Viracta Therapeutics Reports Second Quarter 2023 Financial Results and Provides Business Update

Achieved efficacy threshold to advance Epstein-Barr virus-positive (EBV+) peripheral T-cell lymphoma into Stage 2 becoming the leading indication in pivotal NAVAL-1 study of Nana-val
Prioritized EBV+ diffuse large B-cell lymphoma and EBV+ post-transplant lymphoproliferative disease as key follow-on indications in NAVAL-1 trial
Published Phase 1b/2 clinical trial data reporting promising durable signal of efficacy for Nana-val in patients with relapsed or refractory EBV+ lymphoma in Blood Advances, a Journal of the American Society of Hematology
Completed enrollment into the fifth dose escalation level of the Phase 1b/2 study of Nana-val in advanced EBV+ solid tumors without any dose-limiting toxicities
Strengthened leadership with the appointment of Darrel P. Cohen, M.D., Ph.D. as Chief Medical Officer

San Diego, August 14, 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 provided a business update and reported financial results for the second quarter of 2023.

“In the second quarter of 2023, we achieved key milestones in the pivotal NAVAL-1 study of Nana-val by enabling the advancement of this global clinical trial into Stage 2 and establishing EBV-positive PTCL as Nana-val’s leading indication. This milestone was based on a strong signal of efficacy with a favorable safety profile, consistent with our promising Phase 1b/2 clinical trial data,” said Mark Rothera, President and Chief Executive Officer of Viracta. “Given the high unmet medical need in patients with EBV-positive PTCL and our positioning of Nana-val as a potential important treatment option for these patients, our goal is to move forward rapidly towards registration in the U.S. We intend to complete Stage 2 enrollment and meet with the U.S. Food and Drug Administration in 2024 to discuss additional requirements for regulatory approval.”

Darrel P. Cohen, M.D., Ph.D., Chief Medical Officer of Viracta commented, “We are thrilled to have our Phase 1b/2 study results published in a high-quality peer-reviewed journal, such as *Blood Advances*, which underscores the potential of Nana-val to treat patients with EBV-positive lymphoma and elevates the importance of the NAVAL-1 trial. Following the advancement of the PTCL cohort and to optimize our resources behind this trial, we have strategically prioritized key subtypes of EBV-positive lymphoma where we can address high unmet medical needs, increase the probability of success, and focus on the largest EBV-positive lymphoma patient populations.”

Clinical Trial Updates and Anticipated Milestones

Pivotal NAVAL-1 study of Nana-val in patients withrelapsed or refractory (R/R) EBV$^+$ lymphoma

- The EBV$^+$ peripheral T-cell lymphoma (PTCL) cohort of the pivotal NAVAL-1 clinical trial met the efficacy threshold for expansion into Stage 2 of the study, which was based upon a pre-specified minimum number of objective responses achieved; initial data are consistent with results from the Phase 1b/2 study and establish EBV$^+$ PTCL as Nana-val’s leading indication.
- Strategically prioritized three lymphoma subtypes: (1) EBV$^+$ PTCL, a T-cell lymphoma with high unmet medical need; (2) EBV$^+$ diffuse large B-cell lymphoma (DLBCL), an aggressive and distinct B-cell lymphoma subtype characterized by adverse clinical outcomes, and (3) EBV$^+$ PTLD, a potentially fatal complication after transplantation, which is highly associated with EBV.
    - Prioritization also enables the allocation of resources to those indications with the greatest probability of success and market opportunity in key geographies.
    - Enrollment into HIV-lymphoma and Hodgkin lymphoma cohorts will be discontinued.
    - Patients with extranodal NK/T-cell lymphoma (ENKTL) and other ultra-rare subtypes of EBV$^+$ lymphoma will continue to be enrolled.
- Completion of enrollment into Stage 2 of the R/R EBV$^+$ PTCL cohort and engagement with FDA on additional requirements for regulatory approval is anticipated in 2024.

Phase 1b/2 clinical trial of Nana-val in patients withR/R EBV$^+$ lymphoma

- In August 2023, Viracta announced the publication in *Blood Advances* featuring results from an open-label, multicenter, Phase 1b/2 study of Nana-val in patients with R/R EBV$^+$ lymphoma titled, “Targeted therapy with nanatinostat and valganciclovir in recurrent Epstein-Barr virus-positive lymphoid malignancies: a Phase 1b/2 study.”
    - The publication included a more recent data cut reflecting multiple patients with an ongoing durable response exceeding 30 months across multiple EBV$^+$ lymphoma subtypes, including EBV$^+$ PTCL and EBV$^+$ DLBCL, and two patients with an ongoing response of approximately 36 months.
    - Nana-val was generally well tolerated with reversible low-grade toxicities. The most commonly observed treatment emergent adverse events were reversible cytopenias, low-grade creatinine elevations, and gastrointestinal symptoms.

