Viracta Therapeutics Reports First Quarter 2021 Financial Results and Provides Clinical and Corporate Updates

NAVAL-1, a global pivotal trial for the treatment of relapsed/refractory EBV-positive lymphoma is on track to be initiated in Q2 2021
NAVAL-1 trial design to be featured in a Key Opinion Leader webinar taking place on May 20, 2021
Closed merger with Sunesis Pharmaceuticals and $65 million private placement
Cash and cash equivalents of approximately $129.2 million as of March 31, 2021

SAN DIEGO, May 12, 2021 /PRNewswire/ -- Viracta Therapeutics, Inc. (Nasdaq: VIRX) (Viracta or the Company), a precision oncology company targeting virus-associated malignancies, today announced financial results for the first quarter of 2021 and provided a clinical and corporate update.

"Viracta has emerged from our first quarter as a publicly traded company well-positioned to make a significant impact on patients and create meaningful value for our shareholders. We are on track to initiate our pivotal NAVAL-1 trial as planned this quarter for the treatment of EBV-associated lymphoma, and we look forward to expanding into our second global clinical program in EBV-associated solid tumors in the second half of 2021," said Ivor Royston, M.D., President and Chief Executive Officer of Viracta.

Dr. Royston continued, "Today, we are excited to provide additional details of the NAVAL-1 trial design, which has been reviewed by the United States Food and Drug Administration. We believe the innovative and adaptive design of this registration-enabling pivotal trial will allow us to simultaneously progress towards potential NDA filings in multiple lymphoma subtypes."

First Quarter 2021 and Recent Highlights

Clinical

- **Announced design of NAVAL-1, a global pivotal trial in Epstein-Barr virus (EBV)-positive relapsed/refractory (R/R) lymphoma.** NAVAL-1 (**Na**natinostat in Combination with **Val**ganciclovir) is a multinational, multicenter, open-label Phase 2 basket trial. The trial, which will include multiple subtype-specific cohorts of R/R EBV-positive lymphoma patients, is designed to evaluate the anti-tumor activity of the combination treatment of nanatinostat with valganciclovir and is anticipated to enroll up to 140 patients. The primary endpoint of the trial is objective tumor response rate as assessed by an independent review committee. If successful, Viracta believes this trial could support multiple NDA filings across various EBV-positive lymphoma subtypes. Viracta remains on track to initiate NAVAL-1 in Q2 2021.
- **Completed enrollment in Phase 2 expansion cohort of its Phase 1b/2 R/R EBV-positive lymphoma trial, with updated data expected in H2 2021.** VT3996-201, Viracta's Phase 1b/2 open-label, dose escalation/expansion trial of nanatinostat-valganciclovir combination treatment in R/R EBV-positive lymphoma has generated promising efficacy and safety data to date, as presented at the 62nd American Society of Hematology Annual Meeting in December 2020, including preliminary objective response and complete response rates (ORR/CR) of 80%/40% (n=10) and 67%/33% (n=6) in T/NK cell non-Hodgkin's lymphoma and diffuse large B-cell lymphoma, respectively. The median duration of response was 10.4 months.

Corporate

- **Closed merger with Sunesis Pharmaceuticals, Inc.** Shares of the combined company, Viracta Therapeutics, Inc., commenced trading on the Nasdaq Global Select Market under the ticker symbol "VIRX" on February 25, 2021.
- **Completed a $65 million private placement.** On February 24, 2021, Viracta closed a private financing featuring a premier investor syndicate of biotechnology-focused and institutional accredited investors.
- **Strengthened balance sheet through a multi-license milestone and royalty monetization transaction with XOMA.** In March 2021, Viracta announced that XOMA had purchased the potential future milestones and royalties associated with existing licenses relating to two clinical-stage drug candidates that Viracta obtained in the merger in exchange for an upfront payment of $13.5 million and up to $20 million in a pre-commercialization, event-based milestone. In the merger, Viracta also obtained exclusive and global rights to assets previously held by Sunesis including SNS-510, a PDK-1 inhibitor, and vecabrutinib, a BTK inhibitor. Viracta is evaluating future development and collaboration opportunities for SNS-510 and potential partnering opportunities for vecabrutinib.
- **Extended intellectual property protection around lead lymphoma program.** In March 2021, the U.S. Patent and Trademark Office (USPTO) granted patent 10,953,011, which covers the anticipated dose regimen to be advanced in the NAVAL-1 trial. The patent provides Viracta with intellectual property protection into at least 2040.

