

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

Reported preliminary clinical data from the pivotal NAVAL-1 clinical trial of Nana-val in patients with relapsed or refractory EBV+ peripheral T-cell lymphoma showing an overall response rate and complete response rate of 40%

Reported interim data from the Phase 1b/2 trial of Nana-val in advanced EBV+ solid tumors with confirmed partial responses at higher doses and no dose-limiting toxicities observed to date

SAN DIEGO, November 9, 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 third quarter of 2023.

“During our recently held R&D Day, we provided multiple clinical and strategic updates, which further positioned Nana-val as a differentiated potential therapeutic option for patients with EBV-associated cancers,” said Mark Rothera, President and Chief Executive Officer of Viracta. “Preliminary results from the PTCL cohort of the NAVAL-1 trial demonstrated overall and complete response rates of 40%, which are consistent with results from our previous Phase 1b/2 study and exceeds the current standard of care for this patient population with high unmet medical need. We continue to believe that Nana-val is an ideal candidate for the accelerated approval pathway and we remain on track to complete enrollment of the Nana-val PTCL Stage 2 cohort and engage with FDA in 2024.”

“We also reported interim data from the Phase 1b/2 trial of Nana-val in advanced EBV-positive solid tumors with partial responses confirmed at higher doses. Given there have been no dose-limiting toxicities observed to date, we plan to evaluate higher doses of Nana-val that incorporate a novel split daily dosing schedule and determine the recommended Phase 2 dose of Nana-val for our solid tumor program in 2024. We have a well-defined strategic path forward, and with the PTCL indication leading the way, we continue to explore opportunities to maximize the therapeutic potential of Nana-val across other indications.”

Clinical Trial Updates and Anticipated Milestones

Pivotal NAVAL-1 study of Nana-val in patients with relapsed or refractory (R/R) Epstein-Barr virus-positive (EBV⁺) lymphoma

- As of the data cutoff date of June 30, 2023, initial results from the first five patients with R/R EBV⁺ peripheral T-cell lymphoma (PTCL) treated with Nana-val showed an overall response rate (ORR) and complete response rate (CRR) of 40%.
- Completion of enrollment into the nanatinostat monotherapy arm (n=10) and Nana-val combination arm (n=10) of the NAVAL-1 R/R EBV⁺ PTCL cohort is anticipated by year-end 2023.
- Amended the NAVAL-1 protocol to additionally enroll second-line patients across all cohorts, including diffuse large B-cell lymphoma (DLBCL) and post-transplant lymphoproliferative disorder (PTLD).
- **Anticipated 2024 milestones:**
 - Stage 1 data from both arms of the R/R EBV⁺ PTCL cohort (in patients treated with nanatinostat with or without valganciclovir).
 - Completion of enrollment into Stage 2 of the Nana-val R/R EBV⁺ PTCL cohort (n=21).
 - U.S. Food and Drug Administration (FDA) meeting to discuss additional requirements for accelerated approval for the treatment of patients with R/R EBV⁺ PTCL.
 - Stage 2 data from the Nana-val R/R EBV⁺ PTCL cohort.

Additional response and durability assessments from the Phase 1b/2 trial (Study 201) of Nana-val in patients with R/R EBV⁺ lymphoma as of the May 4, 2023 data cutoff date

- For patients with R/R EBV⁺ PTCL, median duration of response (DoR) was 17.3 months with an ORR/CRR of 50%/38% (n=8).
- For patients with R/R EBV⁺ DLBCL, median DoR has not yet been reached, with three patients remaining in response with DoRs of 11.1 months (complete response [CR]), 36.8 months (partial response [PR]), and 41.9 months (CR), with an ORR/CRR of 67%/33% (n=9).
- Expanded and extended safety data demonstrated Nana-val regimen was generally well-tolerated with the potential to combine with other chemo/immunotherapies.

New interim clinical data in Phase 1b/2 study of Nana-val in patients with advanced EBV⁺ solid tumors (Study 301) highlight the opportunity to dose escalate further with a novel dosing regimen to potentially drive additional responses in this patient population. This approach is supported by growing preclinical data.