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

- Enrollment completed through the fifth dose level of the Phase 1b dose escalation portion of the trial without any dose-limiting toxicities reported.
- The Company remains on track to report complete Phase 1b dose escalation data and select a Recommended Phase 2 Dose (RP2D) of Nana-val in the second half of 2023.
- Initiation of the trial’s randomized Phase 2 expansion cohort designed to evaluate Nana-val at the RP2D with or without pembrolizumab in patients with R/M EBV$^+$ NPC is expected in the second half of 2023.
- Initiation of the trial’s exploratory Phase 1b expansion cohort designed to evaluate Nana-val at the RP2D in patients with other advanced EBV$^+$ solid tumors, including gastric carcinoma, leiomyosarcoma, and lymphoepithelioma, is expected in the second half of 2023.

Business Updates

Strengthened the leadership team with the appointment of Darrel P. Cohen, M.D., Ph.D. as Chief Medical Officer (CMO)

- In August 2023, Dr. Cohen was appointed as CMO to oversee the clinical development and regulatory advancement of Viracta’s pipeline. Dr. Cohen is a highly accomplished physician and biopharmaceutical executive with more than 25 years of oncology clinical research and drug development experience in both solid tumors and hematologic malignancies. Dr. Cohen was involved in multiple successful regulatory submissions of new targeted cancer drugs such as SUTENT® (sunitinib), XALKORI® (crizotinib), and IBRANCE® (palbociclib) while at Pfizer Oncology.

Strengthened intellectual property estate

- In July 2023, Viracta received a Notice of Allowance from the US Patent and Trademark Office on Viracta’s patent claims directed to a next-generation formulation of nanatinostat. This Notice of Allowance supports Viracta’s life-cycle management strategy, and upon issuance, the claims will expire in October 2041.

Second Quarter 2023 Financial Results

- **Cash position** – Cash, cash equivalents, and short-term investments totaled approximately $72.9 million as of June 30, 2023, which Viracta expects will be

sufficient to fund its operations into late 2024 excluding any additional borrowing under a $50.0 million credit facility, of which $25.0 million remains available, at the Company's request and subject to the discretion of the lenders.

- **Research and development expenses** – Research and development (R&D) expenses were approximately $8.2 million and $15.8 million for the three and six months ended June 30, 2023, respectively, compared to approximately $6.3 million and $12.4 million for the same periods in 2022. This increase in R&D expenses was primarily driven by increases in costs incurred to support the advancement and expansion of our clinical development programs, including incremental costs to support NAVAL-1, our pivotal study of Nana-val in patients with R/R EBV$^+$ lymphoma, and the initiation of our Phase 1b/2 study of Nana-val for the treatment of patients with EBV$^+$ solid tumors, as well as an increase in personnel-related costs.
- **General and administrative expenses** – General and administrative (G&A) expenses were approximately $4.3 million and $8.9 million for the three and six months ended June 30, 2023, respectively, compared to $4.2 million and $8.5 million for the same periods in 2022. The increase in G&A expenses can be primarily attributed to an increase in personnel-related costs.
- **Net loss** – Net loss was approximately $12.5 million, or $0.32 per share, (basic and diluted) for the quarter ended June 30, 2023, compared to a net loss of $10.6 million, or $0.28 per share, (basic and diluted) for the same period in 2022. Net loss was approximately $24.7 million, or $0.64 per share, (basic and diluted) for the six months ended June 30, 2023, compared to a net loss of $21.1 million, or $0.56 per share, (basic and diluted) for the same period in 2022.

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$^+$) lymphoma. This trial employs a Simon two-stage design where, in Stage 1, participants are enrolled into one of six indication cohorts based on EBV$^+$ 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$^+$ 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$^+$ NPC and Other EBV$^+$ 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$^+$) nasopharyngeal carcinoma (NPC). In Phase 2, 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 EBV$^+$ 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$^+$) 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, 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; Viracta's ability to identify additional products or product candidates with significant commercial potential; developments and projections relating to Viracta's competitors and its industry; the impact of government laws and regulations; Viracta's ability to protect its intellectual property position; and Viracta's estimates regarding 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.

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SOURCE Viracta Therapeutics, Inc.

-- Financial tables attached –

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

	June 30, 2023	December 31, 2022
	(Unaudited)	
Cash, cash equivalents and short-term investments	$ 72,867	$ 91,043
Total assets	$ 76,859	$ 95,991
Total liabilities	$ 36,077	$ 34,888
Stockholders' equity	$ 40,782	$ 61,103

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 8,197	$ 6,324	$ 15,804	$ 12,420
General and administrative	4,253	4,181	8,853	8,517
Total operating expenses	12,450	10,505	24,657	20,937
Loss from operations	(12,450)	(10,505)	(24,657)	(20,937)
Total other expense	(34)	(77)	(36)	(191)
Net loss	(12,484)	(10,582)	(24,693)	(21,128)
Unrealized (loss) gain on short-term investments	(28)	—	63	—
Comprehensive loss	(12,512)	(10,582)	(24,630)	(21,128)
Net loss per share, basic and diluted	$ (0.32)	$ (0.28)	$ (0.64)	$ (0.56)
Weighted-average common shares outstanding, basic and diluted	38,560,376	37,599,244	38,509,887	37,567,734