Viracta Therapeutics Announces Orphan Drug Designation Granted for the Treatment of T-cell Lymphoma

PR Newswire, San Diego, June 24, 2020 - Viracta Therapeutics, Inc., a precision oncology company targeting virus-associated malignancies, today announced that its Phase 2 all-oral combination product of nanatinostat and valganciclovir has been granted orphan drug designation from the U.S. Food and Drug Administration (FDA) for the treatment of T-cell lymphoma. Viracta's combination product candidate previously received orphan drug designations for the treatment of post-transplant lymphoproliferative disorder, plasmablastic lymphoma and angioimmunoblastic T-cell lymphoma.

"We are very pleased that the FDA has granted this additional orphan drug designation for our oral therapy for the treatment of all T-cell lymphomas," said Ivor Royston, MD, President and Chief Executive Officer of Viracta. "Importantly, we believe it highlights the broad applicability of our biomarker-driven treatment approach and substantiates the Phase 1b data previously reported at the 2019 American Society of Hematology Annual Meeting, which showed encouraging preliminary efficacy across Epstein-Barr virus (EBV)-associated lymphomas, including subtypes of T-cell lymphoma."

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 (independent from intellectual property protection) upon regulatory approval for the disease or condition for which the drug has the orphan drug designation.

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 in EBV-associated malignancies. The nanatinostat and valganciclovir combination is being investigated in EBV-associated lymphomas in an ongoing Phase 2 clinical trial [NCT03397706].

Viracta has received Fast Track designation from the FDA for the nanatinostat and valganciclovir combination in relapsed/refractory EBV-positive lymphomas, as well as orphan drug designations for the treatment of post-transplant lymphoproliferative disorder, plasmablastic lymphoma, and T-cell lymphomas, including angioimmunoblastic T-cell lymphoma and extranodal NK/T-cell lymphoma.

About EBV-Associated Cancers

Approximately 95% of the world's adult population is infected with EBV. Infections are commonly asymptomatic. Following infection, the virus remains latent in a small subset of lymphatic cells for the duration of the patient's life. Under certain circumstances, such cells may undergo malignant transformation and become lymphoma. In addition to lymphomas, EBV is 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. The company's proprietary investigational drug, nanatinostat, is currently being evaluated in combination with the antiviral agent valganciclovir as an oral combination therapy in a Phase 2 clinical trial for EBV-positive lymphomas. Viracta is pursuing application of this Kick and Kill platform approach in other EBV-associated malignancies, such as nasopharyngeal carcinoma and gastric carcinoma, and other viral-related cancers.

For additional information please visit www.viracta.com.

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