Day One Announces New OJEMDA™ (tovorafenib) Data to be Presented in Oral Session at the 2025 Society for Neuro-Oncology (SNO) Annual Meeting

Nov 10, 2025

Three-year follow-up data from FIREFLY-1 demonstrates durable responses with evidence of clinical stability off treatment, with the potential for retreatment after progression

Treatment-free interval data to also be disclosed for the first time

BRISBANE, Calif., Nov. 10, 2025 (GLOBE NEWSWIRE) -- Day One Biopharmaceuticals, Inc. (Nasdaq: DAWN) ("Day One" or the "Company"), a biopharmaceutical company dedicated to developing and commercializing targeted therapies for people of all ages with life-threatening diseases, today announced it will present new OJEMDA durability and clinical stability data from the registrational FIREFLY-1 study at the 30th Annual Meeting & Education Day of the Society for Neuro-Oncology (SNO), being held November 19-23, 2025. The abstract includes an earlier data cut; updated data from the study will be presented during the meeting.

In an oral presentation, Dr. Cassie Kline, Director of Clinical Research in the Department of Neuro-Oncology at the Children's Hospital of Pennsylvania, will report results with >36-months follow up from the pivotal Phase 2 FIREFLY-1 trial evaluating tovorafenib as once-weekly oral monotherapy in patients aged 6 months to 25 years with relapsed or progressive pediatric Low-Grade Glioma (pLGG) harboring a known activating BRAF alteration. Dr. Kline will also provide an update on the treatment-free interval (TFI) achieved in patients who stopped treatment after completing the full 26 cycles (~24 months) of tovorafenib.

"We look forward to the upcoming data presentation at SNO, which highlights sustained efficacy and long-term response in patients with relapsed or refractory low-grade glioma who are taking tovorafenib," said Michael Vasconcelles, M.D., Head of Research & Development (R&D). "These findings underscore the durability of response we have seen in earlier analyses and continue to strengthen the clinical evidence supporting OJEMDA's differentiated profile."

Presentation Details
Clinical stability following tovorafenib treatment in relapsed/refractory pediatric low-grade glioma: updated results from the phase 2 FIREFLY-1 trial

Oral Presentation
Abstract#: CTP-17
Date: November 23, 2025
Time: 11:49 am
Location: Hawaii Convention Center, Lili'u Theater 310

About tovorafenib
Tovorafenib (known as OJEMDA™ in the U.S.) is a Type II RAF kinase inhibitor indicated for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (LGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. This indication is approved under accelerated approval based, in part, on response rate and duration of response according to multiple response assessment criteria: Response Assessment in Neuro-Oncology High-Grade Glioma (RANO-HGG) , Response Assessment in Pediatric Neuro-Oncology Low-Grade Glioma (RAPNO LGG) , and Response Assessment for Neuro-Oncology Low-Grade Glioma (RANO LGG) . Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Tovorafenib is under evaluation as a therapy for patients aged 6 months to 25 years with pLGG harboring BRAF fusion or rearrangement, or BRAF V600 mutation requiring front-line treatment (Phase III FIREFLY-2/LOGGIC).

Tovorafenib was granted Breakthrough Therapy and Rare Pediatric Disease designations by the FDA for the treatment of patients with pLGG harboring an activating RAF alteration, and it was evaluated by the FDA under priority review. Tovorafenib has also received Orphan Drug designation from the FDA for the treatment of malignant glioma and from the European Commission for the treatment of glioma.

For more information, please visit www.ojemda.com.

About FIREFLY-1
FIREFLY-1 is evaluating tovorafenib as once-weekly monotherapy in patients aged 6 months to 25 years with relapsed or

progressive pLGG harboring a known activating BRAF alteration. The trial is being conducted in collaboration with the Pacific Pediatric Neuro-Oncology Consortium. The pivotal and ongoing Phase II FIREFLY-1 study[v] evaluated the safety and efficacy of tovorafenib in 137 relapsed or refractory BRAF-altered pLGG patients, who had received at least one line of prior therapy, across two study arms. Arm 1 (n=77) was used for the efficacy analyses and Arm 2 provided safety data for an additional 60 patients, initiated to enable access to tovorafenib once Arm 1 had fully recruited.[ii,iii] The primary endpoint in Arm 1 of best overall response rate (ORR), determined by independent radiology review committee (IRC) and based on Response Assessment in Neuro-Oncology High-Grade Glioma (RANO-HGG) criteria, achieved ORR of 67% and median time to response (TTR) of 3 months. At the time of data cutoff on 5 June 2023 there was a median duration of response (DOR) of 16.6 months. The secondary endpoint of best ORR by IRC according to Response Assessment in Pediatric Neuro-Oncology Low-Grade Glioma (RAPNO LGG) criteria was 51% with a median DOR of 13.8 months and median TTR of 5.3 months. Among 137 patients (arms 1 and 2), the most common all-grade treatment-related adverse events (TRAEs) were hair color changes (76%), elevated creatine phosphokinase (56%) and anemia (49%). Grade ≥3 TRAEs occurred in 42% of patients with elevated creatine phosphokinase (12%) and anemia (10%) as the most common. Nine (7%) patients had TRAEs leading to discontinuation of tovorafenib.[vi] Additional information about FIREFLY-1 may be found at ClinicalTrials.gov, using Identifier NCT04775485.

