

Viracta Receives Fast Track Designation for Nanatinostat Combination for the Treatment of EBV-Associated Lymphomas

SAN DIEGO, Nov. 12, 2019 [PRNewswire](#)/ - Viracta Therapeutics, Inc. (the "Company"), a precision oncology company targeting virus-associated malignancies, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for nanatinostat in combination with valganciclovir for the treatment of relapsed/refractory Epstein-Barr virus (EBV)-positive lymphoid malignancies. Fast Track is one of the expedited programs offered by the FDA to facilitate and expedite development and review of new drugs to address unmet medical need in the treatment of a serious or life-threatening condition. Fast track designation is intended to facilitate development and expedite review of drugs to treat serious and life-threatening conditions so that an approved product can reach the market expeditiously.

The Company previously announced [interim data](#) from the Phase 1b portion of an ongoing Phase 1b/2a clinical trial of nanatinostat in combination with the antiviral valganciclovir in patients with relapsed/refractory EBV-associated lymphomas. These data were provided to the FDA in support of the Fast Track Designation request. Updated clinical data will be presented during an oral session at the American Society of Hematology (ASH) meeting in Orlando, Florida on December 8, 2019.

"We are thrilled to receive Fast Track designation for our lead program and look forward to working closely with the FDA to bring this novel treatment option to patients," said Ivor Royston, MD, President and Chief Executive Officer of Viracta. "We believe our approach to EBV-associated lymphomas represents a novel treatment option for patients where the presence of EBV has not historically been actionable. We look forward to advancing our lead program toward registration studies in 2020 and expanding our clinical pipeline into additional EBV-positive malignancies."

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 1 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 [\[NCT03397706\]](#).

About EBV-Associated Cancers

Approximately 95% of the world's adult population is infected with Epstein-Barr virus (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 valganciclovir as an oral combination therapy in a Phase 2 clinical trial for Epstein-Barr virus-associated lymphomas. Viracta is pursuing application of this *Kick and Kill* treatment approach in other EBV-associated malignancies, such as nasopharyngeal carcinoma, and other viral-related cancers.

For additional information please visit www.viracta.com.

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