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

- Reported combined Stage 1 and Stage 2 results from the relapsed or refractory EBV-positive peripheral T-cell lymphoma (PTCL) cohort of the Phase 2 NAVAL-1 trial demonstrating Nana-val's substantial antitumor activity and generally well-tolerated safety profile -

- New positive data and productive feedback from the FDA support updated Nana-val clinical development plan in EBV-positive PTCL patients; randomized controlled trial planned to begin in the second half of 2025 to support potential registration -

- Appointed Michael Faerm as Chief Financial Officer -

SAN DIEGO, August 14, 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 second quarter of 2024 and provided a business update.

"In the second quarter, we took several important steps to drive forward our clinical development program for Nana-val, our first-in-class, all-oral combination treatment regimen for Epstein-Barr virus (EBV) associated cancers," said Mark Rothera, President and Chief Executive Officer of Viracta. "We received productive feedback from our meeting with the FDA and are encouraged by additional positive data from the ongoing NAVAL-1 trial, particularly in the second-line EBV-positive PTCL subgroup. To optimize the clinical benefit of Nana-val, we plan to focus on the second-line EBV-positive PTCL subpopulation in the NAVAL-1 trial's expansion phase and initiate a randomized controlled trial in 2025 to potentially support registration. We believe our sharpened focus on the EBV-positive lymphoma program will propel us forward to key milestones and support our speed to market strategy. We look forward to providing more updates on our progress."

Clinical Trial Updates and Anticipated Milestones

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:

- Announced positive combined Stage 1 and Stage 2 data (n=21) in the R/R EBV$^+$ PTCL cohort of patients treated with nanatinostat (20 mg orally once daily, 4 days/week) in combination with valganciclovir (900 mg orally once daily, 7 days/week) across the first two stages of the study.
    - As of the June 28, 2024 data cutoff, combined Stages 1 and 2 data demonstrated Nana-val's substantial antitumor activity and generally well-tolerated safety profile with a median duration of response (DOR) that has not yet been reached.
        - In the R/R EBV$^+$ PTCL population, the overall response rate (ORR) was 33% and the complete response rate (CRR) was 19% in the intent-to-treat (ITT) population (N=21); the ORR was 41% and the CRR was 24% in the efficacy-evaluable (EE) population (N=17).
        - Notably, there was a particularly robust clinical response observed in the second-line EBV$^+$ PTCL subpopulation, as the ORR was 60% and the CRR was 30% in the intent-to-treat population (n=10), and the ORR was 67% and the CRR was 33% in the efficacy-evaluable population (n=9).
- Held a productive FDA meeting to align on a potential regulatory path forward for Nana-val in patients with R/R EBV$^+$ PTCL. Based on feedback from the FDA and the particularly robust response rates observed in the second-line treatment setting, Viracta will focus the primary analysis on the second-line EBV$^+$ PTCL subpopulation in the ongoing NAVAL-1 trial's expansion phase. The Company plans to begin a randomized controlled trial (RCT) of Nana-val in the second-line treatment of EBV+ PTCL patients in 2025.
    - Viracta believes this strategy will best position Nana-val for a potential NDA filing in 2026 for accelerated approval based on an interim analysis of second-line EBV+ PTCL patient data from the NAVAL-1 trial, provided that the ORR and DOR are compelling and the RCT is well underway; for accelerated approval based on final analysis of NAVAL-1 trial data; or for accelerated or full approval based on the outcomes of the RCT at interim or final analysis, respectively.

Anticipated Milestones

Viracta plans to deliver on the following milestones:

- The recommended Phase 2 dose in patients with advanced EBV+ solid tumors is expected to be determined in the second half of 2024.
- Report additional data from the expansion phase of the NAVAL-1 trial in second-line EBV+ PTCL patients in the fourth quarter of 2024.
- Report Stage 1 data from patients with R/R EBV+ diffuse large B-cell lymphoma (DLBCL) in the first half of 2025.
- Meet with the FDA to finalize the proposed RCT design in the second-line treatment of patients with EBV+ PTCL in the first half of 2025.
    - Initiate the RCT in the second half of 2025.
- Present interim analysis outcomes from the NAVAL-1 trial in second-line EBV+ PTCL patients in 2026.
- File NDA for accelerated approval in 2026 based on interim analysis of the NAVAL-1 trial's expansion cohort.

