Viracta Therapeutics Announces Final Phase 1b/2 Data Showing Promising and Durable Signal of Efficacy for Nana-val in Relapsed/Refractory Epstein-Barr Virus-Positive Lymphoma in an Oral Presentation at ASH 2021

Complete responses (CR) observed across multiple Epstein-Barr virus-positive (EBV+) lymphoma subtypes; overall response rate (ORR)/CR of 60%/27% in T/NK-NHL and 67%/33% in DLBCL
Orally dosed Nana-val (nanatinostat plus valganciclovir) was well tolerated and led to a median duration of response (DoR) of 10.4 months in heavily pre-treated patients

SAN DIEGO, Dec. 13, 2021 /PRNewswire/ -- Viracta Therapeutics, Inc. (Nasdaq: VIRX), a precision oncology company targeting virus-associated malignancies, today announced that final data from its Phase 1b/2 trial of Nana-val in relapsed/refractory (R/R) EBV^+ lymphoma (VT3996-201) were presented in an oral presentation at the 2021 American Society of Hematology (ASH) Annual Meeting by Bradley Haverkos, M.D., Associate Professor at the University of Colorado School of Medicine. Nana-val was well tolerated and continues to demonstrate promising activity with complete responses observed across multiple EBV^+ lymphoma subtypes and a median duration of response of 10.4 months.

Key data and conclusions from the ASH presentation:

As of the October 28, 2021, data cutoff, 55 patients were enrolled. Patients had a median age of 60 (range 19-84) and had a median of two prior therapies. 75% (41/55) were refractory to their last therapy, and 96% (53/55) had exhausted all standard therapies (per Investigator).

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

Efficacy in evaluable patient (n=43):

- Across all lymphoma subtypes: ORR = 40% (17/43); CR = 19% (8/43); Clinical Benefit Rate (CBR) [(CR+ partial response (PR) + stable disease (SD) ≥6 months] = 56% (24/43)
- T/NK-NHL: ORR = 60% (9/15); CR = 27% (4/15); CBR = 67% (10/15)
    - Extranodal NK/T-Cell Lymphoma (ENKTL): ORR = 63% (5/8); CR = 13% (1/8); CBR = 63% (5/8)
    - Peripheral T-cell lymphoma (PTCL)/ Angioimmunoblastic T-cell lymphoma (AITL): ORR = 67% (4/6); CR = 50% (3/6); CBR = 83% (5/6)
- DLBCL: ORR = 67% (4/6); CR = 33% (2/6); CBR = 83% (5/6)
    - Both DLBCL complete responses were in patients refractory to first line R-CHOP
- IA-LPD: ORR = 50% (3/6); CR = 33% (2/6); CBR = 50% (3/6)

Durable responses:

- Median DoR was 10.4 months
- Three patients achieved responses with durations >2 years

"EBV is easily detectable and can be associated with a number of lymphoma subtypes, having a negative impact on clinical outcomes such as survival," said Dr. Haverkos, lead investigator of the VT3996-201 study. "The clinical safety and efficacy profile demonstrated thus far in this refractory patient population is very encouraging and underscores the utility of this unique EBV-targeted approach."

"Clinicians and key opinion leaders have shown a high level of enthusiasm for our potentially registration-enabling NAVAL-1 study, which we believe underscores the strength of the clinical dataset supporting the trial and the urgency of the unmet need in EBV-associated cancers. We expect this enthusiasm to be further bolstered following this oral presentation at ASH, which has provided us with the opportunity to broadly discuss the final Phase 1b/2 results with the clinical community," said Ivor Royston, M.D., President and Chief Executive Officer of Viracta. "We are encouraged by the final Phase 1b/2 data, as the response rates and median durations observed in the B- and T-cell lymphoma subtypes compare favorably to those seen in other single arm R/R lymphoma studies that have led to accelerated approvals and demonstrate Nana-val's potential to provide meaningful clinical benefit to patients who currently lack effective treatment options. We look forward to the continued evaluation of this promising combination therapy in NAVAL-1 and anticipate providing further clinical program updates in 2022."

A copy of the ASH presentation will be available by visiting the Events and Webcasts page of the Viracta website following the conference's conclusion.

About Nana-Val (Nanatinostat and Valganciclovir)

Nanatinostat (VRx-3996) 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 registration-enabling 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 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, Nana-Val, in a registration-enabling Phase 2 clinical trial for EBV-positive (EBV^+) lymphoma and a Phase 1b/2 trial in patients with EBV^+ 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 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; 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.

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