Viracta Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results and Provides a Corporate Update

Final Phase 1b/2 data showing promising and durable signal of efficacy for Nana-val in patients with relapsed/refractory Epstein-Barr virus-positive (EBV$^+$) lymphoma featured in an oral presentation at ASH 2021

Pivotal NAVAL-1 trial of Nana-val for the treatment of EBV$^+$ lymphoma is enrolling patients and an update on the initial cohort(s) expanding into Stage 2 is anticipated in the second half of 2022

Preliminary safety and efficacy data from the Phase 1b/2 trial of Nana-val for the treatment of advanced EBV$^+$ solid tumors is expected in the second half of 2022

Cash balance of $103.6 million as of December 31, 2021, expected to be sufficient to fund operations into mid-2024

SAN DIEGO, March 16, 2022 /PRNewswire/ -- Viracta Therapeutics, Inc. (Nasdaq: VIRX), a precision oncology company targeting virus-associated malignancies, today announced financial results for the fourth quarter and full year 2021 and provided an update on recent corporate activities.

"In 2021, we achieved key corporate and clinical milestones that we believe positioned us for an exciting year ahead," said Ivor Royston, M.D., President and Chief Executive Officer of Viracta. "We entered the public market while simultaneously completing a successful equity financing, and initiated two clinical studies of our all-oral combination therapy, Nana-val. These included our pivotal NAVAL-1 trial in EBV-positive relapsed/refractory lymphoma and our Phase 1b/2 trial in advanced EBV-positive solid tumors. In addition, we ended the year by presenting final data from Nana-val's Phase 1b/2 EBV-positive lymphoma trial in an oral presentation at ASH 2021, which showed complete responses in a heavily pre-treated patient population in need of a new therapeutic option."

Dr. Royston continued, "In the year ahead, we anticipate several important advancements and milestones in our clinical programs, including meaningful progress in NAVAL-1, and a preliminary data readout from our ongoing Phase 1b/2 trial in solid tumors. Should we see early efficacy signals for Nana-val in solid tumors, as we did in the Phase 1b/2 EBV-positive lymphoma trial, it could serve as initial support for our pursuit of a tissue agnostic approach to EBV-associated malignancies and expand our addressable patient population. With a cash runway into mid-2024, we are well capitalized to execute on these milestones and our broader corporate strategy."

Fourth Quarter 2021 and Recent Highlights

Clinical

- **Presented final results from the Phase 1b/2 trial of Nana-val (nanatinostat and valganciclovir) in relapsed/refractory (R/R) EBV$^+$ lymphoma, in an oral presentation at the 2021 American Society of Hematology (ASH) Annual Meeting.** Data featured in the presentation were from 55 patients with a median of two prior therapies. 75% (41/55) of patients were refractory to their last therapy, and 96% (53/55) had exhausted all standard therapies (per Investigator).

Efficacy data in evaluable patient (n=43):

  - Across all lymphoma subtypes: overall response rate (ORR) = 40% (17/43); complete response (CR) = 19% (8/43)
  - T/NK- non-Hodgkin lymphoma: ORR = 60% (9/15); CR = 27% (4/15)
  - Extranodal NK/T-Cell Lymphoma (ENKTL): ORR = 63% (5/8); CR = 13% (1/8)
  - Peripheral T-cell lymphoma (PTCL)/ Angioimmunoblastic T-cell lymphoma (AITL): ORR = 67% (4/6); CR = 50% (3/6)
  - Diffuse large B cell lymphoma (DLBCL): ORR = 67% (4/6); CR = 33% (2/6); Both DLBCL complete responses were in patients refractory to first line R-CHOP
  - Immunodeficiency-associated lymphoproliferative disorders (IA-LPD): ORR = 50% (3/6); CR = 33% (2/6)
  - Median duration of response was 10.4 months

  Nana-val was generally well tolerated with reversible low-grade toxicities. The most commonly reported treatment emergent adverse events were reversible cytopenias, low grade creatinine elevations, and gastrointestinal symptoms.

