

Viracta Therapeutics Announces First Patient Dosed in Phase 1b/2 Trial of Nana-val in Patients with Advanced Epstein-Barr Virus-Positive Solid Tumors

First clinical trial to evaluate the safety and efficacy of Nana-val beyond lymphoma
Preliminary safety and efficacy data anticipated in the second half of 2022

SAN DIEGO, Jan. 31, 2022 /PRNewswire/ -- [Viracta](#) Therapeutics, Inc. (Nasdaq: VIRX), a precision oncology company targeting virus-associated malignancies, today announced that the first patient has been dosed in the multinational Phase 1b/2 trial of its all-oral combination product, Nana-val (nanatinostat and valganciclovir), in patients with Epstein-Barr virus-positive (EBV⁺) recurrent or metastatic nasopharyngeal carcinoma (R/M NPC) and other advanced EBV⁺ solid tumors. The trial is designed to evaluate the safety and preliminary efficacy of Nana-val alone and in combination with the PD-1 inhibitor pembrolizumab.

"The initiation of dosing in this clinical trial represents an important milestone for Viracta and is a critical step in potentially expanding the clinical applicability of the targeted all-oral Nana-val combination beyond lymphoma," said Lisa Rojkjaer, M.D., Chief Medical Officer of Viracta. "Advanced NPC patients have poor outcomes and are in urgent need of effective treatment options. We are looking forward to evaluating the clinical profile of this novel combination therapy and exploring potential synergies with a PD-1 inhibitor."

The 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 portion is designed to evaluate safety and to determine the recommended Phase 2 dose (RP2D) of Nana-val in patients with EBV⁺ R/M NPC. In Phase 2, up to sixty patients with EBV⁺ R/M 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 (VRx-3996) is an orally available histone deacetylase (HDAC) inhibitor being developed by Viracta. Nanatinostat selectively inhibits specific isoforms of Class I HDACs, an activity that is key to inducing viral genes 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 90% of the world's adult population is infected with Epstein-Barr virus (EBV), which persists as a life-long latent infection and remains dormant in cell nuclei. Cells containing latent EBV are increasingly susceptible to malignant transformation. EBV infection is directly linked to the development of multiple forms of human lymphoid and epithelial cancers contributing to approximately 2% of all new cancer cases globally. The lack of approved therapies for EBV⁺ cancers creates a pressing unmet medical need as these malignancies have poor prognoses and are responsible for approximately 180,000 annual deaths.

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 pivotal Phase 2 clinical trial for Epstein-Barr virus-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: preliminary data update from

Phase 1b being anticipated in the second half of 2022, including the significance of such data; expanding the applicability Nana-val beyond lymphoma; the details of the Phase 1b/2 trial and related expectations; 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

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