Viracta Therapeutics Announces Publication in Blood Advances Demonstrating Promising and Durable Signal of Nana-val Efficacy in Patients with Relapsed or Refractory (R/R) Epstein-Barr Virus-Positive (EBV+) Lymphoma

Results from Phase 1b/2 trial showed complete responses achieved and ongoing durable responses observed out to approximately 36 months across multiple EBV+ lymphoma subtypes, including some of the most aggressive cancers

All-oral Nana-val was well tolerated, with the most common adverse events (AEs) being low-grade nausea, constipation, and reversible cytopenias

SAN DIEGO, Calif August 8, 2023 – Viracta Therapeutics, Inc. (Nasdaq: VIRX), a clinical-stage precision oncology company focused on the treatment and prevention of virus-associated cancers that impact patients worldwide, today announced the publication of clinical data from an open-label, multicenter, Phase 1b/2 study of Nana-val in 55 patients with R/R EBV^+ lymphoma in *Blood Advances*. Results showed complete responses (CRs) achieved and ongoing durable responses observed out to approximately 36 months across multiple EBV^+ lymphoma subtypes, including some of the most aggressive cancers: peripheral T-cell lymphoma (PTCL), diffuse large B-cell lymphoma (DLBCL), and post-transplant lymphoproliferative disease (PTLD). This paper titled, “Targeted therapy with nanatinostat and valganciclovir in recurrent Epstein-Barr virus-positive lymphoid malignancies: a Phase 1b/2 study,” can be found here.

“Results from both retrospective and prospective clinical studies link EBV-positivity to significantly inferior survival in multiple lymphoma subtypes, highlighting the pressing need for novel therapies for this underserved patient population,” said Pierluigi Porcu, M.D., Professor of Medical Oncology, Director of the Division of Hematologic Malignancies and Hematopoietic Stem Cell Transplantation, Department of Medical Oncology at Thomas Jefferson University, and corresponding author on the paper. “The newly published Phase 1b/2 study data showcase the potential of Viracta’s innovative ‘*Kick and Kill*’ approach to effectively address this need, with results demonstrating Nana-val’s favorable safety and tolerability profile and promising durable signal of efficacy in heavily pre-treated patients. These data served as a catalyst for the advancement of Nana-val into the confirmatory NAVAL-1 trial, which has an elegant multi-stage design to potentially support registration.”

Darrel P. Cohen, M.D., Ph.D., Viracta's newly appointed Chief Medical Officer added, “Having these Phase 1b/2 clinical trial data peer-reviewed and published in such a prestigious journal of the American Society of Hematology provides important external validation for Nana-val’s therapeutic potential. The substantial number, depth, and durability of Nana-val's clinical responses with a favorable safety profile observed in this heavily pre-treated EBV-positive lymphoma patient population are impressive, several of which are still ongoing. This publication further supports the recently announced expansion of the NAVAL-1 trial’s EBV-positive peripheral T-cell lymphoma cohort, representing an exciting time for our clinical trial program, and we look forward to providing more updates on its progress in the future.”

Data published from the study showed that CRs were achieved across multiple EBV^+ lymphoma subtypes, with a reported overall response rate (ORR)/CR rate of 40%/19% in 43 evaluable patients. In patients with EBV^+ PTCL, which was recently established as the leading indication in Viracta’s pivotal NAVAL-1 trial, ORR/CR rates of 67%/50% were reported (n=6 including both EBV^+ PTCL-not otherwise specified [PTCL-NOS] and angioimmunoblastic T-cell lymphoma [AITL] patients). Of note, one of the CRs was achieved in a patient whose disease never responded to second-line histone deacetylase inhibitor (HDACi) treatment. In 6 patients with EBV^+ DLBCL, a rare aggressive and distinct B-cell lymphoma subtype characterized by an adverse clinical outcome, ORR/CR rates of 67%/33% were reported. Of note, one of the CRs was achieved in a patient whose disease never responded to first-line R-CHOP chemotherapy.

The published paper includes an additional 10-month follow-up period, which demonstrated durable response durations across multiple EBV^+ lymphoma subtypes. As of the expanded data cutoff date of September 1, 2022, multiple patients remained in an ongoing durable response in excess of 30 months, with two patients in an ongoing response of approximately 36 months. The median time to response was 1.8 months, and the median duration of response was approximately 10 months in a heavily pre-treated patient population. Overall, trial participants received a median of two prior therapies before entering the trial, with 75% (41/55) being refractory to their last therapy.