- Enrollment completed through the fifth dose level without any dose-limiting toxicities reported.
- Best responses to date included two confirmed PRs at the higher dose levels and five stable diseases in 17 patients with recurrent or metastatic (R/M) EBV⁺ nasopharyngeal carcinoma (NPC).
- In a preclinical murine xenograft model, split daily dosing (SDD) of Nana-val had superior anti-tumor activity than intermittent (four days on/three days off) once-daily dosing, which supports the evaluation of an SDD regimen in patients with advanced EBV⁺ solid tumors.
- **Anticipated 2024 milestones:**
 - Additional dose levels are planned with Nana-val on an SDD schedule to select a recommended Phase 2 dose (RP2D); enrollment anticipated to be resumed by year-end 2023.
 - Initiation of the clinical trial's randomized Phase 2 expansion cohort designed to further evaluate Nana-val at the RP2D.

Business Update

- On October 4, 2023, Viracta hosted an R&D Day highlighting Nana-val clinical programs in EBV-associated cancers. The R&D Day featured key opinion leaders, Pierluigi Porcu, M.D. and Robert A. Baiocchi, M.D., Ph.D.
 - Drs. Porcu and Baiocchi discussed the current treatment landscape of EBV⁺ lymphomas and Nana-val's opportunity to address the unmet medical needs of this unique cancer segment.
 - Members of Viracta's senior management team provided updates on the Nana-val clinical development programs in patients with R/R EBV⁺ lymphoma and in patients with R/M EBV⁺ NPC.
 - A replay of the presentation is available [here](#)

Third Quarter 2023 Financial Results

- **Cash position** – Cash, cash equivalents, and short-term investments totaled approximately \$63.0 million as of September 30, 2023, which is anticipated to fund Viracta's operations through late 2024 and does not include any adjustments that may arise from uncertainties related to our ability to continue as a going concern. This also excludes 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 \$24.0 million for the three and nine months ended September 30, 2023, respectively, compared to approximately \$7.1 million and \$19.6 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 \$13.2 million for the three and nine months ended September 30, 2023, respectively, compared to \$10.9 million and \$19.5 million for the same periods in 2022. The decrease in G&A expenses was largely due to a non-recurring share-based compensation expense of \$5.6 million associated with modifications to certain equity awards in conjunction with a separation agreement for the former Chief Executive Officer in September 2022. In addition, \$0.8 million in one-time severance-related charges were recorded in the three and nine months ended September 30, 2022 in accordance with the terms of the separation agreement.
- **Net loss** – Net loss was approximately \$12.6 million, or \$0.33 per share, (basic and diluted) for the quarter ended September 30, 2023, compared to a net loss of \$17.7 million, or \$0.47 per share, (basic and diluted) for the same period in 2022. Net loss was approximately \$37.3 million, or \$0.97 per share, (basic and diluted) for the nine months ended September 30, 2023, compared to a net loss of \$38.9 million, or \$1.03 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 three 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 Advanced 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 its ability to fund ongoing operations to or beyond late 2024, 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

SOURCE Viracta Therapeutics, Inc.

-- Financial tables attached --

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

	September 30, 2023	December 31, 2022
	<i>(Unaudited)</i>	
Cash, cash equivalents and short-term investments	\$ 62,952	\$ 91,043
Total assets	\$ 66,437	\$ 95,991
Total liabilities	\$ 36,429	\$ 34,888
Stockholders' equity	\$ 30,008	\$ 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 8,158	\$ 7,139	\$ 23,962	\$ 19,559
General and administrative	4,317	10,939	13,170	19,456
Total operating expenses	12,475	18,078	37,132	39,015
Loss from operations	(12,475)	(18,078)	(37,132)	(39,015)
Total other income (expense)	(125)	335	(161)	144
Net loss	(12,600)	(17,743)	(37,293)	(38,871)
Unrealized gain (loss) on short-term investments	50	(199)	113	(199)
Comprehensive loss	(12,550)	(17,942)	(37,180)	(39,070)
Net loss per share, basic and diluted	\$ (0.33)	\$ (0.47)	\$ (0.97)	\$ (1.03)
Weighted-average common shares outstanding, basic and diluted	38,683,858	37,705,517	38,568,515	37,614,166

<https://viracta.investorroom.com/2023-11-09-Viracta-Therapeutics-Reports-Third-Quarter-2023-Financial-Results-and-Provides-Business-Update>