

# Day One Announces Upcoming Presentations at 2022 Society for Neuro-Oncology Annual Meeting

November 11, 2022

SOUTH SAN FRANCISCO, Calif., Nov. 11, 2022 (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 two upcoming presentations at the Society for Neuro-Oncology (SNO) annual meeting, being held from November 16-20, 2022 in Tampa, FL.

Details are as follows:

<u>Title:</u> FIREFLY-1 (PNOC026): Phase 2 Study of Pan-RAF Inhibitor Tovorafenib in Pediatric and Young Adult Patients with RAF-altered Recurrent or Progressive Low-grade Glioma or Advanced Solid Tumors

<u>Format:</u> Poster presentation <u>Abstract Number:</u> CTNI-68

Date and Time: Friday, November 18, 2022; 7:30 PM - 9:30 PM ET

Location: West/Central Hall

Presenter: Lindsay Kilburn, MD, Children's National Medical Center

Title: LOGGIC/FIREFLY-2: A Phase 3, Randomized Trial of Tovorafenib vs. Chemotherapy in Pediatric Patients with Newly Diagnosed Low-grade

Glioma Harboring an Activating RAF Alteration

<u>Format:</u> Poster presentation <u>Abstract Number:</u> CTNI-30

Date and Time: Friday, November 18, 2022; 7:30 PM - 9:30 PM ET

Location: West/Central Hall

Presenter: Cornelis M. van Tilburg, Hopp Children's Cancer Center Heidelberg

#### 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 and solid tumors harboring activating RAF alterations. 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 pediatric low-grade glioma (pLGG), which is an area of considerable unmet need with no approved therapies for the majority of patients. Day One has also initiated a pivotal Phase 3 study (FIREFLY-2/LOGGIC) in newly-diagnosed patients with pLGG. Beyond pLGG, tovorafenib is 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 (DAY101), 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 South San Francisco. For more information, please visit <a href="https://www.dayonebio.com">www.dayonebio.com</a> 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 DAY101 as designed, any expectations about safety, efficacy, timing and ability to complete clinical trials, release data results and to obtain regulatory approvals for DAY101 and other candidates in development, and the ability of DAY101 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 the COVID-19 pandemic 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 MEDIA**

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