Foundation Medicine and Day One Biopharmaceuticals Announce Global Collaboration to Advance Pediatric Cancer Care

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Efforts will focus on the development of FoundationOne®CDx as a companion diagnostic for Day One's tovorafenib, which is in late-stage clinical development for pediatric low-grade glioma

CAMBRIDGE, Mass., and SOUTH SAN FRANCISCO, Calif., Sept. 21, 2022 - Foundation Medicine, Inc., a pioneer in molecular profiling for cancer, and 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 a collaboration to develop FoundationOne®CDx as a companion diagnostic for Day One's lead investigational therapy, tovorafenib (DAY101).

Tovorafenib is an investigational, oral, brain-penetrant, highly selective type II pan-RAF kinase inhibitor, which is currently being evaluated in an ongoing pivotal Phase 2 clinical trial (FIREFLY-1) for the treatment of pediatric, adolescent and young adult patients with relapsed pediatric low-grade glioma (pLGG). In June 2022, Day One reported positive initial data from the FIREFLY-1 study and topline results for the full pivotal study population are expected in the first quarter of 2023. Day One has also initiated a pivotal Phase 3 study (FIREFLY-2/LOGGIC) with tovorafenib in newly-diagnosed patients with pLGG and tovorafenib is additionally being evaluated alone and as a combination therapy for other recurrent or progressive solid tumors with MAPK pathway aberrations.

"New advancements in pediatric cancer research, including novel targeted therapies and companion diagnostics, have the ability to provide a more precise perspective into a patient's disease helping to inform a tailored therapeutic strategy that may increase the odds of long-term success for children with these diseases," said Samuel Blackman, M.D., Ph.D., co-founder and chief medical officer of Day One. "Combining our purposeful approach to drug development with Foundation Medicine's genomic profiling expertise and global reach, will enable greater patient access to tovorafenib once approved, and ultimately help more children living with this debilitating form of cancer."

Foundation Medicine's portfolio of FDA-approved comprehensive genomic profiling tests offer physicians both blood- and tissue-based testing options for detecting genomic alterations that help guide personalized treatment decisions. Currently, Foundation Medicine's tissue and blood-based tests have more than 60 companion diagnostic indications collectively in the United States and Japan and are available in more than 100 countries globally.

"Foundation Medicine and Day One Biopharmaceuticals have a shared commitment to deepening our understanding of cancer biology so we can deliver more treatment options to patients of all ages, faster," said Sanket Agrawal, Chief Biopharma Business Officer at Foundation Medicine. "We're proud to partner with Day One to provide access to tovorafenib through companion diagnostic development once approved and look forward to our ongoing collaboration to address significant unmet needs in pediatric oncology."

If tovorafenib, and Foundation Medicine's companion diagnostic are approved, this would be the first companion diagnostic indication for FoundationOne CDx in pediatric oncology.

About Foundation Medicine: Your Essential Partner in Cancer Care

Foundation Medicine is a pioneer in molecular profiling for cancer, working to shape the future of clinical care and research. We collaborate with a broad range of partners across the cancer community and strive to set the standard for quality, scientific excellence, and regulatory leadership. Our deep understanding of cancer biology helps physicians make informed treatment decisions for their patients and empowers researchers to develop new medicines. Every day, we are driven to help our partners find answers and take action, enabling more people around the world to benefit from precision cancer care. For more information, please visit us on www.FoundationMedicine.com and follow us on Twitter and LinkedIn.

About FoundationOne®CDx

FoundationOne CDx is a next-generation sequencing based in vitro diagnostic device for detection of substitutions, insertion and deletion alterations (indels), and copy number alterations (CNAs) in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) using DNA isolated from formalin-fixed, paraffin-embedded (FFPE) tumor tissue specimens. FoundationOne CDx is for prescription use only and is intended as a companion diagnostic to identify patients who may benefit from treatment with certain targeted therapies in accordance with their approved therapeutic product labeling. Additionally, FoundationOne CDx is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms. Use of the test does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. Some patients may require a biopsy. For a full list of targeted therapies for which FoundationOne CDx is indicated as a companion diagnostic, please visit http://www.foundationmedicine.com/genomic-testing/foundation-one-cdx.

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.

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.

Day One Biopharmaceuticals 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, the timing or success of the development of a companion diagnostic using FoundationOne Liquid CDx, 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.

Source: Foundation Medicine

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