 3 frontline trial in newly diagnosed pLGG and expanded development into evaluating tovorafenib as a monotherapy and as a combination with the investigational MEK inhibitor, pimasertib.

- Lauren Merendino, MBA, will lead Day One's commercial organization as Chief Commercial Officer (CCO) and will focus on finalizing preparations for the commercial launch of tovorafenib and bringing commercial perspective to key company decisions. Ms. Merendino has over 25 years of commercial experience, building and leading commercial teams through multiple product launches, including both oncology and pediatric rare diseases. Most recently, she was the CCO at Myovant Sciences where she oversaw the successful launch of 2 products across 3 indications in less than 2 years. Previously, she was the VP of Neurological Rare Diseases at Genentech where she led a cross-functional team to launch a new treatment for spinal muscular atrophy, a pediatric rare disease, where the product ultimately became a new standard of care.

- Raphaël Rousseau, MD, PhD, is appointed Chief Medical Officer (CMO) and will focus on executing and expanding Day One's clinical development programs. Dr. Rousseau was previously the CMO at Neogene Therapeutics and Gritstone Bio. Dr. Rousseau has more than 25 years of global oncology drug development experience and specifically, pediatric oncology clinical trial design. During his long tenure at Roche and Genentech, Dr. Rousseau built a team solely dedicated to developing innovative treatments for children with cancer, led or co-led the pediatric development and registration of bevacizumab, rituximab and capecitabine, and initiated the pediatric development of cobimetinib and atezolizumab in close collaboration with European and North American academic pediatric oncology consortiums.

**Fourth Quarter and Full Year 2022 Financial Highlights**

- **Cash Position:** Cash, cash equivalents and short-term investments totaled $318.2 million on March 31, 2023. Based on Day One's current operating plan, management believes it has sufficient capital resources to fund anticipated operations into 2025.

- **R&D Expenses:** Research and development expenses were $27.8 million for the first quarter of 2023 compared to $15.0 million for the first quarter of 2022. The increase was primarily due to additional employee compensation costs, as well as clinical trial and pre-commercial manufacturing activities related to Day One's lead product candidate, tovorafenib.

- **G&A Expenses:** General and administrative expenses were $18.0 million for the first quarter of 2023 compared to $12.7 million for the first quarter of 2022. The increase was primarily due to additional employee compensation costs, an ongoing commercial buildout, and professional service expenses to support company growth.

- **Net Loss:** Net loss totaled $42.4 million for the first quarter of 2023 with non-cash stock compensation expense of $9.4 million, compared to $27.7 million for the first quarter of 2022 with non-cash stock compensation expense of $6.2 million.

**Upcoming Events**

- Day One will present two posters at the 2023 American Society of Pediatric Oncology/Hematology (ASPHO) Conference May 10-13, 2023, focused on the pLGG burden of illness and healthcare utilization data.

- 2023 American Society of Clinical Oncology (ASCO) Annual Meeting, June 2-6, 2023

    - To join the Company's conference call and webcast on Sunday, June 4, 2023, at 6:00 PM CT, participants can access the conference call live via webcast from the Investors & Media page of Day One's website.

- Goldman Sachs 44th Annual Global Healthcare Conference, June 12-15, 2023

- Clinical data from the FIREFLY-1 study have been accepted as an oral presentation at the Society for Neuro-Oncology (SNO) 7th Biennial Pediatric Neuro-Oncology Research Conference from June 23-24, 2023.

**About Tovorafenib**
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, which is being investigated in primary brain tumors or brain metastases of solid tumors. Tovorafenib has been studied in over 325 patients to date. Currently tovorafenib is under evaluation in a pivotal Phase 2 clinical trial (FIREFLY-1) among pediatric, adolescent and young adult patients with relapsed or progressive pLGG, which is an area of considerable unmet need with no approved therapies for the vast majority of patients. Tovorafenib is also being evaluated alone or as a combination therapy for adolescent and adult patient populations with relapsed or progressive solid tumors with MAPK pathway aberrations (FIRELIGHT-1).

Tovorafenib has been granted Breakthrough Therapy and Rare Pediatric Disease designations by the U.S. Food and Drug Administration (FDA) for the treatment of patients with pLGG harboring an activating RAF alteration. Tovorafenib (DAY101) has also received Orphan Drug designation from the FDA for the treatment of malignant glioma, and from the European Commission (EC) for the treatment of glioma.

**About Day One Biopharmaceuticals**
Day One Biopharmaceuticals is a clinical-stage biopharmaceutical company that believes when it comes to pediatric cancer, we can do better. We put kids first and are developing targeted therapies that deliver to their needs. Day One was founded to address a critical unmet need: the dire lack of therapeutic development in pediatric cancer. The Company's name was 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 emerging cancer treatments. The Company's lead product candidate, tovorafenib, is an investigational, oral, brain-penetrant, highly-selective type II pan-RAF kinase inhibitor. The Company's pipeline also includes pimasertib, an investigational, oral, highly-selective small molecule inhibitor of mitogen-activated protein kinases 1 and 2 (MEK-1/-2). Day One is based in Brisbane. For more information, please visit www.dayonebio.com or find the company on LinkedIn or Twitter.

**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 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 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 the COVID-19 pandemic, inflation and rising interest rates 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.**
**Consolidated Statements of Operations**
**(unaudited)**
**(In thousands)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2023** | **2022** |
| Operating expenses: | | |
| Research and development | $ 27,828 | $ 15,003 |
| General and administrative | 18,027 | 12,745 |
| Total operating expenses | 45,855 | 27,748 |
| Loss from operations | (45,855) | (27,748) |
| Investment income, net | 3,466 | 2 |
| Other income (expense), net | (4) | (1) |
| Net loss attributable to common stockholders | (42,393) | (27,747) |
| Net loss per share, basic and diluted | $ (0.59) | $ (0.48) |
| Weighted-average number of common shares used in computing net loss per share, basic and diluted | 71,972,888 | 58,382,444 |

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

| | March 31, 2023 | December 31, 2022 |
|---|---|---|
| Cash, cash equivalents and short-term investments | $ 318,179 | $ 342,269 |
| Total assets | 323,563 | 349,062 |
| Total liabilities | 23,148 | 17,023 |
| Accumulated deficit | (312,061) | (269,668) |
| Total stockholders' equity | 300,415 | 332,039 |

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