Viracta | Investor Relations

Viracta Therapeutics Announces the Initiation of NAVAL-1, a Global Pivotal Trial for the Treatment of Relapsed/Refractory Epstein-Barr Virus-Positive Lymphoma Now open for enrollment, NAVAL-1 is a multicenter basket trial with an adaptive Simon 2-stage design

SAN DIEGO, June 1, 2021 /<u>PRNewswire</u>/ -- <u>Viracta</u> Therapeutics, Inc. (Nasdaq: VIRX), a precision oncology company targeting virus-associated malignancies, today announced the initiation of NAVAL-1 (**Na**natinostat in Combination with **Val**ganciclovir), a global, multicenter, open-label Phase 2 basket trial for the treatment of relapsed/refractory (R/R) EBV-positive (EBV⁺) lymphoma. NAVAL-1 is designed to potentially support multiple new drug application filings across various EBV⁺ lymphoma subtypes.

"Effective therapies for patients with recurrent lymphomas are limited, and those with EBV-positive lymphoma have even worse outcomes with standard of care therapies. Following the promising Phase 1b/2 data presented at the American Society of Hematology Annual Meeting in December 2020, we are excited to initiate the NAVAL-1 trial and continue the evaluation of our all-oral combination regimen in patients with a variety of relapsed/refractory EBV-positive lymphomas," said Lisa Rojkjaer, M.D., Chief Medical Officer of Viracta. "We are seeing enthusiasm for NAVAL-1 and our therapeutic approach from physicians, both in the United States and internationally, as this is an area of significant unmet medical need."

NAVAL-1 will evaluate nanatinostat in combination with valganciclovir in patients with EBV⁺ R/R lymphoma and is anticipated to enroll approximately 140 patients at centers in North America, Europe, and Asia-Pacific. The primary endpoint of the trial is objective response rate, with key secondary endpoints including duration of response, survival outcomes, and the safety profile of the combined treatment. Patients with EBV⁺ relapsed or refractory disease following two or more prior therapies (one or more for extranodal NK/T cell lymphoma) without curative treatment options will be eligible for enrollment.

Ivor Royston, M.D., President and Chief Executive Officer of Viracta, added, "The initiation of NAVAL-1 is an important milestone for Viracta, and we are thrilled to have this pivotal trial open for enrollment. We believe we are uniquely positioned with our all-oral therapeutic approach, together with our novel trial design, to expand the impact and broaden the reach to patients with various lymphoma subtypes in key geographies around the world."

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 latent viral genes which are epigenetically silenced in EBV-associated malignancies. The nanatinostat and valganciclovir combination is being investigated in multiple subtypes of R/R EBV⁺ lymphoma in two ongoing Phase 2 trials, including a registration-enabling global, multicenter, open-label basket trial.

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 lymphoma. Viracta is also pursuing application of its inducible synthetic lethality approach in other EBV-associated malignancies, such as nasopharyngeal carcinoma, gastric carcinoma, and other virus-related cancers.

For additional information please visit <u>www.viracta.com</u>.

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 initiation, details and timeline for the NAVAL-1 trial and related expectations; the ability of Viracta to support multiple new drug application filings from the NAVAL-1 trial; Viracta's ability to expand the impact and broaden the reach of its therapeutic approach; 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 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 <u>www.sec.gov</u>.

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:

Company Contact:

Joyce Allaire LifeSci Advisors jallaire@lifesciadvisors.com (212) 915-2569 Dan Chevallard Chief Operating Officer and Chief Financial Officer <u>dchevallard@viracta.com</u> (858) 771-4193

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