Viracta Therapeutics Announces Orphan Drug Designation Granted by FDA for its All-Oral Combination of Nanatinostat and Valganciclovir (Nana-val) for the Treatment of Epstein Barr Virus-Positive Diffuse Large B-cell Lymphoma

Fourth U.S. FDA orphan drug designation granted for Nana-val
First Orphan Drug Designation for EBV-Positive diffuse large B-cell lymphoma granted by U.S. FDA

SAN DIEGO, Nov. 29, 2021 /PRNewswire/ -- Viracta Therapeutics, Inc. (Nasdaq: VIRX), a precision oncology company targeting virus-associated malignancies, today announced that the U.S. Food and Drug Administration (FDA) has granted its all-oral combination product candidate, nanatinostat and valganciclovir (Nana-val), orphan drug designation (ODD) for the treatment of Epstein Barr virus-positive diffuse large B-cell lymphoma, not otherwise specified (EBV$^+$ DLBCL, NOS). DLBCL is the most common subtype of non-Hodgkin lymphoma (NHL) in the U.S. and worldwide, accounting for approximately 25% of newly diagnosed cases of NHL in the U.S, of which a subset are EBV$^+$. Viracta has previously received ODD from the FDA for the treatment of T-cell lymphoma, post-transplant lymphoproliferative disorder (PTLD) and plasmablastic lymphoma.

"This latest orphan drug designation underscores the potential benefits of our all-oral *kick and kill* approach to targeting EBV-positive cancers," said Ivor Royston, M.D., President and Chief Executive Officer of Viracta. "Nana-val has shown promising preliminary efficacy across multiple subtypes of relapsed/refractory EBV-positive lymphoma, including DLBCL. We are dosing patients in the pivotal NAVAL-1 trial, which includes patients with EBV-positive DLBCL, and look forward to its continued momentum with sites now open for enrollment in the U.S., Europe, and Asia. Through NAVAL-1's progress, we aim to further develop Nana-val as a new and actionable therapy in indications where many patients recur from the standard of care and have particularly poor prognoses."

The FDA grants orphan drug designations to investigational drugs and biologics that are intended for the treatment of rare diseases that affect fewer than 200,000 people in the U.S. Orphan drug status is intended to facilitate drug development for rare diseases and may provide several benefits to drug developers, including tax credits toward qualified clinical trial costs, assistance with clinical study design and drug development, exemptions from certain FDA application fees, and seven years of market exclusivity upon regulatory approval for the disease or condition for which the drug has the orphan drug designation. In 2020, 31 of the 53 novel drug approvals, or 58%, in the FDA's Center for Drug Evaluation and Research, were orphan designated products.

About NAVAL-1

NAVAL-1 (**Na**natinostat in Combination with **Val**ganciclovir) is a global, multicenter, open-label Phase 2 basket trial. The trial, which will include patients with multiple subtypes of relapsed/refractory EBV-positive (EBV$^+$) lymphoma, is designed to evaluate the anti-tumor activity of Nana-val and enroll approximately 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 potentially support multiple new drug application filings across various EBV$^+$ lymphoma subtypes. The study employs a Simon two-stage design where a limited number of patients are enrolled into each cohort in Stage 1 and, if a pre-specified activity threshold is reached, additional patients will be enrolled in Stage 2. During Stage 2, Viracta anticipates discussing the preliminary results with the FDA and may amend the protocol to include additional patients as necessary to enable registration.

About Nanatinostat

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. Nana-val (nanatinostat and valganciclovir) is being investigated in multiple subtypes of relapsed/refractory EBV$^+$ lymphoma and in advanced EBV$^+$ solid tumors in three ongoing trials, one of which is a registration-enabling global, multicenter, open-label Phase 2 basket trial in relapsed/refractory EBV$^+$ lymphoma (NAVAL-1).

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 patients' life. Cells containing latent virus are increasingly susceptible to malignant transformation. Patients who are immunocompromised are at an increased risk of

developing EBV$^+$ lymphomas. In addition, EBV 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 in two Phase 2 clinical trials for EBV-positive (EBV$^+$) lymphoma and one 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 importance of the orphan drug designation in EBV$^+$ DLBCL, NOS; the details, timeline and expected progress for Viracta's ongoing trials, including plans to discuss preliminary results with the FDA in the future; 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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