Viracta Therapeutics Reports First Quarter 2023 Financial Results and Provides Clinical Program Updates

Pivotal NAVAL-1 trial of Nana-val in Epstein-Barr virus-positive (EBV+) lymphoma accelerating globally; update on first lymphoma subtype that may advance from Stage 1 to Stage 2 anticipated in 2Q 2023

Enrollment into fifth dose level in the dose escalation portion of the Phase 1b/2 trial of Nana-val in advanced EBV+ solid tumors underway; data from complete dose escalation portion expected in 2H 2023

Cash, cash equivalents and investments of $80.3 million as of March 31, 2023 provides anticipated cash runway into late 2024

San Diego, May 8, 2023 – Viracta Therapeutics, Inc. (Nasdaq: VIRX), a precision oncology company focused on the treatment and prevention of virus-associated cancers that impact patients worldwide, today announced financial results for the first quarter of 2023 and recent clinical program updates.

“With progress from both of our clinical programs accelerating, we have the opportunity to achieve several important milestones this year. NAVAL-1 is enrolling at a rapid pace, and we look forward to readouts across multiple subtypes that could trigger our first advancement into Stage 2 in the months ahead,” said Mark Rothera, President and Chief Executive Officer of Viracta. “On the solid tumor front, we are currently seeking to optimize the dose of Nana-val and are pleased to see that its safety profile continues to support further dose escalation into our trial’s fifth dose level. Following the completion of the Phase 1b portion of the trial, we look forward to selecting our recommended Phase 2 dose and advancing our efforts around Nana-val as a potential tumor agnostic therapy for EBV-associated cancers.”

Program Highlights and Anticipated Milestones

Pivotal NAVAL-1 trial of Nana-val in relapsed/refractory (R/R) EBV$^+$ lymphoma

- NAVAL-1 continues to enroll across each of the trial’s lymphoma subtype cohorts with more than 70 sites open globally.
- An update on NAVAL-1’s first lymphoma subtype that may advance from Stage 1 to Stage 2 is anticipated in the second quarter of 2023.
- Potential for additional update(s) on other NAVAL-1 lymphoma subtype(s) in the second half of 2023.

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

- The trial has advanced into the fifth dose level of the Phase 1b dose escalation portion; no dose-limiting toxicities have been reported to date.
- Clinical data previously reported across the first three dose levels (n=10) include one confirmed partial response (PR) at the third dose level and three patients achieving stable disease.
- The Company remains on track to report complete Phase 1b dose escalation data and select a recommended Phase 2 dose (RP2D) in the second half of 2023.
- Initiation of the trial’s Phase 2 randomized 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.

First Quarter 2023 Financial Results

- **Cash position –** Cash, cash equivalents and short-term investments totaled approximately $80.3 million as of March 31, 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, subject to the discretion of the lenders.
- **Research and development expenses** – Research and development expenses were approximately $7.6 million for the three months ended March 31, 2023, compared to approximately $6.1 million for the three months ended March 31, 2022. The increase in research and development expenses was primarily driven by increases in costs incurred to support the advancement and expansion of our clinical development programs, including incremental costs to support NAVAL-1, our pivotal trial in R/R EBV$^+$ lymphoma, and the initiation of our Phase 1b/2 trial for the treatment of EBV$^+$ solid tumors, as well as an increase in personnel-related costs.

- **General and administrative expenses** – General and administrative expenses were approximately $4.6 million for the three months ended March 31, 2023, compared to $4.3 million for the same period in 2022. The increase in general and administrative expenses can be attributed to an increase in personnel-related costs.
- **Net loss** – Net loss was approximately $12.2 million, or $0.32 per share, (basic and diluted) for the quarter ended March 31, 2023, compared to a net loss of $10.5 million, or $0.28 per share (basic and diluted) for the same period in 2022.

About NAVAL-1

NAVAL-1 (NCT05011058) is a global, multicenter trial of Nana-val in R/R EBV^+ lymphoma. The trial employs a Simon two-stage design where participants are enrolled into six indication cohorts based on EBV^+ lymphoma subtype in Stage 1. If a pre-specified activity threshold is reached within a lymphoma subtype in Stage 1 (n=10), additional patients will be enrolled in Stage 2 for a total of 21 patients. EBV^+ lymphoma subtypes demonstrating promising activity in Stage 2 may be further expanded following discussion with regulators to potentially support registration.

About the Phase 1b/2 Trial of Nana-val in R/M EBV^+ NPC and Other EBV^+ Solid Tumors

This Phase 1b/2 trial (NCT05166577) is an open-label, multinational 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 RP2D of Nana-val in patients with R/M EBV^+ 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 evaluate safety, overall response rate, and potential pharmacodynamic markers. 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/refractory EBV^+ lymphoma (NAVAL-1) as well as a multinational Phase 1b/2 trial in patients with EBV^+ recurrent or metastatic nasopharyngeal carcinoma and other EBV^+ solid tumors.

About Viracta Therapeutics, Inc.

Viracta is a 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/refractory Epstein-Barr virus-positive (EBV^+) lymphoma (NAVAL-1), as well as a multinational, open-label Phase 1b/2 trial for the treatment of EBV^+ recurrent or metastatic nasopharyngeal carcinoma 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 trials and updates regarding the same, including NAVAL- 1 and the Phase 1b/2 trial of Nana-val in EBV^+ solid tumor and the sufficiency of current cash reserves to fund ongoing operations for the specified period. 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; 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 supplying nanatinostat, valganciclovir and pembrolizumab for clinical testing; and Viracta's estimates regarding future expenses, capital requirements and need for additional financing in the future.

These risks and uncertainties may be amplified by the ongoing COVID-19 pandemic, which has caused significant economic uncertainty. 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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-- Financial tables attached –

Download Financial Tables
(14 KB)
