

## Viracta Therapeutics Announces Interim Data from Phase 1b/2 Clinical Trial of Nana-val in Patients with Epstein-Barr Virus-Positive Solid Tumors that Show Confirmed Tumor Responses at Higher Dose Levels

**Confirmed partial responses without dose-limiting toxicities during dose escalation along with new preclinical data support the opportunity to further enhance efficacy through a novel split daily dosing regimen at higher dose levels of Nana-val**

**Enrollment is underway for the sixth dose cohort of the Phase 1b dose escalation portion of the study with plans to initiate a recommended Phase 2 dose-optimization cohort as part of the study's Phase 2 expansion in 2024**

**Data featured in an oral presentation at the European Society of Medical Oncology Asia Congress**

**SAN DIEGO** December 4, 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 that additional data from the Phase 1b/2 clinical trial of Nana-val (nanatinostat in combination with valganciclovir) in patients with recurrent or metastatic (R/M) Epstein-Barr virus-positive (EBV<sup>+</sup>) nasopharyngeal carcinoma (NPC) showed two ongoing confirmed partial responses (PRs) at higher dose levels. These data were featured in an oral presentation made by A. Dimitrios Colevas, M.D., Professor of Medicine (Oncology) at the Stanford Cancer Institute, during the European Society for Medical Oncology (ESMO) Asia Congress being held in Singapore. Nana-val is the company's all-oral investigational therapy targeting Epstein-Barr virus (EBV)-associated cancers.

"The initial efficacy, safety, and pharmacokinetic data from the first five dose cohorts of the Phase 1b trial in patients with recurrent or metastatic EBV-positive NPC are very encouraging," said Darrel P. Cohen, M.D., Ph.D., Chief Medical Officer of Viracta. "These results support the continued advancement and dose escalation of the study, especially given the two durable confirmed partial responses, the emerging dose-response relationship, and the favorable safety and tolerability profile observed to date."

Dr. Cohen continued, "There is a high unmet medical need to address the adverse survival outcomes seen in patients with recurrent or metastatic EBV-positive NPC. Planning for success, we incorporated FDA's [Project Optimus](#) initiative into the Phase 2 study design, which is intended to confirm the recommended Phase 2 dose of Nana-val that maximizes efficacy as well as safety and tolerability in patients with advanced EBV-positive solid tumors. Study sites are now open and enrolling the sixth dose cohort of the study, which is investigating the novel split daily dosing regimen at higher dose levels of Nana-val, and we are on track to expand into the Phase 2 portion of the study in 2024."

### Key Data from the Oral ESMO Asia Congress Presentation

Interim data from the Phase 1b/2 study of Nana-val in patients with R/M EBV<sup>+</sup> NPC revealed two ongoing confirmed partial responses (PRs) at higher dose levels plus new nonclinical data that support the evaluation of a novel split daily dosing (SDD) regimen.

- Best antitumor responses to date have included two PRs (both ongoing for >10 months and >four months on study treatment) at the higher dose levels plus five stable diseases out of 17 patients treated to date.
  - Confirmed PR at the third dose level demonstrated >50% reduction in tumor size through 50 weeks and confirmed PR at the fifth dose level demonstrated ~30-40% reduction in tumor size through 14 weeks.
- Increased antitumor activity observed in a preclinical murine EBV<sup>+</sup> gastric cancer xenograft model supports investigation of Nana-val on an SDD schedule as a next step.
  - In comparison to once daily dosing, split dosing four hours apart each day increased the expression of EBV protein kinase, which translated into increased antitumor activity.
  - In comparison to intermittent (four days on/three days off) dosing, daily (seven days/week) dosing increased the exposure to Nana-val leading to a more sustained antitumor effect.

A copy of the ESMO Asia Congress presentation titled, "*A Phase 1b/2 Study of Nanatinostat (Nstat) Plus Valganciclovir (VGCV) in EBV<sup>+</sup> Solid Tumors and with Pembrolizumab (PEM) in Recurrent/Metastatic Nasopharyngeal Carcinoma (R/M NPC)*", will be accessible on the [Events and Webcasts](#) page in the Investors section of Viracta's website.

Investigative sites are now open for enrollment into the sixth dose cohort of the Phase 1b dose escalation portion of the study, which incorporates Nana-val's novel SDD regimen. Once the Phase 2 dose (RP2D) is determined, the company plans to incorporate a dose-optimization cohort to confirm the RP2D based on safety and efficacy by randomizing up to 40 patients with R/M EBV<sup>+</sup> NPC to receive either the RP2D or a dose level below the RP2D.

### About the Phase 1b/2 Study of Nana-val in R/M EBV<sup>+</sup> NPC and Other EBV<sup>+</sup> Solid Tumors

This Phase 1b/2 trial (NCT05166577) is an open-label, multinational clinical trial evaluating Nana-val alone and in combination

with pembrolizumab. The Phase 1b dose escalation part is designed to evaluate safety and to select the recommended Phase 2 dose (RP2D) of Nana-val in patients with recurrent or metastatic (R/M) Epstein-Barr virus-positive (EBV<sup>+</sup>) nasopharyngeal carcinoma (NPC). Along with the U.S. Food and Drug Administration's [Project Optimus](#) initiative at the start of Phase 2, up to 40 patients with R/M EBV<sup>+</sup> NPC will be randomized to receive either the RP2D or a dose level below the RP2D in a dose-optimization cohort. Once the RP2D has been confirmed, up to 60 patients with R/M EBV<sup>+</sup> NPC will be randomized to receive Nana-val at the RP2D with or without pembrolizumab to further evaluate antitumor activity, safety and tolerability, pharmacokinetics, and potential pharmacodynamic biomarkers. Additionally, patients with other advanced EBV<sup>+</sup> solid tumors will be enrolled to receive Nana-val at the RP2D in a Phase 1b dose expansion cohort.

#### **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<sup>+</sup> lymphoma (NAVAL-1) as well as a multinational Phase 1b/2 clinical trial in patients with recurrent or metastatic (R/M) EBV<sup>+</sup> NPC and other EBV<sup>+</sup> 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-positive (EBV<sup>+</sup>) 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<sup>+</sup>) 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<sup>+</sup> nasopharyngeal carcinoma (NPC) and other advanced EBV<sup>+</sup> 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](http://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 of the significance and implications of the preliminary interim data from its clinical trials and preclinical studies disclosed herein, the Company's expectations related to the FDA submission process and timelines and 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 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](http://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/2023-12-04-Viracta-Therapeutics-Announces-Interim-Data-from-Phase-1b-2-Clinical-Trial-of-Nana-val-in-Patients-with-Epstein-Barr-Virus-Positive-Solid-Tumors-that-Show-Confirmed-Tumor-Responses-at-Higher-Dose-Levels>