Day One Expands Pipeline with Potential First-in-Class Clinical-Stage Antibody Drug Conjugate (ADC) Targeting PTK7 in Solid Tumors for Adult and Pediatric Cancers

June 18, 2024

Day One receives exclusive license for development and commercialization of MTX-13 (DAY301), which received IND clearance by the FDA in April 2024

Targets PTK7, highly expressed in broad range of adult and pediatric solid tumors

BRISBANE, Calif., June 18, 2024 (GLOBE NEWSWIRE) -- Day One Biopharmaceuticals (Nasdaq: DAWN) ("Day One" or the "Company"), a commercial-stage biopharmaceutical company dedicated to developing and commercializing targeted therapies for people of all ages with life-threatening diseases, today announced it has entered into an exclusive licensing agreement (the Agreement) with MabCare Therapeutics (MabCare) for MTX-13, a novel ADC targeting protein-tyrosine kinase 7 (PTK7). Pursuant to the terms of the Agreement, Day One has exclusive rights to develop, manufacture, and commercialize MTX-13 worldwide, excluding Greater China.

In April 2024, the U.S. Food and Drug Administration (FDA) cleared the investigational new drug (IND) application for MTX-13, which going forward will be identified as DAY301. In pre-clinical studies, DAY301 showed antitumor activity in a wide range of solid tumors.

"Our priorities for 2024 are to successfully launch OJEMDA™ (tovorafenib), to advance our existing programs and to expand our pipeline by in-licensing clinical-stage assets that have the potential to transform outcomes for patients of all ages living with cancers," said Jeremy Bender, Ph.D., chief executive officer of Day One. "We are excited by the opportunity presented by DAY301, and we believe we have the right team in place to develop the program to its full potential."

DAY301 targets PTK7, a highly-conserved, catalytically inactive transmembrane protein that is overexpressed in multiple adult cancers, including esophageal, ovarian, lung, and endometrial cancer, as well as pediatric cancers such as neuroblastoma, rhabdomyosarcoma and osteosarcoma. PTK7 has limited expression in normal tissues or organs, making it an attractive target for therapeutic development.

"The addition of DAY301 to our pipeline strategically fits our mission of advancing both pediatric and adult medicines in areas of unmet need with equal urgency," said Dr. Samuel Blackman, co-founder and head of research and development at Day One. "We believe the linker-payload technology embodied in DAY301 will overcome the limitations of earlier PTK7-targeted ADCs, giving us a potential first-in-class drug against a clinically-validated target. We are excited to add this program to Day One and will look to enter the clinic in the coming months."

Under the terms of the licensing agreement, MabCare will receive $55 million upfront, and is eligible to receive an additional $1.152 billion in development, regulatory and commercial success-based milestones, plus low-to-mid single-digit royalties on net sales outside of Greater China. Day One expects the first patient to be dosed in the Phase I study in the fourth quarter of 2024 or first quarter of 2025.

About Day One Biopharmaceuticals
Day One Biopharmaceuticals is a commercial-stage biopharmaceutical company that believes when it comes to pediatric cancer, we can do better. The Company was founded to address a critical unmet need: the dire lack of therapeutic development in pediatric cancer. 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 targeted cancer treatments. The Company's pipeline includes tovorafenib (OJEMDA™) and pimasertib.

Day One is based in Brisbane, California. For more information, please visit www.dayonebio.com or find the Company on LinkedIn or X.

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, including DAY301, expectations regarding planned and current clinical trials 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, instability in the global banking system, geopolitical conflicts 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
Laura Cooper, Head of Communications
media@dayonebio.com

DAY ONE INVESTORS
LifeSci Advisors, PJ Kelleher
pkelleher@lifesciadvisors.com