- **Continued enrollment into, and global expansion of, pivotal NAVAL-1 trial of Nana-val for the treatment of R/R EBV$^+$ lymphoma.** NAVAL-1 employs a Simon two-stage design where patients are initially enrolled into six cohorts based on lymphoma subtype in Stage 1. If a pre-specified activity threshold is reached, additional patients will be enrolled in Stage 2. Lymphoma subtypes demonstrating promising activity in Stage 2 may be further expanded. If successful, the Company believes NAVAL-1 could potentially support multiple new drug application (NDA) filings across various EBV$^+$ lymphoma subtypes. The Company anticipates providing an update on the initial cohort(s) that expand into Stage 2 in the second half of 2022.
- **Dosed first patient in the Phase 1b/2 trial of Nana-val for the treatment of EBV$^+$ recurrent or metastatic nasopharyngeal carcinoma (R/M NPC) and other EBV$^+$ solid tumors.** The Phase 1b dose escalation portion of the study will evaluate safety and determine the recommended Phase 2 dose (RP2D) of Nana-val in patients with EBV$^+$ R/M NPC. In Phase 2, up to 60 patients with EBV$^+$ R/M NPC will be randomized to receive Nana-val at the RP2D with or without pembrolizumab to evaluate safety and preliminary efficacy. Additionally, patients with other EBV$^+$ solid tumors will be enrolled to receive Nana-val at the RP2D in a Phase 1b dose expansion cohort. Viracta anticipates reporting preliminary Phase 1b safety and efficacy data from the trial in the second half of 2022.
- **Received orphan drug designation (ODD) from U.S. Food and Drug Administration (FDA) for Nana-val for the treatment of EBV$^+$ Diffuse large B cell lymphoma, not otherwise specified (DLBCL, NOS).** This represents the first ODD for EBV$^+$ DLBCL, NOS granted by the FDA, and the fourth ODD granted for Nana-val overall. The FDA previously granted ODD to Nana-val for the treatment of T-cell lymphoma, post-transplant lymphoproliferative disorder and plasmablastic lymphoma.

Preclinical

- **Presented preclinical data on vecabrutinib, a reversible inhibitor of Bruton's tyrosine kinase (BTK) and interleukin-2-inducible kinase (ITK), at the 2021 ASH Annual Meeting.** Two presentations were featured, oral and poster, with data that demonstrate the capacity of vecabrutinib to modulate immune responses. Data featured in the oral presentation showed vecabrutinib enhancing the efficacy of chimeric antigen receptor (CAR) T-cells in a murine mantle cell lymphoma model. Vecabrutinib also inhibited secretion of pro-inflammatory cytokines known to cause toxicities associated with CAR T-cell therapy, an observation that was consistent with data from a prior Phase 1 clinical trial evaluating vecabrutinib as a treatment for patients with B-cell malignancies. Data featured in the poster presentation show vecabrutinib significantly reducing signs of sclerodermatous chronic graft versus host disease (cGVHD), including skin irritation, redness, alopecia, and diarrhea, via modulation of pathogenetic B- and T-cell subsets in a murine disease model.

Corporate

- **Announced addition to the Nasdaq Biotechnology Index (NBI).** The NBI is designed to track the performance of a set of securities listed on The Nasdaq Stock Market® (Nasdaq®) that are classified as either biotechnology or pharmaceutical according to the Industry Classification Benchmark (ICB). The NBI is re-ranked each year and is calculated under a modified capitalization-weighted methodology. Additionally, the NBI forms the basis for a number of Exchange Traded Funds (ETFs).
- **Secured expanded $50 million credit facility from Silicon Valley Bank (SVB) and Oxford Finance.** The credit facility replaces Viracta's prior $15 million loan and security agreement with SVB and provides the Company with the option to obtain additional non-dilutive funding at a single-digit cost of capital. Through this expanded credit facility, the Company's existing $5.0 million debt balance was refinanced. The remaining $45.0 million is available to the Company, which is under no obligation to draw funds in the future.

Anticipated 2022 Milestones

- Provide preliminary Phase 1b safety and efficacy data from the Phase 1b/2 trial in advanced EBV$^+$ solid tumors: 2H 2022
- Update on NAVAL-1 cohort(s) progressing from Stage 1 to Stage 2: 2H 2022

Fourth Quarter and Full Year 2021 Financial Results

- **Cash Position –** Cash and cash equivalents totaled approximately $103.6 million as of December 31, 2021, which Viracta expects will be sufficient to fund its operations into mid-2024, excluding any additional borrowings under the $50.0 million credit facility.
- **Research and development expenses** – Research and development expenses were approximately $7.3 million and $3.6 million for the fourth quarters ended 2021 and 2020, respectively. Research and

development expenses were approximately $23.9 million and $13.5 million for years ended December 31, 2021, and December 31, 2020, respectively. The increase in research and development expenses was primarily due to increases in costs incurred to support the initiation of the NAVAL-1 and solid tumor trials as well as an increase in headcount and non-cash share-based compensation.