Business Updates

- Appointed Michael Faerm as Chief Financial Officer. Mr. Faerm is a seasoned biotech executive with more than 25 years of experience in life sciences companies, equity research and investment banking.
- Viracta has aligned resources to prioritize its more advanced EBV+ lymphoma and will pause its EBV+ solid tumor program. Along with this pipeline reprioritization, a reduction in force has been implemented that impacts approximately 23% of the company's employees.

Second Quarter 2024 Financial Results

- **Cash position** – Cash, cash equivalents, and short-term investments totaled approximately $30.0 million as of June 30, 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 $6.5 million and $16.5 million for the three and six months ended June 30, 2024, respectively, compared to approximately $8.2 million and $15.8 million for the same periods in 2023. The decrease in research and development expenses for the three months ended June 30, 2024 compared to the same period in 2023, was driven by decreases in costs incurred to support the advancement and expansion of our clinical development programs, including incremental costs to support NAVAL-1, our Phase 2 trial of Nana-val in patients with R/R EBV^+ lymphomas and personnel-related costs. The increase in research and development expenses for the six months ended June 30, 2024 compared to the same period in 2023, 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, partially offset by decrease in costs incurred related to our clinical development programs and personnel-related costs.
- **General and administrative expenses** – General and administrative expenses were approximately $3.0 million and $7.0 million for the three and six months ended June 30, 2024, respectively, compared to $4.3 million and $8.9 million for the same periods in 2023. The decrease in general and administrative expenses was largely due to decreases in personnel-related costs, corporate liability insurance premiums and legal costs.
- **Net loss** – Net loss was approximately $9.8 million, or $0.25 per share (basic and diluted), for the quarter ended June 30, 2024, compared to a net loss of $12.5 million, or $0.32 per share (basic and diluted), for the same period in 2023. This change was primarily the result of decreases in research and development expenses and personnel-related costs. Net loss was approximately $19.0 million, or $0.48 per share, (basic and diluted) for the six months ended June 30, 2024, compared to a net loss of $24.7 million, or $0.64 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 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 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 potentially registrational, 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 potentially registrational, 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, Viracta's clinical focus and strategy, the Company's expectations related to the FDA submission process and timelines, expectations regarding the Company's target patient populations, and expectations regarding the Company's 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:
Michael Faerm
Chief Financial Officer
Viracta Therapeutics, Inc.
ir@viracta.com

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Viracta Therapeutics, Inc.		
Selected Balance Sheet Highlights		
(in thousands)		
	June 30, 2024	**December 31, 2023**
	(Unaudited)	
Cash, cash equivalents and short-term investments	$ 30,005	$ 53,691
Total assets	$ 31,322	$ 56,692
Total liabilities	$ 28,651	$ 38,373
Stockholders' equity	$ 2,671	$ 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 June 30,		**Six Months Ended June 30,**	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 6,548	$ 8,197	$ 16,504	$ 15,804
General and administrative	3,041	4,253	6,961	8,853
Total operating expenses	9,589	12,450	23,465	24,657
Loss from operations	(9,589)	(12,450)	(23,465)	(24,657)
Total other income (expense)	(241)	(34)	4,494	(36)
Net loss	(9,830)	(12,484)	(18,971)	(24,693)
Unrealized gain (loss) on short-term investments	1	(28)	(14)	63
Comprehensive loss	(9,829)	(12,512)	(18,985)	(24,630)
Net loss per share, basic and diluted	$ (0.25)	$ (0.32)	$ (0.48)	$ (0.64)
Weighted-average common shares outstanding, basic and diluted	39,404,975	38,560,376	39,364,469	38,509,887

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https://viracta.investorroom.com/2024-08-14-Viracta-Therapeutics-Reports-Second-Quarter-2024-Financial-Results-and-Provides-Business-Update