- **Strengthened company leadership with new appointments to the Board of Directors and management team.** Throughout the first quarter, Viracta appointed the following life sciences industry veterans to the Board of Directors: Stephen Rubino, Ph.D., MBA, and Barry J. Simon, M.D., who were each appointed following the closing of the merger, Thomas Darcy, who was appointed in connection with the closing of the merger, and Nicole Onetto, M.D., who remained on the combined company's Board of Directors following the merger. The Company also appointed Cheryl A. Madsen, RAC as Senior Vice President, Regulatory Affairs.

Anticipated 2021 Milestones

- Initiation of NAVAL-1, a global Phase 2 pivotal trial for R/R EBV-positive lymphoma: Q2 2021
- Clearance of IND for a Phase 1b/2 clinical trial in EBV-positive solid tumors: mid-2021
- Initiation of a global Phase 1b/2 clinical trial in EBV-positive solid tumors: H2 2021
- Updated data from Phase 1b/2 trial in R/R EBV-positive lymphoma (VT3996-201): H2 2021

First Quarter 2021 Financial Results

- **Cash Position –** Cash and cash equivalents totaled approximately $129.2 million as of March 31, 2021. Viracta expects to end 2021 with greater than $100 million in cash and cash equivalents, which it expects will be sufficient to fund its operations into 2024.
- **Research and Development Expenses –** Research and development expenses were $4.0 million for the quarter ending March 31, 2021, compared to $3.4 million for the same period in 2020. This increase was primarily due to costs incurred to support study initiation activities for NAVAL–1, in addition to an increase in headcount and non-cash share-based compensation.
- **General and Administrative Expenses –** General and administrative expenses were $3.8 million for the quarter ending March 31, 2021, compared to $1.0 million for the same period in 2020. This increase was primarily due to non-recurring, merger-related costs of approximately $2.0 million incurred in the period, in addition to incremental costs associated with being a publicly traded company and non-cash share-based compensation.
- **Acquired in-process research and development –** Non-recurring, non-cash operating expenses of $84.5 million associated with the write-off of in-process research and development acquired in the merger were recorded for the quarter ending March 31, 2021.
- **Gain on Royalty Purchase Agreement –** Gain on Royalty Purchase Agreement for the quarter ended March 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 income or loss from operations** – Adjusted income from operations for the quarter ended March 31, 2021, excluding the non-recurring and non-cash operating expenses associated with the write-off of in-process research and development acquired in the merger (a non-GAAP measure) was $5.6 million, compared to an unadjusted loss from operations of $78.8 million. There is not a comparative adjustment to loss from operations for the same period in 2020.
- **Net loss –** Net loss was $79.2 million, or $5.22 per share (basic and diluted) for quarter ended March 31, 2021, compared to $4.4 million, or $1.86 per share (basic and diluted), for the same period in 2020.

Key Opinion Leader Webinar

The design of NAVAL-1, a global pivotal trial in EBV-positive R/R lymphoma, will be discussed during a Key Opinion Leader webinar on May 20, 2021 at 2pm EST. The webinar will feature presentations by Pierluigi Porcu, M.D. (Thomas Jefferson University) and Kristen Cunanan, Ph.D. (Stanford University School of Medicine), who will discuss the current treatment landscape, unmet medical need in EBV-associated lymphoma and the trial design of NAVAL-1. The formal presentations will then be followed by a Q&A session with Drs. Porcu and Cunanan, accompanied by Company management. A link to register for the webcast is here: https://media.rampard.com/202105203/

About NAVAL-1

NAVAL-1 (**Na**natinostat in Combination with **Val**ganciclovir) is a registration-enabling multinational, multicenter, open-label Phase 2 basket trial. The trial will include multiple subtype-specific with various EBV-positive relapsed/refractory lymphoma and is anticipated to enroll up to 140 patients. The primary endpoint of the trial is objective tumor response rate, while secondary endpoints include duration of response, survival outcomes, and the safety profile of the combined treatment. Trial eligibility includes patients with EBV-positive R/R lymphoma following two or more prior systemic therapies with no available standard therapies. For ENKTL patients only, eligibility includes patients with R/R disease following one or more prior systemic therapies with no available standard therapies who have failed an asparaginase-containing regimen.

