

## Viracta Therapeutics to Host R&D Day Highlighting Nana-val in Epstein-Barr Virus (EBV)-Associated Cancers

**Preliminary clinical data from patients with relapsed/refractory EBV+ peripheral T-cell lymphoma in the pivotal NAVAL-1 trial demonstrated overall and complete response rates of 40%; follow-up from the Phase 1b/2 study demonstrated median duration of response extended to 17.3 months**

**Additional response and durability data in patients with relapsed/refractory EBV+ diffuse large B-cell lymphoma in the Phase 1b/2 study demonstrated sustained overall response rate of 67%; median duration of response not yet reached, with several patients continuing on study treatment in ongoing response out to 42 months**

**Partial responses observed in recurrent/metastatic EBV+ nasopharyngeal carcinoma in Phase 1b dose escalation study suggestive of dose response without any dose-limiting toxicities observed**

**Discussion to feature Key Opinion Leaders Pierluigi Porcu, M.D. and Robert A. Baiocchi, M.D., Ph.D. today at 8:00 a.m. EDT**

**SAN DIEGO** October 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 it plans to highlight new preliminary clinical and preclinical data from studies of nanatinostat and valganciclovir (Nana-val), its all-oral investigational therapy targeting Epstein-Barr virus (EBV)-associated cancers, during an R&D Day today, Wednesday, October 4, 2023, at 8:00 a.m. EDT.

“We are pleased by the growing clinical data that we believe underscores the therapeutic potential of Nana-val’s innovative ‘*Kick and Kill*’ approach to target EBV-positive cancer cells and address the adverse survival outcomes seen with most EBV-associated cancers,” said Mark Rothera, President and Chief Executive Officer of Viracta. “The clinical responses and favorable safety profile observed in multiple relapsed or refractory EBV-positive lymphoma patient populations continue to be encouraging. New Stage 1 clinical data from patients in the PTCL cohort of the NAVAL-1 trial demonstrated preliminary overall and complete response rates of 40%, which are consistent with our previous Phase 1b/2 study data. Importantly, the combination of response rates and duration of response observed to date in these studies exceeds the current standard of care in this relapsed/refractory patient population. We are on track to complete Stage 2 of the PTCL cohort, targeting to engage with FDA in 2024 on additional requirements for a potential accelerated approval. In addition, we are excited about the emerging signal of dose response in patients with recurrent or metastatic EBV-positive nasopharyngeal carcinoma, now with responses observed at the higher dose levels without dose-limiting toxicities. We look forward to the evaluation of our novel split daily dosing regimen in patients with advanced EBV-positive solid tumors based on compelling preclinical data.”

The R&D Day will feature presentations by members of Viracta’s senior management team focusing on its highest priority EBV<sup>+</sup> lymphoma indications in the pivotal NAVAL-1 trial, namely, peripheral T-cell lymphoma (PTCL) and diffuse large B-cell lymphoma (DLBCL), as well as its advanced EBV<sup>+</sup> solid tumor program in patients with recurrent or metastatic (R/M) EBV<sup>+</sup> nasopharyngeal carcinoma (NPC). In addition, the R&D Day will feature presentations by expert key opinion leaders who will discuss the high unmet medical needs of EBV-associated lymphomas.

External speakers will include:

- 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
- Robert A. Baiocchi, M.D., Ph.D., Professor of Internal Medicine, Associate Director for Translational and Clinical Science in the Division of Hematology at The Ohio State University

### Key R&D Day Topics and Highlights

*Initial preliminary data from the pivotal NAVAL-1 clinical trial of Nana-val in patients with relapsed or refractory (R/R) EBV<sup>+</sup> lymphoma*

- As of the data cutoff date of June 30, 2023, initial results from the first five patients with R/R EBV<sup>+</sup> PTCL treated with Nana-val showed an overall response rate (ORR) and complete response rate (CRR) of 40%.
- The EBV<sup>+</sup> PTCL cohort met the efficacy threshold for expansion into Stage 2 of the study, which was based upon having achieved two objective responses within the first five of 10 patients to be enrolled in Stage 1 of the study.
- Median duration of response (DoR) has not yet been reached.
- Anticipated 2024 milestones:

- Completion of enrollment into Stage 2 of the R/R EBV<sup>+</sup> PTCL cohort,
- Engagement with FDA on additional requirements for accelerated approval,
- Presentation of Stage 2 data.

