Day One Announces Cooperative Research and Development Agreement with National Cancer Institute to Expand Development of Tovorafenib (DAY101)

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SOUTH SAN FRANCISCO, Calif., Oct. 17, 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 that it has entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute's (NCI) Division of Cancer Treatment and Diagnosis, Cancer Therapy Evaluation Program (CTEP) to expand therapeutic research opportunities using tovorafenib (DAY101). Under the terms of the CRADA, NCI investigators will have the opportunity to study tovorafenib in CTEP-sponsored trials to be conducted by NCI funded extramural clinical networks in several solid tumor and hematologic cancers based upon encouraging anti-tumor activity observed in previous studies.

Tovorafenib is Day One's investigational, oral, brain-penetrant, highly selective type II pan-RAF kinase inhibitor designed to target a key enzyme in the MAPK signaling pathway with potential broad utilization in a variety of solid tumors harboring activating RAF alterations. In June 2022, Day One reported positive initial clinical data from its ongoing pivotal Phase 2 clinical trial (FIREFLY-1) with tovorafenib for the treatment of pediatric, adolescent and young adult patients with relapsed pediatric low-grade glioma (pLGG), which is the most common brain tumor diagnosed in children and for which there are no approved therapies for the vast majority of patients, as well as no recognized standard of care.

"Our CRADA with the NCI's CTEP reinforces our strategy to maximize the extensive clinical potential of tovorafenib in a variety of RAF-altered cancer indications beyond pLGG and our other internal development efforts," said Samuel Blackman, M.D., Ph.D., co-founder and chief medical officer of Day One. "We believe this collaboration will help build upon the current development plans for tovorafenib in pediatric and adult cancers and expand the body of evidence for tovorafenib's clinical profile, including its potential utility in multiple cancer types with MAPK alterations, which could represent indications we may choose to pursue in the future."

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 "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 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 (DAY101) as designed, any expectations about safety, efficacy, timing and ability to complete clinical trials, release data results and to obtain regulatory approvals for tovorafenib (DAY101) and other candidates in development, and the ability of tovorafenib (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.

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