Viracta Therapeutics Announces Orphan Drug Designation Granted by the European Commission to Nana-val for the Treatment of Diffuse Large B-cell Lymphoma

Sixth orphan drug designation for Nana-val globally; second granted by the European Commission

San Diego, January 19, 2023 – Viracta Therapeutics, Inc. (Nasdaq: VIRX), a precision oncology company focused on the treatment and prevention of virus-associated cancers that impact patients worldwide, today announced that the European Commission (EC) has granted an orphan drug designation (ODD) to Viracta's all-oral combination product candidate, Nana-val (nanatinostat and valganciclovir), for the treatment of diffuse large B-cell lymphoma (DLBCL). The EC previously granted ODD to Nana-val for the treatment of peripheral T-cell lymphoma. In addition, Nana-val was previously granted ODD by the U.S. Food and Drug Administration for the treatment of T-cell lymphoma, post-transplant lymphoproliferative disorder, plasmablastic lymphoma, and Epstein-Barr virus-positive (EBV^+) DLBCL, not otherwise specified.

"Nana-val's sixth orphan drug designation across the U.S. and Europe underscores the high unmet medical need for EBV-positive lymphoma patients worldwide, the broad therapeutic potential of its novel mechanism of action, and the global nature of our clinical and regulatory strategy," said Mark Rothera, President and Chief Executive Officer of Viracta. "This strategy is embodied by our pivotal trial, NAVAL-1, which has more than 60 sites open globally, and cohorts dedicated to multiple subtypes of EBV-positive lymphoma, including DLBCL. Emerging data have shown that EBV-positive DLBCL is a differentiated disease with a significantly lower survival outcome compared to EBV-negative disease. Nana-val has displayed promising preliminary efficacy in EBV-positive DLBCL, leaving it uniquely positioned to treat this underserved patient population."

ODD in the European Union (EU) is granted by the EC based on a positive opinion issued by the European Medicines Agency (EMA) Committee for Orphan Medical Products. To qualify for ODD from the EC, 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 ODD from the EC 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 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 are 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. 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 Viracta Therapeutics, Inc.

Viracta is a precision oncology company focused on the treatment and prevention of virus-associated cancers that impact patients worldwide. 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, open-label 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 "*Kick and Kill"* 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 and anticipated trials and updates regarding the same. 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;

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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