About Pediatric Low-Grade Glioma
Pediatric low-grade glioma (pLGG) is the most common brain tumor in children with an estimated US incidence of 1,100 and Europe incidence of 700 children per year who are eligible for front-line systemic therapy.[i,viii] BRAF is the gene most commonly altered in pLGG, which include two primary types of BRAF alterations – a BRAF gene fusion and BRAF point mutation. These BRAF alterations account for >50% of pLGG cases worldwide and until OJEMDA there were no approved treatments for people with pLGG driven by BRAF fusions.[i,vi]

Pediatric low-grade gliomas can be chronic and relentless, with patients suffering profound side effects from both the tumor and the treatment, which may include chemotherapy and radiation. These side effects can impact their life over the long term, and may include muscle weakness, loss of vision, and difficulty speaking. This type of tumor has a high risk of progression, and many children with pLGG require long-term treatment. While most children with pLGG survive their cancer, children who do not achieve a complete resection following surgery may face years of increasingly aggressive treatment.

About the Pacific Pediatric Neuro-Oncology Consortium
The Pacific Pediatric Neuro-Oncology Consortium (PNOC) is an international consortium with study sites within the United States, Canada, Europe and Australia dedicated to bringing new therapies to children and young adults with brain tumors.

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 DAY 301.

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 and commercialize cancer therapies, expectations from current and planned clinical trials, the execution of the Phase 2 and Phase 3 clinical trial for tovorafenib as designed, expectations with respect to the timing of Day One’s Phase 1a/b clinical trial of DAY301, any expectations about safety, efficacy, timing and ability to complete clinical trials, release data results and to obtain regulatory approvals for tovorafenib and other candidates in development, 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 and retain 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, changing interest rates, government shutdowns, cybersecurity incidents, significant political or regulatory developments or changes in trade policy, including tariffs, shifting priorities within the U.S. Food and Drug Administration and reduced funding to federal healthcare programs, global regional 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.

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[i] Ryall S, et al. *Acta Neuropathol Commun*. 2020;8(1):30.

[ii] FDA grants accelerated approval to tovorafenib for patients with relapsed or refractory BRAF-altered pediatric low-grade glioma | FDA (last accessed July 2024)

[iii] Day One Press Release. April 2024. Available here: Day One's OJEMDA™ (tovorafenib) Receives US FDA Accelerated Approval for Relapsed or Refractory BRAF-altered Pediatric Low-Grade Glioma (pLGG), the Most Common Form of Childhood Brain Tumor | Day One Biopharmaceuticals, Inc. (last accessed July 2024)

[iv] Sholl LM. *Precis Cancer Med*. 2020;3:26

[v]Dana-Farber Cancer Institute. Childhood low-grade gliomas. https://www.dana-farber.org/cancer-care/types/childhood-low-grade-gliomas Last accessed: July 2024

[vi] Traunwieser T, et al. *Neurooncol Adv.* 2020;2(1):vdaa094.

[vii] Armstrong GT, et al. *Neuro Oncol.* 2011;13(2):223-234.

[viii] Estimates of annual incidence and prevalence for addressable patient population in E.U. 4 + U.K. are based on Ipsen calculations from publicly available data (Eurostat, <25yo population; Global Burden of Disease 2019; Desandes et al. Incidence and survival of children with central nervous system primitive tumors in the French National Registry of Childhood Solid Tumors. Neuro Oncol. 2014 Jul;16(7):975-83. doi: 10.1093/neuonc/not309; Qaddoumi et al. Outcome and prognostic features in pediatric gliomas: a review of 6212 cases from the Surveillance, Epidemiology, and End Results database. Cancer. 2009 Dec 15;115(24):5761-70. doi: 10.1002/cncr.24663)