Viracta Therapeutics Announces Positive Topline Nana-val Results from Stage 1 of the NAVAL-1 Trial in Patients with Relapsed or Refractory Epstein-Barr Virus-Positive (EBV+) Peripheral T-Cell Lymphoma

- Patients in the Nana-val (nanatinostat in combination with valganciclovir) treatment arm achieved clinically meaningful anti-tumor responses with an overall response rate of 50% and a complete response rate of 20% in the intent-to-treat population (71% and 29% in the efficacy-evaluable population) with a generally manageable safety profile -

- Nana-val demonstrated substantially greater efficacy than nanatinostat monotherapy, further validating its 'Kick and Kill' mechanism of action -

- Data were presented in an oral presentation at the 2024 Joint Annual Congress of Taiwan Society of Blood and Marrow Transplantation and The Hematology Society of Taiwan -

San Diego, April 15, 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 reported positive topline results from Stage 1 of the pivotal Phase 2 NAVAL-1 trial from both arms of the relapsed or refractory (R/R) Epstein-Barr virus-positive (EBV<sup>+</sup>) peripheral T-cell lymphoma (PTCL) cohort. Patients were randomized to either nanatinostat monotherapy (n=10) or to nanatinostat in combination with valganciclovir (Nana-val, n=10). These data were featured in an oral presentation during the 2024 Joint Annual Congress of Taiwan Society of Blood and Marrow Transplantation and The Hematology Society of Taiwan.

"Nana-val demonstrated an impressive clinical response in patients with relapsed or refractory EBV-positive PTCL with a generally manageable safety profile, including one patient who was able to proceed to allogeneic stem-cell transplant and remains in response for over 8 months to date," said Hung Chang, M.D., Professor of Hematology, Linkou Chang Gung Memorial Hospital, Chang Gung University College of Medicine, Taoyuan, Taiwan and principal investigator in the NAVAL-1 trial. "The substantially greater clinical efficacy of Nana-val relative to nanatinostat monotherapy suggests that both agents in the combination regimen are contributing to its anti-tumor activity as predicted by their mechanisms of action. Nana-val is emerging as a promising, generally well-tolerated, convenient all-oral treatment for patients with relapsed or refractory EBV-positive PTCL."

Darrel P. Cohen, M.D., Ph.D., Chief Medical Officer of Viracta added, "Patients with relapsed or refractory EBVpositive PTCL have a very poor prognosis, worse than those with EBV-negative disease, yet there are presently no EBV-targeted treatment options available. We are encouraged by the Stage 1 data from patients with relapsed or refractory EBV-positive PTCL in the pivotal Phase 2 NAVAL-1 trial that further validates Nana-val's differentiated '*Kick and Kill*' mechanism of action. Building on these promising clinical outcomes emerging from the NAVAL-1 trial, which are consistent with those from our preceding Phase 1b/2 study, we will continue to advance Nana-val in this lead indication through regulatory approval as quickly as possible. We look forward to engaging with the FDA on a potential accelerated approval pathway midyear and sharing topline results from Stage 2 together with additional data from Stage 1 in the third quarter of 2024."

**Key takeaways from the pivotal Phase 2 NAVAL-1 trial in patients with R/R EBV<sup>+</sup> PTCL:** Nana-val (nanatinostat in combination with valganciclovir) demonstrated greater efficacy than nanatinostat monotherapy and was generally well-tolerated. The median duration of response continues to mature.

- Overview: A total of 20 patients with primarily Stage III-IV disease (who had received ≥1 [median of 2] prior systemic PTCL therapies) were randomized (1:1) to receive nanatinostat (20 mg orally once daily, 4 days/week) alone or as Nana-val in combination with valganciclovir (900 mg orally once daily, 7 days/week). Patients who did not respond to nanatinostat monotherapy after 6 weeks of treatment were offered the opportunity to cross over to receive Nana-val.
- Efficacy was evaluated as of the February 7, 2024 data cutoff date.
  - In the Nana-val arm, the overall response rate (ORR) was 50% and the complete response rate (CRR) was 20% in the intent-to-treat (ITT) population (N=10); the ORR was 71% and the CRR was 29% in the efficacy-evaluable population (N=7).
  - In the nanatinostat monotherapy arm, the ORR and CRR were 10% and 0%, respectively, in the ITT population (N=10), and the ORR was 13% in the efficacy-evaluable population (N=8).
    - Five nanatinostat monotherapy patients crossed over to receive Nana-val, two of whom remain on Nana-val treatment with stable disease as of the data cutoff.
- Safety was also evaluated as of the February 7, 2024 data cutoff date.

- The most common treatment-related adverse events in both treatment arms were thrombocytopenia, anemia, fatigue, decreased appetite, nausea, diarrhea, and weight loss.
  - These adverse events were primarily mild to moderate in severity and generally manageable or reversible.

A copy of the data presentation is accessible under the "<u>Events and Presentations</u>" section of Viracta's website at <u>www.viracta.com</u>.

## 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<sup>+</sup>) lymphoma. This Phase 2 trial employs a Simon two-stage design where, in Stage 1, participants are enrolled into one of three indication cohorts based on EBV<sup>+</sup> 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<sup>+</sup> lymphoma subtypes demonstrating promising anti-tumor 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, openlabel, 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 advanced EBV<sup>+</sup> solid tumors.

### **About Peripheral T-Cell Lymphoma**

T-cell lymphomas comprise a heterogeneous group of rare and aggressive malignancies, including peripheral Tcell 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<sup>+</sup> PTCL are inferior to those whose disease is EBV-negative. There is no approved targeted treatment specific for EBV<sup>+</sup> 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<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 virusassociated 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 <u>www.viracta.com</u>.

#### 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 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 and 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 <u>www.sec.gov</u>.

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.

#### **Investor Relations Contact:**

Ashleigh Barreto Head of Investor Relations & Corporate Communications Viracta Therapeutics, Inc. <u>abarreto@viracta.com</u>

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https://viracta.investorroom.com/2024-04-15-Viracta-Therapeutics-Announces-Positive-Topline-Nana-val-Resultsfrom-Stage-1-of-the-NAVAL-1-Trial-in-Patients-with-Relapsed-or-Refractory-Epstein-Barr-Virus-Positive-EBV-Peripheral-T-Cell-Lymphoma