Viracta Therapeutics Reports First Quarter 2024 Financial Results and Provides Business Update

Presented positive topline Nana-val results from Stage 1 of the pivotal Phase 2 NAVAL-1 trial in patients with relapsed or refractory (R/R) Epstein-Barr virus-positive (EBV+) peripheral T-cell lymphoma (PTCL)

Initial results from the ongoing NAVAL-1 trial further validate Nana-val's "Kick and Kill" mechanism of action; additional data are expected in the third quarter of 2024

Plan to engage with U.S. Food and Drug Administration (FDA) in mid-2024 to align on requirements for accelerated approval and support speed to market strategy

Progressed the Phase 1b/2 study of Nana-val in patients with advanced EBV+ solid tumors; on track to determine the recommended Phase 2 dose (RP2D) in the second half of 2024

Positive engagement with the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) enables patients in Japan to be enrolled directly into the NAVAL-1 trial without a preceding Japanese Phase 1 safety/pharmacokinetics study

SAN DIEGO, May 9, 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 financial results for the first quarter of 2024 and provided a business update.

"Our near-term goal is to address the high unmet medical needs of patients living with relapsed or refractory EBV-positive PTCL by advancing Nana-val through regulatory approval as quickly as possible," said Mark Rothera, President and Chief Executive Officer of Viracta. "Topline results from Stage 1 of the ongoing pivotal Phase 2 NAVAL-1 trial provided a strong signal of efficacy with a generally well-tolerated safety profile that were consistent with outcomes from the prior Phase 1b/2 study of Nana-val. The observed objective and complete response rates of Nana-val far exceeded the nanatinostat monotherapy arm, further validating the combined mechanism of action of Nana-val treatment. We look forward to sharing additional data from Stage 1, which continue to mature, as well as initial results from Stage 2 in the third quarter of 2024. We are encouraged by the growing data from the NAVAL-1 trial that underscore the benefit of Nana-val, our first-in-class, all-oral combination treatment regimen, and plan to engage with the FDA on a potential accelerated approval pathway in mid-2024."

Clinical Trial Updates and Anticipated Milestones

Pivotal Phase 2 NAVAL-1 trial of Nana-val (nanatinostat in combination with valganciclovir) in patients with relapsed or refractory (R/R) Epstein-Barr virus-positive (EBV+) lymphoma

Clinical Trial Updates:

- Presented positive topline Stage 1 data from both arms of the R/R EBV+ peripheral T-cell lymphoma (PTCL) cohort, patients randomized to either nanatinostat monotherapy (n=10) or to nanatinostat in combination with valganciclovir (Nana-val, n=10), at the 2024 Joint Annual Congress of Taiwan Society of Blood and Marrow Transplantation and The Hematology Society of Taiwan.
    - As of the February 7, 2024 data cutoff date, Nana-val demonstrated greater efficacy than nanatinostat alone and was generally well-tolerated. The median duration of response (DoR) continues to mature.
        - In the Nana-val arm, the objective response rate (ORR) was 50% and the complete response rate (CRR) was 20% in the intent-to-treat population, while the ORR was 71% and the CRR was 29% in the efficacy-evaluable population.
        - In the nanatinostat monotherapy arm, the ORR and CRR were 10% and 0% in the intent-to-treat population, while the ORR was 13% in the efficacy-evaluable population.
    - Data also showed that Nana-val was generally well tolerated, with the most common treatment-related adverse events in both treatment arms of 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.
        - The type, frequency, and severity of these adverse events were generally consistent with those from over 135 patients with R/R EBV+ lymphomas who have been treated with Nana-val to date.

Anticipated 2024 Milestones:

- Engage with 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.
- Present Stage 1 + Stage 2 data (n=21) in the R/R EBV$^+$ PTCL cohort in patients treated with Nana-val in the third quarter of 2024.
- Report Stage 1 data from patients with R/R EBV$^+$ diffuse large B-cell lymphoma (DLBCL) and R/R EBV$^+$ post-transplant lymphoproliferative disorder (PTLD) by year-end 2024.

Phase 1b/2 trial of Nana-val in patients with recurrent/metastatic (R/M) EBV$^+$ nasopharyngeal carcinoma (NPC) and other advanced EBV$^+$ solid tumors (Study 301)

Clinical Trial Updates:

- Completed enrollment of the sixth dose cohort from the Phase 1b dose escalation portion of the trial evaluating the novel split daily dosing (SDD) regimen in patients with R/M EBV$^+$ NPC.
- Started enrolling patients into the seventh dose cohort also evaluating the SDD regimen in the Phase 1b dose escalation portion of the trial.

