Day One Announces Tovorafenib FIREFLY-1 Data Published in Nature Medicine

November 17, 2023

Data subsets to be shared today in plenary oral presentations at the 2023 Society for Neuro-Oncology Annual Meeting

BRISBANE, Calif., Nov. 17, 2023 (GLOBE NEWSWIRE) -- Day One Biopharmaceuticals (Nasdaq: DAWN) ("Day One" or the "Company"), 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 the registrational Phase 2 FIREFLY-1 trial results evaluating the investigational agent tovorafenib in patients with BRAF-altered, relapsed or progressive pediatric low-grade glioma (pLGG) in *Nature Medicine*. Subsets of the data will also be presented today in two oral plenary presentations at the 2023 Society for Neuro-Oncology (SNO) Annual Meeting in Vancouver, Canada.

"The study results published in *Nature Medicine* demonstrate promising evidence with respect to the impact of tovorafenib for children and young adults with BRAF-altered relapsed or progressive pLGG, a debilitating form of brain tumor that currently has no approved systemic therapies," said Dr. Samuel Blackman, co-founder and head of research and development, Day One. "We look forward to continued development of tovorafenib."

Details on today's oral presentations and corresponding abstracts:

Title: *Clinical Activity and Safety of the RAF Inhibitor Tovorafenib in Patients with Optic Pathway Gliomas in the Registrational Pediatric Low-Grade Glioma Arm of the Phase 2 FIREFLY-1 (PNOC026) Study
Abstract Number: CTNI-24
Time: 10:15 – 10:25 AM PT
Location: Exhibit Hall C
Presenter: Karsten Nysom, MD, PhD, Copenhagen University Hospital - Rigshospitalet
**Presenter Karsten Nysom, MD, PhD received the 2023 SNO Annual Meeting Abstract Award for Excellence in Clinical Trials in connection to this oral presentation.*

Title: Clinical Activity of RAF Inhibitor Tovorafenib According to Prior MAPK Inhibitor Treatment in the Registrational Pediatric Low-Grade Glioma Arm of the Phase 2 FIREFLY-1 (PNOC026) Study
Abstract Number: CTNI-37
Time: 10:25 – 10:35 AM PT
Location: Exhibit Hall C
Presenter: Daniel Landi, MD, Duke University

A New Drug Application for tovorafenib monotherapy in BRAF-altered relapsed or progressive pLGG is currently under priority review by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act target action date of April 30, 2024. In addition to FIREFLY-1, the Phase 3 FIREFLY-2/LOGGIC randomized clinical trial is evaluating tovorafenib frontline therapy for patients newly diagnosed with pLGG.

About Tovorafenib
Tovorafenib is an investigational, oral, brain-penetrant, highly-selective type II 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 350 patients to date and is currently under evaluation in two pivotal clinical trials for pLGG. Tovorafenib is also being evaluated 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 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 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 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 trial for tovorafenib as designed, any expectations about safety, efficacy, timing and ability to complete clinical trials, release data results, the ability of Day One to obtain regulatory approvals for and to commercialize 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, cybersecurity events, instability in the global banking system, government shutdowns, uncertainty with respect to the federal budget, global regional conflicts and the sufficiency of Day One’s cash, cash equivalents and short-term 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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