Viracta Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

Completed Stage 2 enrollment in the NAVAL-1 trial of Nana-val in patients with relapsed or refractory EBV+ peripheral T-cell lymphoma supporting its speed to market strategy; topline results from Stage 1 of the study expected in the second quarter of 2024
Completed enrollment into first split daily dosing cohort of the Phase 1b/2 study of Nana-val in patients with advanced EBV+ solid tumors
Strengthened balance sheet following receipt of non-dilutive proceeds of $5.0 million through monetization of a pre-commercialization, event-based milestone from Day One Biopharmaceuticals, Inc., extending cash runway into mid-Q1 2025

San Diego, March 7, 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 fourth quarter and full-year of 2023 and provided a business update.

“Nana-val is a first-in-class, all-oral combination treatment regimen that has entered late-stage development to target and treat EBV-associated cancers. Our near-term goal is to address the high unmet medical need of patients living with relapsed or refractory EBV-positive PTCL by advancing Nana-val in this lead indication through regulatory approval as quickly as possible,” said Mark Rothera, President and Chief Executive Officer of Viracta. “We are pleased to have successfully completed patient enrollment across both Stage 1 and Stage 2 of the PTCL cohort in our pivotal NAVAL-1 trial. Building on this momentum, we anticipate reporting topline data from Stage 1 in the second quarter of 2024 and engaging with the FDA on a potential accelerated approval pathway in mid-2024.”

Clinical Trial Updates and Anticipated Milestones

Pivotal 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:

- Completed enrollment of Stage 1 in the R/R EBV$^+$ PTCL cohort (in patients treated with nanatinostat with [n=10] or without [n=10] valganciclovir) in the fourth quarter of 2023.
- Completed enrollment of Stage 2 in the R/R EBV$^+$ PTCL cohort of patients treated with Nana-val (n=21, Stage 1 + Stage 2 patients) in the first quarter of 2024.
- Amended protocol to additionally enable enrollment of second-line R/R EBV$^+$ DLBCL patients and R/R EBV$^+$ PTLD patients, including pediatric EBV$^+$ PTLD patients ≥ 12 years of age.

Anticipated 2024 Milestones:

- Present topline Stage 1 data from both arms of the R/R EBV$^+$ PTCL cohort (in patients treated with nanatinostat with [n=10] or without [n=10] valganciclovir) in the second quarter of 2024, with an aim to clearly delineate the differentiation of Nana-val’s ‘*kick and kill*’ mechanism of action.
- 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:

- In December 2023, the FDA granted an orphan drug designation (ODD) to Nana-val for the treatment of NPC, the fifth ODD granted to Nana-val by the FDA, the seventh ODD for Nana-val globally, and the first ODD granted to Nana-val in EBV$^+$ solid tumors.
- Presented data at ESMO Asia Congress 2023 that confirmed partial responses without dose-limiting toxicities through the initial five dose cohorts, supporting continued dose escalation to potentially enhance Nana-val’s antitumor activity.
- Completed enrollment of the sixth dose cohort of patients with R/M EBV$^+$ NPC, evaluating the novel split daily dosing (SDD) regimen.

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

- Executed an amended license agreement with Day One Biopharmaceuticals
    - In March 2024, to receive non-dilutive proceeds of $5.0 million related to monetization of a pre-commercialization, event-based milestone from Day One Biopharmaceuticals, Inc.
- Executed an amended Royalty Purchase Agreement with XOMA
    - Amended the Royalty Purchase Agreement with XOMA, modifying the economic value-share under the Royalty Purchase Agreement by which the Company has retained the right, under certain circumstances, to participate in a pre-commercialization event-based milestone up to $5.0 million.
- Executed the second amendment under the SVB-Oxford Loan Facility
    - Amended the SVB-Oxford Loan Facility, providing for a modification of the loan amortization period and a pro-rata reduction in the prospective debt amortization schedule, in exchange for a partial prepayment of the term loan. Pursuant to the terms of the second amendment, the Company has agreed to remit a prepayment of $5.0 million toward the outstanding principal, plus a pro-rata portion of the final payment, by March 15, 2024. Under the terms of the amendment, principal amortization will be deferred between March 2024 and June 2024, totaling approximately $2.9 million. Amortization payments will recommence in July 2024, reflecting the prepayment and reducing prospective amortization payments in 2024 by approximately $3.3 million, in addition to significantly reducing interest owed over the term of the loan. There were no changes to the maturity date of the term loan, which is November 2026.

