



## **Day One Biopharmaceuticals shares plans to rapidly develop new cancer treatments for people of all ages and announces \$60M Series A funding and lead clinical-stage program acquired through Takeda**

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- Inspired and enabled by the pediatric oncology community, Day One prioritizes promising new medicines that can be rapidly brought to market for children with cancer
- \$60M Series A; Incubated by Canaan; Funded by Access Biotechnology, Atlas Venture, and Canaan
- Day One acquires Takeda's rights to develop and commercialize DAY101 worldwide and amends license agreement with Sunesis
- Day One plans to study for the treatment of children with relapsed gliomas

SOUTH SAN FRANCISCO, Calif., May 21, 2020 — DAY ONE Biopharmaceuticals, LLC. Using new insights from the biology of pediatric cancer, Day One Biopharmaceuticals develops promising new oncology therapies that change outcomes for people of all ages. Today, Day One unveils its team, \$60M Series A financing, and announces its first promising clinical-stage oncology treatment, which Day One acquired through Takeda Pharmaceutical Company Limited.

Advances in cancer research enable drug developers to identify children and adults who may benefit from the same medicine. Yet, children with cancer continue to be left behind. "In the US, children with cancer first gain access to cutting-edge investigational treatments an average of 6.5 years later than adults. This disparity in access occurs for multiple reasons, including the prioritization of adult cancers that can create larger markets; a development model that remains centered on adult conditions versus mechanism of action; and outdated assumptions around trial feasibility in pediatric oncology. As a result, only 10 new drugs for pediatric cancer have been FDA approved over the last 30 years," explained Dr. Samuel Blackman, co-founder, pediatric oncologist, and Chief Medical Officer of Day One. "Our goal is to dramatically change the pace of new cancer drug development for children by identifying and developing novel therapies based on pediatric cancer biology, and then following the biology to the benefit of all patients whether they are children or adults."

Enabled by advances in the understanding of the biology of childhood cancers, and informed by its network of leading pediatric oncologists, Day One is equipped to identify patients across the age spectrum who are likely to benefit from a new treatment based upon their tumor's biology. In parallel, Day One leverages improvements in pediatric oncology clinical trial infrastructure and modern study designs to execute faster and more efficient clinical trials for children with cancer. "This confluence allows new targeted therapies to be developed for both childhood and adult cancers with equal speed and intensity. A small focused company, like Day One, can execute rapidly to deliver new treatments for people with cancer. I am delighted to back Day One on this mission," Dr. Daniel Becker, Principal at Access Biotechnology.

Day One was incubated at Canaan through a focused effort to identify, acquire, and develop promising new treatments that could address childhood cancers. "Cancer impacts patients of all ages. New treatments should, too," noted Julie Grant, acting-CEO at Day One and General Partner at Canaan. "At Day One we ask – what is the fastest path to FDA approval and insurance coverage for this product? Treating patients whose tumors are most likely to respond to treatment, irrespective of age, as quickly as possible is a simple and often underutilized strategy. Our team is focused on development innovation and rapid execution, in addition to being at the forefront of cancer biology."

To execute on its strategy, Day One recruited a deeply experienced and creative team of drug developers to urgently pursue innovative clinical trials for children and adults with cancer. Details about Day One's team can be found [here](#). Day One's extended community of supporters also includes leading physician-scientists and clinical investigators who help inform Day One's translational and clinical plans, and members of the patient/parent advocacy community who ensure patient-centricity and a focus on the greatest unmet needs. "It is clear that Day One was purpose-built to serve the mission of accelerating pediatric oncology drug development," notes Dr. Daphne Haas-Kogan, Chair of the Department of Radiation Oncology at the Dana-Farber Cancer Institute, who treats both children and adults with cancer. "The depth and experience of their team, their deep commitment to the needs of these patients and their families, and their willingness to include families, investigators, and regulators from the start are unparalleled."

Day One also announced today that it acquired Takeda's rights to develop and commercialize DAY101 (formerly TAK-580) worldwide, including certain rights previously licensed by Takeda from Sunesis Pharmaceuticals. In parallel, Day One re-negotiated with Sunesis the terms of the licensing agreement acquired from Takeda. Takeda retains license to develop and commercialize DAY101 in certain rare disease indications.

"With its strong expertise in pediatric oncology, Day One is the ideal partner to continue advancing DAY101, which may one day

provide a new treatment option for children with relapsed gliomas,” said Chris Arendt, PhD, Head of Takeda’s Oncology Therapeutic Area Unit.

DAY101 is a potent selective oral, once-a-week, small molecule type II inhibitor of RAF, an oncogenic driver in a range of cancers including pediatric glioma and adult solid tumors. Over 250 patients have received DAY101 in clinical trials thus far. DAY101 demonstrated early clinical activity across adult and pediatric populations with specific genetic alterations in the RAS/MAP kinase pathway. Details of the clinical safety and efficacy data will be announced in 2020 and 2021.

Tumors harboring genetic alterations, such as BRAF wildtype fusions, BRAF mutations, and other alterations in the MAPK pathway could be addressed by DAY101. Many of these populations cannot be adequately treated with incumbent BRAF or MEK inhibitors. Michael Gladstone, Principal at Atlas Venture, said “Targeted oncology therapies in the RAS/MAP kinase pathway can deliver tremendous benefit to patients young and old. Our priority is developing DAY101 as both a monotherapy and in combination with complementary therapies to treat a range of aggressive cancers that are not served by existing drugs.” Canaan, Access Biotechnology, and Atlas Venture jointly funded the \$60M series A round to develop DAY101 and to expand the pipeline through additional partnerships.

An investigator sponsored trial of DAY101 to treat children with relapsed pediatric glioma is ongoing through the [Pacific Pediatric Neuro-Oncology Consortium](#). The preclinical work establishing the potential of DAY101 in pediatric glioma was performed by grants from a range of philanthropic organizations including the [PLGA Fund at PBTF](#), the [Team Jack Foundation](#), [Team Nathan](#) and Takeda.

#### **About DAY ONE Biopharmaceuticals**

Inspired by children with cancer, Day One Biopharmaceuticals creatively and intentionally develops promising new therapies that change the outcome for people of all ages living with cancer. Day One’s first announced program is DAY101, an oral, once-a-week, type II pan-RAF inhibitor that is currently being evaluated in human clinical trials. Day One partners with leading clinical oncologists, families, and scientists to identify, acquire, and develop emerging cancer treatments that can help both children and adults living with cancer. Through Day One and its collaborators, cancer drug development comes of age. For more information, please visit [www.dayonebio.com](http://www.dayonebio.com)

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#### **About SUNESIS**

Sunesis is a biopharmaceutical company developing novel targeted inhibitors for the treatment of hematologic and solid cancers. Sunesis has built an experienced drug development organization committed to improving the lives of people with cancer. The Company is focused on advancing its novel kinase inhibitor pipeline, including its oral non-covalent BTK inhibitor vecabrutinib and first-in-class PDK1 inhibitor SNS-510. Vecabrutinib is currently being evaluated in a Phase 1b/2 study in adults with chronic lymphocytic leukemia and other B-cell malignancies that have progressed after prior therapies. For additional information on Sunesis, please visit [www.sunesis.com](http://www.sunesis.com).

#### **Investor and Media Contact:**

Media contact: [wnevius@canaan.com](mailto:wnevius@canaan.com)

Day One Biopharmaceuticals LLC can be reached at [info@dayonebio.com](mailto:info@dayonebio.com)