Day One Announces Tovorafenib (DAY101) Data and Additional Abstracts to be Presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting

May 25, 2023

New clinical data from registrational FIREFLY-1 study to be featured as an oral presentation

Conference call and webcast scheduled on Sunday, June 4, 2023 at 6:00 p.m. CT

BRISBANE, Calif., May 25, 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 the publication of three abstracts on the American Society of Clinical Oncology (ASCO) website.

Dr. Lindsay Kilburn of Children's National Hospital will present new and updated clinical data from the registrational FIREFLY-1 trial on June 4, 2023 during an oral session from 10:57 -11:09 a.m. CT at the ASCO Annual Meeting. The presentation will include updated overall response rate, duration of response, and safety data, including evaluations by RANO-HGG, RAPNO-LGG and RANO-LGG criteria. Previously released data as of September 28, 2022 is reflected in the abstract published today. The presentation will be available on the Day One investor website shortly after the live presentation, with a conference call and webcast to follow later that evening.

Oral Presentation Details
Title: Clinical activity of pan-RAF inhibitor tovorafenib in the registrational pediatric low-grade glioma arm of the phase 2 FIREFLY-1 (PNOC026) study.
Abstract Number: 10004
Abstract Session: Pediatric Oncology I
Date/Time: June 4, 2023, 10:57 - 11:09 a.m. CT
Presenter: Lindsay Kilburn, M.D., Neuro-Oncology Center for Cancer and Blood Disorders, Children's National Medical Center

In addition, two posters will be presented on tovorafenib and healthcare resource data:
Poster Presentation Details
Title: A phase 3, randomized trial of tovorafenib vs. chemotherapy in pediatric and young adult patients with newly diagnosed low-grade glioma harboring an activating RAF alteration.
Abstract Number: TPS10067
Abstract Session: Pediatric Oncology
Date/Time: June 5, 2023, 1:15 - 4:15 p.m. CT
Presenter: Cornelis M. van Tilburg, MD, PhD, Hopp Children's Cancer Center Heidelberg, Heidelberg University Hospital and German Cancer Research Center

Title: Healthcare resource use for pediatric low-grade glioma care: A cohort of linked electronic health records and claims data.
Abstract Number: 10038
Abstract Session: Pediatric Oncology
Date/Time: June 5, 2023, 1:15 - 4:15 p.m. CT
Presenter: Tab Cooney, MD, Day One Biopharmaceuticals

Day One will also have a Medical Information booth at the 2023 ASCO Annual Meeting at booth number 27155.

Conference Call and Webcast Information
Day One will host a conference call and webcast on June 4, 2023, at 6:00 p.m. CT. Participants can access the conference call live via webcast from the Investors & Media page of Day One's website. To participate via telephone, please register in advance at this link. Upon registration, all telephone participants will receive a confirmation email detailing how to join the conference call, including the dial-in number along with a unique passcode that can be used to access the call.

The webcast will be made available for replay on the Company's website after the event and will be available for 30 days following the live presentation.

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 recurrent 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 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, California. 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 trials 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 inflation, rising interest rates, instability in the global banking system, and 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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