Data also showed that all-oral Nana-val was well tolerated with reversible low-grade AEs. The most commonly observed treatment-emergent AEs were reversible cytopenias, low-grade creatinine elevations, and gastrointestinal symptoms. Initial data from the Nana-val Phase 1b/2 clinical trial were previously presented at the 2021 American Society of Hematology (ASH) Annual Meeting.

About Nana-val (Nanatinostat and Valganciclovir)
Nanatinostat is an orally available HDACi being developed by Viracta. Nanatinostat is selective for specific isoforms of Class I HDACs, which are key to inducing viral genes that are epigenetically silenced in Epstein-Barr virus (EBV)-associated malignancies. Nanatinostat is currently being investigated in combination with the antiviral agent valganciclovir as an all-oral combination therapy, Nana-val, in various subtypes of EBV-associated malignancies. Ongoing clinical trials include a pivotal, global, multicenter, open-label Phase 2 basket trial in multiple subtypes of relapsed or refractory EBV^+ lymphoma (NAVAL-1) as well as in combination with pembrolizumab in a multinational Phase 1b/2 trial in patients with recurrent or metastatic EBV^+ nasopharyngeal carcinoma and other EBV^+ solid tumors.

About EBV-Associated Cancers
Approximately 90% of the world's adult population is infected with EBV. Infections are commonly asymptomatic or associated with mononucleosis. Following infection, the virus remains latent in a small subset of cells for the duration of the patient's life. Cells containing latent virus are increasingly susceptible to malignant transformation. Patients who are immunocompromised are at an increased risk of developing EBV^+ lymphomas. EBV is estimated to be associated with approximately 2% of the global cancer burden, including lymphoma, nasopharyngeal carcinoma, and gastric cancer.

About Viracta Therapeutics, Inc.
Viracta is a clinical-stage precision oncology company focused on the treatment and prevention of virus-associated cancers that impact patients worldwide. Viracta's lead product candidate is an all-oral combination therapy of its proprietary investigational drug, nanatinostat, and the antiviral agent valganciclovir (collectively referred to as Nana-val). Nana-val is currently being evaluated in multiple ongoing clinical trials, including a pivotal, global, multicenter, open-label Phase 2 basket trial for the treatment of multiple subtypes of relapsed or refractory Epstein-Barr virus-positive (EBV^+) lymphoma (NAVAL-1), as well as a multinational, open-label Phase 1b/2 trial for the treatment of patients with recurrent or metastatic EBV^+ nasopharyngeal carcinoma and other advanced EBV^+ solid tumors. Viracta is also pursuing the application of its "*Kick and Kill*" approach in other virus-related cancers.

For additional information please visit www.viracta.com.

Forward-Looking Statements
This communication contains "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, statements regarding: the details, timeline, and expected progress for Viracta's ongoing and anticipated clinical trials and updates regarding the same, including the progress and potential cohort advancements of NAVAL-1. Risks and uncertainties related to Viracta that may cause actual results to differ materially from those expressed or implied in any forward-looking statement include, but are not limited to: Viracta's ability to successfully enroll patients in and complete its ongoing and planned clinical trials; Viracta's plans to develop and commercialize its product candidates, including all oral combinations of nanatinostat and valganciclovir; the timing of initiation of Viracta's planned clinical trials; the timing of the availability of data from Viracta's clinical trials; previous preclinical and clinical results may not be predictive of future clinical results; the timing of any planned investigational new drug application or new drug application; Viracta's plans to research, develop, and commercialize its current and future product candidates; the clinical utility, potential benefits, and market acceptance of Viracta's product candidates; and Viracta's ability to manufacture or supply nanatinostat, valganciclovir, and pembrolizumab for clinical testing.

If any of these risks materialize or underlying assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements. Additional risks and uncertainties that could cause actual outcomes and results to differ materially from those contemplated by the forward-looking statements are included under the caption "Risk Factors" and elsewhere in Viracta's reports and other documents that Viracta has filed, or will file, with the SEC from time to time and available at www.sec.gov.

The forward-looking statements included in this communication are made only as of the date hereof. Viracta assumes no obligation and does not intend to update these forward-looking statements, except as required by law or applicable regulation.

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https://viracta.investorroom.com/2023-08-08-Viracta-Therapeutics-Announces-Publication-in-Blood-Advances-Demonstrating-Promising-and-Durable-Signal-of-Nana-val-Efficacy-in-Patients-with-Relapsed-or-Refractory-R-R-Epstein-Barr-Virus-Positive-EBV-Lymphoma