



Day One Appoints Garry Nicholson as Chairman of the Board of Directors

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SOUTH SAN FRANCISCO, Calif., Sept. 12, 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 the appointment of Garry Nicholson as chairman of its board of directors. Mr. Nicholson brings more than 30 years of pharmaceutical and biotech oncology experience and previously served as president of Pfizer Oncology where he led its global oncology franchise. Day One co-founder Julie Grant, who served as board chair since 2021, will continue to serve as a member of the board of directors.

"Garry is an accomplished leader in the development and commercialization of new cancer therapies and we are thrilled to welcome him as chairman of our board of directors," said Jeremy Bender, Ph.D., chief executive officer of Day One. "Garry's expertise and guidance will be critical as tovorafenib continues to advance in our pivotal FIREFLY-1 trial towards potential commercialization for relapsed pediatric low-grade glioma and as our other ongoing clinical trials continue to progress."

Mr. Nicholson currently serves as chairman of the board of directors for G1 Therapeutics and as a board member for Tmunity Therapeutics and NextCure. He also previously served on the board of directors for Turning Point Therapeutics, Five Prime Therapeutics and TESARO prior to their acquisitions by large pharmaceutical companies. As former president of Pfizer Oncology, his responsibilities included global commercialization, sales, clinical development, regulatory strategy and business development for Pfizer's oncology portfolio. Earlier in his career, Mr. Nicholson held various leadership positions in the oncology division of Eli Lilly and Company, including global oncology platform leader. He has also served as president and CEO of XTuit Pharmaceuticals. Mr. Nicholson earned a B.S. in Pharmacy from the University of North Carolina at Chapel Hill and an M.B.A. from the University of South Carolina.

"Day One is an innovative company dedicated to advancing new cancer therapies for people of all ages and I could not be more excited to join its board of directors as chairman," said Mr. Nicholson. "Tovorafenib has the potential to become a meaningful new targeted treatment for pediatric low-grade glioma, a devastating form of childhood brain cancer, and I look forward to applying my oncology market experience as the company prepares for potential commercialization."

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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