- **Purchased and acquired in-process research and development** – Purchased and acquired in-process research and development expenses were $88.5 million for the year ended December 31, 2021. The expenses were related to the $4.0 million payment associated with the termination of the collaboration and license agreement with Shenzhen Salubris Pharmaceutical Co. Ltd. and non-cash and non-recurring costs of $84.5 million related to the write-off of in-process research and development acquired in the merger with Sunesis Pharmaceuticals.
- **General and administrative expenses** – General and administrative expenses were approximately $4.0 million and $2.6 million for the fourth quarters ended 2021 and 2020, respectively. General and administrative expenses were approximately $15.4 million and $5.3 million for the years ended December 31, 2021, and December 31, 2020, respectively. The increase was largely due to significant and non-recurring costs associated with the merger, in addition to incremental costs associated with being a publicly traded company, including legal fees, audit fees, consulting expenses, filing fees and increased directors' and officers' insurance costs, in addition to an increase in non-cash share-based compensation.
- **Gain on Royalty Purchase Agreement** – Gain on Royalty Purchase Agreement the year ended December 31, 2021, was associated with upfront proceeds of $13.5 million received in connection with the multi-license milestone and royalty monetization transaction with XOMA Corporation in March 2021.
- **Adjusted loss from operations** – Adjusted loss from operations for the year ended December 31, 2021, excluding the non-recurring operating expenses associated with the write-off of in-process research and development acquired in the merger and the termination agreement with Salubris Pharmaceutical Co. Ltd. (a non-GAAP measure) was $25.8 million, compared to a loss from operations of $114.3 million. There is not a comparative adjustment to loss from operations for the same period in 2020.
- **Net loss** – Net loss was approximately $11.4 million, or $0.31 per share (basic and diluted), and approximately $6.3 million, or $13.31 per share (basic and diluted), for the fourth quarters ended 2021 and 2020, respectively. Net loss was approximately $114.8 million, or $3.60 per share (basic and diluted) for the year ended December 31, 2021, compared to a net loss of approximately $19.0 million, or $58.56 per share (basic and diluted) for the year ended December 31, 2020.

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 is key to inducing viral genes that are epigenetically silenced in 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 EBV-Associated Cancers

Approximately 95% of the world's adult population is infected with Epstein-Barr virus (EBV). Infections are commonly asymptomatic or associated with mononucleosis. Following infection, the virus remains latent in a small subset of lymphatic 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^+ lymphomas. EBV is estimated to be associated with approximately 2% of the global cancer burden and is also associated with a variety of solid tumors, including nasopharyngeal carcinoma and gastric cancer.

About Vecabrutinib

Vecabrutinib is a well-tolerated, selective, reversible, non-covalent inhibitor of Bruton's tyrosine kinase (BTK) and interleukin-2-inducible kinase (ITK). Vecabrutinib is being studied as a potential enhancer of efficacy and safety of CAR T-cell therapy.

About Viracta Therapeutics, Inc.

Viracta is a precision oncology company targeting virus-associated malignancies. 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 EBV^+ solid tumors. Viracta is also pursuing the application of its inducible synthetic lethality 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 trials and updates regarding the same; the significance of the Nana-val trial results, NAVAL-1 as a potential registration-enabling trial, the utility Viracta's therapeutic approach, the strength of Viracta's clinical dataset, the ability of Viracta to obtain one or more accelerated approvals, the timeline for further clinical program updates in the second half of 2022; Viracta's plans to provide updates on NAVAL-1 in the second half of 2022; expectations regarding the Company's pipeline and potential products; Viracta's cash projections and the sufficiency its cash and cash equivalents to fund operations into 2024; the future availability of capital under Viracta's credit facility; the expected 2022 milestones and key upcoming events and their significance; and other statements that are not historical facts. 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 supplying 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.

These risks and uncertainties may be amplified by the 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.

Investor Relations Contact:

Ashleigh Barreto
Head of Investor Relations & Corporate Communication
Viracta Therapeutics, Inc.
abarreto@viracta.com

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

	December 31, 2021	December 31, 2020
Cash and cash equivalents	$ 103,554	$ 47,089
Total assets	$ 108,552	$ 48,305
Total liabilities	$ 14,181	$ 11,203
Stockholders' equity (deficit)	$ 94,371	$ (46,200)

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

	Three months Ended December 31,		Years Ended December 31,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 7,303	$ 3,555	$ 23,861	$ 13,467
Purchased and acquired in-process research and development	—	—	88,478	—
General and administrative	4,015	2,571	15,437	5,348
Total operating expenses	11,318	6,126	127,776	18,815
Gain on Royalty Purchase Agreement	—	—	13,500	—
Loss from operations	(11,318)	(6,126)	(114,276)	(18,815)
Total other expense	(129)	(159)	(486)	(202)
Net loss and comprehensive loss	$ (11,447)	$ (6,285)	$ (114,762)	$ (19,017)
Net loss per share, basic and diluted	$ (0.31)	$ (13.31)	$ (3.60)	$ (58.56)
Weighted-average common shares outstanding, basic and diluted	37,431,800	472,225	31,870,067	324,728

Viracta Therapeutics, Inc.
Reconciliation of GAAP Loss from Operations to Adjusted Loss from Operations
(in thousands)

	Years Ended December 31,	
	2021	**2020**
Loss from operations	$ (114,276)	$ (18,815)
Less: Purchased and acquired in-process research and development	88,478	-
Adjusted loss from operations	$ (25,798)	$ (18,815)

SOURCE Viracta Therapeutics, Inc.

---

https://viracta.investorroom.com/2022-03-16-Viracta-Therapeutics-Reports-Fourth-Quarter-and-Full-Year-2021-Financial-Results-and-Provides-a-Corporate-Update