About Viracta Therapeutics, Inc.

Viracta is a precision oncology company targeting virus-associated malignancies. Viracta's proprietary investigational drug, nanatinostat, is currently being evaluated in combination with the antiviral agent valganciclovir as an oral combination therapy in a Phase 2 clinical trial for EBV-positive lymphoma. Viracta is pursuing application of this inducible synthetic lethality approach in other EBV-associated malignancies, such as nasopharyngeal carcinoma, gastric carcinoma, and 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: being on track for initiation and the details and timeline for the NAVAL-1 trial and the EBV-associated solid tumor trial and related expectations; the ability of Viracta to simultaneously advance multiple NDA filings from the NAVAL-1 trial; the timing of the clearance of the IND for the solid tumor trial and the updated date from the ongoing Phase1b/2 trial; the sufficiency of the Company's cash and cash equivalents to fund operations into 2024; Viracta's ability to value for its shareholders; 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 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.

Use of Non-GAAP Financial Measures

In addition to our results reported in accordance with U.S. generally accepted accounting principles ("GAAP"), we believe certain non-GAAP, or adjusted, measures are useful in evaluating our operating performance. We use adjusted financial measures to evaluate our ongoing operations and for internal planning and forecasting purposes. We believe that adjusted financial measures, when taken collectively, may be helpful to investors because they can provide consistency and comparability with past financial performance. However, adjusted financial information has limitations as an analytical tool and should not be considered in isolation or as a substitute for financial information presented in accordance with U.S. GAAP. In particular, other companies, including companies in our industry, may calculate similarly titled non-GAAP or adjusted measures differently or may use other measures to evaluate their performance, all of which could reduce the usefulness of our adjusted financial measures as tools for comparison. A reconciliation is provided below for adjusted financial measures to the most directly comparable financial measure stated in accordance with U.S. GAAP. Investors are cautioned that there are a number of limitations associated with the use of non-GAAP, or adjusted, financial measures as analytical tools. Investors are encouraged to review the related U.S. GAAP financial measures and the reconciliation of these adjusted financial measures to their most directly comparable U.S. GAAP financial measure, and not to rely on any single financial measure to evaluate our business.

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

	March 31, 2021	December 31, 2020
	(Unaudited)	
Cash and cash equivalents	$ 129,181	$ 47,089
Total assets	$ 136,209	$ 48,305
Total liabilities	$ 11,465	$ 11,203
Stockholders' equity	$ 124,744	$ (46,200)

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

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	$ 4,024	$ 3,446
Acquired in-process research and development	84,478	-
General and administrative	3,840	1,011
Total operating expenses	92,342	4,457
Gain on Royalty Purchase Agreement	13,500	-
Loss from operations	(78,842)	(4,457)
Total other (expense) income	(389)	40
Net loss and comprehensive loss	$ (79,231)	$ (4,417)
Net loss per share, basic and diluted	$ (5.22)	$ (1.86)
Weighted-average common shares outstanding, basic and diluted	15,166,737	2,373,560

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

	Three Months Ended March 31,	
	2021	2020
Loss from operations	$ (78,842)	$ (4,457)
Less: Acquired in-process research and development	84,478	-
Adjusted income (loss) from operations	$ 5,636	$ (4,457)

SOURCE Viracta

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https://viracta.investorroom.com/2021-05-12-Viracta-Therapeutics-Reports-First-Quarter-2021-Financial-Results-and-Provides-Clinical-and-Corporate-Updates