Anticipated 2024 Milestones:

- Determine the recommended Phase 2 dose (RP2D) in the second half of 2024.
- Initiate a dose-optimization cohort to confirm the RP2D as part of the study's Phase 2 expansion by year-end 2024.

Business Updates

- *Engaged with the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) on the extension of the NAVAL-1 trial into Japan.*
    - At a recent meeting, the PMDA endorsed the enrollment of patients in Japan into the NAVAL-1 trial without a preceding Japanese Phase 1 safety/pharmacokinetics study.
    - Viracta plans to engage with the PMDA in the second half of 2024 to align on a potential approval pathway for Nana-val in R/R EBV$^+$ PTCL.
        - The PMDA has granted full approval for R/R PTCL drugs based on a primary ORR endpoint supported by DoR and safety in single-arm studies.

First Quarter 2024 Financial Results

- **Cash position –** Cash, cash equivalents, and short-term investments totaled approximately $39.6 million as of March 31, 2024, which Viracta expects will be sufficient to fund operations late into the first quarter of 2025.
- **Research and development expenses** – Research and development expenses were approximately $10.0 million for the three months ended March 31, 2024, compared to approximately $7.6 million for the three months ended March 31, 2023. The increase in research and development expenses was largely due to a non-cash adjustment for insurance costs related to the February 2021 reverse merger with Sunesis Pharmaceuticals of $1.8 million, as well as increases in costs incurred to support the advancement and expansion of our clinical development programs, including incremental costs to support NAVAL-1, our pivotal Phase 2 trial of Nana-val in patients with R/R EBV$^+$ lymphomas.
- **General and administrative expenses** – General and administrative expenses were approximately $3.9 million for the three months ended March 31, 2024, compared to $4.6 million for the same period in 2023. The decrease in general and administrative expenses was largely due to lower corporate liability insurance premiums and legal costs.
- **Net loss** – Net loss was approximately $9.1 million, or $0.23 per share (basic and diluted), for the quarter ended March 31, 2024, compared to a net loss of $12.2 million, or $0.32 per share (basic and diluted), for the same period in 2023. This change was primarily the result of $5.0 million of other income received related to the monetization of a pre-commercialization, event-based milestone from Day One Biopharmaceuticals, Inc. in March 2024, partially offset by the non-cash adjustment for insurance costs related to the February 2021 merger of $1.8 million.

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 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$^+$ 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 the Phase 1b/2 Study of Nana-val in Patients with Advanced EBV$^+$ Solid Tumors (Study 301)

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^+) 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^+ 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^+ 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^+ 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^+ 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 EBV-related diseases.

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, and expectations regarding our cash runway. 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; and

Viracta's estimates regarding its ability to fund ongoing operations into 2025, future expenses, capital requirements, and need for additional financing in the future.

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.

Investor Relations Contact:
Ashleigh Barreto
Head of Investor Relations & Corporate Communications
Viracta Therapeutics, Inc.
abarreto@viracta.com

-- Financial tables attached –

Viracta Therapeutics, Inc.
Selected Balance Sheet Highlights
(in thousands)

	March 31, 2024	December 31, 2023
	(Unaudited)	
Cash, cash equivalents and short-term investments	$ 39,566	$ 53,691
Total assets	$ 41,334	$ 56,692
Total liabilities	$ 30,254	$ 38,373
Stockholders' equity	$ 11,080	$ 18,319

Viracta Therapeutics, Inc.
Condensed Consolidated Statement of Operations and Comprehensive Loss
(in thousands except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2024	2023
Operating expenses:		
Research and development	$ 9,956	$ 7,607
General and administrative	3,920	4,600
Total operating expenses	13,876	12,207
Loss from operations	(13,876)	(12,207)
Total other income (expense)	4,735	(2)
Net loss	(9,141)	(12,209)
Unrealized gain (loss) on short-term investments	(15)	91
Comprehensive loss	(9,156)	(12,118)
Net loss per share, basic and diluted	$ (0.23)	$ (0.32)
Weighted-average common shares outstanding, basic and diluted	39,323,964	38,458,837