"We are pleased to have strengthened our balance sheet through the imminent receipt of $5 million in non-dilutive capital at this important time," said Dan Chevallard, Chief Operating Officer and Chief Financial Officer of Viracta. "The proceeds will be used to make a partial prepayment of our outstanding debt balance, while also enabling a concurrent amendment to our credit facility to avail ourselves of an additional interest-only period through June 2024, and further reduce future amortization and interest payments reflecting the prepayment. Pro forma for this prepayment, we will have reduced our debt balance by over 25% since year-end to $18.6M and anticipate ending 2024 with less than $15 million in debt outstanding. The totality of this coordinated set of transactions will extend our cash runway into mid-Q1 2025 and provides a meaningful aggregate cash impact to Viracta well in excess of the proceeds."

Fourth-Quarter and Full-Year 2023 Financial Results

- **Cash position** – Cash, cash equivalents, and short-term investments totaled approximately $53.7 million as of December 31, 2023. Pro forma for the aforementioned business transactions, our cash runway to fund operations is extended into mid-Q1 2025.
- **Research and development expenses** – Research and development expenses were approximately $9.4 million and $6.7 million for the three months ended December 31, 2023 and 2022, respectively. Research and development expenses increased to $33.4 million compared to $26.3 million for the years ended December 31, 2023 and 2022, respectively. The increase in research and development expenses in 2023 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 trial of Nana-val in patients with R/R EBV^+ lymphomas, and our Phase 1b/2 study of Nana-val in patients with advanced EBV^+ solid tumors, as well as an increase in personnel-related costs.
- **General and administrative expenses** – General and administrative (G&A) expenses were approximately $4.2 million and $4.9 million for the three months ended December 31, 2023 and 2022, respectively, compared to $17.3 million and $24.3 million for the years ended December 31, 2023 and 2022. The decrease in G&A expenses year over year was largely due to a one-time expense associated with the modification of certain equity awards totaling $5.6 million and $0.8 million in severance-related charges associated with the transition of the former Chief Executive Officer in 2022. The decrease over the comparative three-month period was primarily due to a decrease in share-based compensation expense and corporate liability insurance premiums.
- **Net loss** – Net loss was approximately $13.8 million, or $0.35 per share (basic and diluted), for the quarter ended December 31, 2023, compared to a net loss of $10.3 million or $0.27 per share (basic and diluted), for the same period in 2022. Net loss was approximately $51.1 million, or $1.32 per share (basic and diluted), for the year ended December 31, 2023, compared to a net loss of $49.2 million or $1.30 per share (basic and diluted), for the same period in 2022.

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 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 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; 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.

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SOURCE Viracta Therapeutics, Inc.

-- Financial tables attached –

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

	December 31, 2023	December 31, 2022
Cash, cash equivalents and short-term investments	$ 53,691	$ 91,043
Total assets	$ 56,692	$ 95,991
Total liabilities	$ 38,373	$ 34,888
Stockholders' equity	$ 18,319	$ 61,103

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 9,406	$ 6,703	$ 33,369	$ 26,262
General and administrative	4,154	4,871	17,324	24,327
Total operating expenses	13,560	11,574	50,693	50,589
Loss from operations	(13,560)	(11,574)	(50,693)	(50,589)
Total other income (expense)	(205)	1,248	(365)	1,392
Net loss	(13,765)	(10,326)	(51,058)	(49,197)
Unrealized gain (loss) on short-term investments	73	21	187	(178)
Comprehensive loss	(13,692)	(10,305)	(50,871)	(49,375)
Net loss per share, basic and diluted	$ (0.35)	$ (0.27)	$ (1.32)	$ (1.30)
Weighted-average common shares outstanding, basic and diluted	38,790,480	38,315,658	38,624,462	37,790,981