*Additional response and durability assessments from the Phase 1b/2 trial (Study 201) of Nana-val in patients with R/R EBV<sup>+</sup> lymphoma as of the May 4, 2023 data cutoff date*

- Median DoR for patients with R/R EBV<sup>+</sup> PTCL was 17.3 months with an ORR/CRR of 50%/38% (n=8).
- In patients with R/R EBV<sup>+</sup> DLBCL, additional response assessments from a formulation pharmacokinetics bridging substudy included two additional responders, one complete response (CR) and one partial response (PR), resulting in an ORR/CRR of 67%/33% (n=9).
- Median DoR in the R/R EBV<sup>+</sup> DLBCL cohort has not yet been reached, with three patients remaining in response and on continued study treatment with DoRs of 11.1 months (CR), 36.8 months (PR), and 41.9 months (CR).
- Additional follow-up further demonstrated that Nana-val was generally well tolerated with manageable, if not reversible, low-grade toxicities; the most commonly observed treatment-emergent adverse events were hematologic or gastrointestinal in nature as well as low-grade creatinine elevations.

*New interim clinical data in Phase 1b/2 study of Nana-val in advanced EBV<sup>+</sup> solid tumors (Study 301) highlight the opportunity to dose escalate further with an innovative dosing regimen supported by new preclinical data to potentially drive additional responses in this patient population*

- Enrollment completed through the fifth dose level of the Phase 1b dose escalation portion of the trial without any dose-limiting toxicities reported.
- Best responses to date included two PRs (one ongoing for more than seven months) at the higher dose levels plus five stable diseases in 17 patients with R/M EBV<sup>+</sup> NPC.
- In a preclinical murine EBV<sup>+</sup> gastric cancer xenograft model, split daily Nana-val dosing had superior anti-tumor activity than intermittent (four days on/three days off) once-daily dosing, which supports the evaluation of this split daily dosing (SDD) regimen in patients with advanced EBV<sup>+</sup> solid tumors.
- Anticipated 2024 milestones:
  - Up to three additional dose levels are planned with Nana-val on an SDD schedule to select a recommended Phase 2 dose,
  - Initiation of the clinical trial's randomized Phase 2 expansion cohort designed to evaluate Nana-val at the recommended Phase 2 Dose (RP2D) with or without pembrolizumab in patients with R/M EBV<sup>+</sup> NPC,
  - Initiation of the clinical trial's exploratory Phase 1b expansion cohort designed to evaluate Nana-val at the RP2D in patients with other advanced EBV<sup>+</sup> solid tumors, including gastric carcinoma, leiomyosarcoma, and lymphoepithelioma.

## **R&D Day Webcast Information**

A live video webcast of the presentation will be available [here](#) and on the Investors section of the Viracta website under "[Events and Webcasts](#)". A replay of the presentation will be available approximately one hour after the presentation and will be archived and available for at least 30 days following the event at the same location.

## **About NAVAL-1**

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<sup>+</sup>) lymphoma. This trial employs a Simon two-stage design where, in Stage 1, participants are enrolled into one of three prioritized indication cohorts based on EBV<sup>+</sup> lymphoma subtype. If a pre-specified antitumor activity threshold is reached 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<sup>+</sup> lymphoma subtypes demonstrating promising antitumor activity in Stage 2 may be further expanded following discussion with regulators to potentially support registration.

## **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 determine 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). In Phase 2, 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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