Day One Expands Clinical-Stage Oncology Pipeline; Announces Global License Agreement with Merck KGaA, Darmstadt, Germany to Develop and Commercialize MEK Inhibitor Pimasertib

February 23, 2021

- Exclusive license agreement broadens Day One's clinical-stage pipeline of targeted cancer therapies with the additions of pimasertib and MSC2015103B
- Day One plans to evaluate the combination of pimasertib and DAY101, the Company's clinical-stage pan-RAF kinase inhibitor, in patients ≥12 years of age with advanced solid tumors

SOUTH SAN FRANCISCO, CA, February 23, 2021 – Day One Biopharmaceuticals, a clinical-stage biopharmaceutical company focused on accelerating new, promising targeted therapies for children and adults with cancer, today announced that it has entered into a global licensing agreement with Merck KGaA, Darmstadt, Germany, for an exclusive license to develop and commercialize pimasertib as well as a second compound, MSC2015103B. Pimasertib and MSC2015103B are oral, highly-selective small molecule allosteric inhibitors of MEK 1/2, a key enzyme in the MAPK signaling pathway. Dysregulation of the MAPK pathway has been shown to occur in many cancers.

Pimasertib has been studied in more than 10 Phase 1/2 clinical trials in approximately 900 patients with various tumor types. Day One plans to initiate a Phase 1/2 study to evaluate the safety, tolerability, and preliminary efficacy of combining pimasertib with DAY101, the Company's potential first-in-class, oral, brain-penetrant, highly selective type II pan-RAF kinase inhibitor, in patients ≥12 years of age with recurrent, progressive, or refractory solid tumors with MAPK pathway aberrations.

"Day One is purpose-built to accelerate innovative targeted therapies designed to help both children and adults with cancer," said Jeremy Bender, Ph.D., chief executive officer of Day One. "This license agreement with Merck KGaA, Darmstadt, Germany, exemplifies our core strategy to identify investigational potential treatment options such as pimasertib and leverage our expertise to rapidly advance them in patients who we believe will benefit the most. We are excited that a leading pharmaceutical company like Merck KGaA, Darmstadt, Germany recognizes the importance of our mission and look forward to the advancement of pimasertib in combination with our pan-RAF kinase inhibitor, DAY101."

"There is strong scientific and clinical rationale for targeting multiple nodes of the MAPK signaling pathway to drive deeper and more durable tumor responses," said Samuel Blackman, M.D., Ph.D., co-founder and chief medical officer of Day One. "DAY101 demonstrated encouraging single agent anti-tumor activity in pediatric low-grade glioma, and we believe the combination of pimasertib and DAY101 will be well-suited for adult patients with solid tumors given their greater heterogeneity. Further, data have shown DAY101 to selectively inhibit both RAF monomers and dimers which may broaden its potential clinical application in combination with MEK inhibition in solid tumors driven by non-BRAF V600 mutations and RAF fusions. We look forward to initiating a Phase 1/2 combination study later this year."

Under the terms of the agreement, Day One will make an upfront payment to Merck KGaA, Darmstadt, Germany plus additional regulatory, approval and sales-based milestone payments. Merck KGaA, Darmstadt, Germany will also receive royalties on potential net sales of pimasertib and MSC2015103B. Specific financial details are not disclosed.

About Pimasertib
Pimasertib is designed as a highly selective, oral, small molecule inhibitor of mitogen-activated protein kinase kinases 1 and 2 (MEK1/2), of the MAPK signaling pathway. Dysregulation of the MAPK pathway has been shown to occur in many cancers. Pimasertib has been studied in more than 10 Phase 1/2 clinical trials in approximately 900 patients with various tumor types and has demonstrated a safety and efficacy profile comparable to other MEK inhibitors.

About Day One Biopharmaceuticals
Day One Biopharmaceuticals is a differentiated company created to find and develop new therapies that meet the needs of people with cancer of all ages, starting with the biology of childhood cancer. The Company's name, Day One, was inspired by the "The Day One Talk" [1] that physicians have with patients and their families about an initial cancer diagnosis and treatment plan. Keeping the needs of patients and oncologists in mind, the Day One team focuses their efforts to bring medicines to families receiving this life-altering news. Together, we aim to re-envision cancer drug development and redefine what's possible for people with cancer – whatever their 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, DAY101, is designed as a first-in-class, oral, highly-selective pan-RAF kinase inhibitor, and the Company has initiated a Phase 2 registration-enabling study (FIREFLY-1) in pediatric, adolescent and young adult patients with recurrent or progressive low-grade glioma (pLGG). The Company's pipeline also includes the investigational agent pimasertib, a clinical-stage, oral, highly selective small molecule inhibitor of MEK. Based in South San Francisco, Day One has raised more than $190 million from leading life sciences investors. Through Day One and its collaborators, cancer drug development comes of age. For more information, please visit www.dayonebio.com.

[1]Jennifer W. Mack and Holcombe E. Grier; Journal of Clinical Oncology 2004 22:3, 563-566

Contact:
1AB
Dan Budwick

dan@1abmedia.com