Viracta Therapeutics Announces Orphan Drug Designation Granted by the European Commission for Nana-val for the Treatment of Peripheral T-cell Lymphoma

First orphan drug designation granted for Nana-val by the European Commission; fifth globally

SAN DIEGO, Sept. 7, 2022 /PRNewswire/ -- Viracta Therapeutics, Inc. (Nasdaq: VIRX), a precision oncology company targeting virus-associated malignancies, today announced that the European Commission has granted an orphan drug designation (ODD) to nanatinostat and valganciclovir (Nana-val), the company's all-oral combination product candidate, for the treatment of peripheral T-cell lymphoma (PTCL). This represents Nana-val's first ODD in Europe and fifth globally. The U.S. Food and Drug Administration previously granted Nana-val ODD for the treatment of T-cell lymphoma, post-transplant lymphoproliferative disorder, plasmablastic lymphoma, and Epstein-Barr virus-positive (EBV^+) diffuse large B-cell lymphoma, not otherwise specified.

"This orphan drug designation acknowledges the high unmet medical need of this patient population as well as the potential of Nana-val to offer therapeutic benefit to patients with recurrent peripheral T-cell lymphoma," said Lisa Rojkjaer, M.D., Chief Medical Officer of Viracta. "Patients with peripheral T-cell lymphoma have few effective treatment options, particularly those with relapsed/refractory disease. Of note, Epstein-Barr virus is frequently associated with peripheral T-cell lymphoma, and reportedly confers a worse overall survival for patients. Following the conclusion of our Phase 1b/2 study, we are now continuing the evaluation of Nana-val in patients with relapsed/refractory Epstein-Barr virus-positive lymphoma in our global Phase 2 NAVAL-1 trial, which is actively enrolling at sites across Europe, North America and Southeast Asia."

ODD in the European Union (EU) is granted by the European Commission based on a positive opinion issued by the European Medicines Agency (EMA) Committee for Orphan Medical Products (COMP). To qualify for ODD from the European Commission, a product candidate must be intended to treat, prevent, or diagnose a life-threatening or chronically debilitating disease that does not affect more than 5 in 10,000 people across the EU. In addition, there must be sufficient clinical or non-clinical data to suggest the product candidate may produce clinically relevant outcomes, and grounds to indicate it can provide a significant benefit over any currently authorized products. Receiving an orphan drug designation from the European Commission provides companies with certain benefits and incentives including clinical protocol assistance, access to a centralized marketing authorization procedure valid in all EU member states, reduced regulatory fees, and ten years of market exclusivity upon receipt of marketing authorization in the EU. The availability of market exclusivity is intended to encourage the development of medicines for rare diseases by protecting them from competition from similar medicines with similar indications, which cannot be marketed during the exclusivity period.

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 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 Epstein-Barr virus (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.

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 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; 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 globally 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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