Viracta Therapeutics Announces Completion of Second-Stage Enrollment into the Peripheral T-Cell Lymphoma Cohort of the NAVAL-1 Trial

Accelerated pace of enrollment supports speed to market strategy
Topline results from Stage 1 expected to be presented in the second quarter of 2024 followed by Stage 2 data in the third quarter of 2024

San Diego, February 29, 2024 – 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 that its lead development program, Nana-val (nanatinostat in combination with valganciclovir), a first-in-class, all-oral investigational therapy targeting Epstein-Barr virus (EBV)-associated cancers, has completed Stage 2 enrollment into the relapsed or refractory (R/R) Epstein-Barr virus-positive (EBV^+) peripheral T-cell lymphoma (PTCL) cohort of the NAVAL-1 trial.

“Given the nature of this serious life-threatening condition and absence of EBV-targeted treatments today, our goal is to bring Nana-val to patients with relapsed or refractory EBV-positive PTCL as quickly as possible,” said Darrel P. Cohen, M.D., Ph.D., Chief Medical Officer of Viracta. “The completion of Stage 2 enrollment of the PTCL cohort in NAVAL-1 is a major milestone for the Nana-val clinical development program. We would like to acknowledge the dedication of our study execution team and the commitment of our investigators for this achievement. We look forward to building upon our previously published positive data from the Phase 1b/2 clinical trial and reporting topline PTCL cohort data from Stage 1 of the NAVAL-1 trial in the second quarter of 2024. Additionally, we plan to meet with FDA in mid-2024 to align on requirements for accelerated approval of Nana-val in this orphan indication.”

Upcoming Anticipated Milestones for the NAVAL-1 Trial of Nana-val in Patients with R/R EBV^+ PTCL

- Present topline Stage 1 data from both arms (in patients treated with nanatinostat with [n=10] or without [n=10] valganciclovir) in the second quarter of 2024, with an aim to clearly delineate the differentiation of Nana-val’s ‘*kick and kill*’ mechanism of action.
- Present Stage 1 + Stage 2 data (n=21) from the R/R EBV^+ PTCL cohort in patients treated with Nana-val in the third quarter of 2024.
- Engage with the U.S. Food and Drug Administration (FDA) in mid-2024, to align on requirements for accelerated approval.
- Enroll patients into the post-Phase 2 expansion cohort to support potential accelerated approval.

About the NAVAL-1 Trial
NAVAL-1 (NCT05011058) is a global, multicenter, clinical trial of Nana-val in patients with relapsed or refractory (R/R) Epstein-Barr virus-positive (EBV^+) lymphoma. This trial employs a Simon two-stage design where, in Stage 1, participants are enrolled into one of three indication cohorts based on EBV^+ lymphoma subtype. If two objective responses are achieved within a lymphoma subtype in Stage 1 (n=10), then additional patients will be enrolled in Stage 2 for a total of 21 patients.
EBV^+ lymphoma subtypes demonstrating promising antitumor activity in Stage 2 may be further expanded following discussion with regulators to potentially support registration.

About Nana-val (Nanatinostat and Valganciclovir)
Nanatinostat is an orally available histone deacetylase (HDAC) inhibitor 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 trials include a pivotal, global, multicenter, open-label Phase 2 basket trial in multiple subtypes of relapsed or refractory (R/R) EBV^+ lymphoma (NAVAL-1) as well as a multinational Phase 1b/2 clinical trial in patients with recurrent or metastatic (R/M) EBV^+ NPC and other advanced EBV^+ solid tumors.

About Peripheral T-Cell Lymphoma
T-cell lymphomas comprise a heterogeneous group of rare and aggressive malignancies, including peripheral T-cell lymphoma not otherwise specified (PTCL-NOS) and angioimmunoblastic T-cell lymphoma (AITL). There are approximately 5,600 newly diagnosed T-cell lymphoma patients and approximately 2,600 newly diagnosed PTCL-NOS and AITL patients in the U.S. annually. Approximately 70% of these patients are either refractory to first-line therapy, or eventually experience relapse of their disease. Clinical trials are currently recommended for all lines of PTCL therapy, and most patients with R/R PTCL have poor outcomes, with median progression-free survival and median overall survival times reported to be 3.7 and 6.5 months, respectively. Approximately 40% to 65% of PTCL is associated with EBV, the incidence of EBV^+ PTCL varies by geography, and reported outcomes for patients with EBV^+ PTCL are inferior to those whose disease is EBV-negative. There is no approved targeted treatment specific for EBV^+ PTCL, and therefore this represents a high unmet medical need.

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-positive (EBV^+) lymphomas. EBV is estimated to be associated with approximately 2% of the global cancer burden including lymphoma, nasopharyngeal carcinoma (NPC), 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 (R/R) Epstein-Barr virus-positive (EBV^+) lymphoma (NAVAL-1), as well as a multinational, open-label Phase 1b/2 clinical trial for the treatment of patients with recurrent or metastatic (R/M) EBV^+ nasopharyngeal carcinoma (NPC) 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, the Company's expectations related to the FDA submission process and timelines, expectations regarding our target patient populations. 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; 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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