

Viracta Receives Orphan Drug Designation from the US FDA for its Lead Epigenetic Drug Candidate Nanatinostat for EBV-Associated Cancers

PR Newswire, San Diego, April 16, 2019 – Viracta Therapeutics, Inc. announced today that the U. S. Food & Drug Administration (FDA) has granted Orphan Drug Designations (ODD) to their Phase 2 drug candidate, nanatinostat, in combination with the antiviral valganciclovir, for the treatment of post-transplant lymphoproliferative disorder (PTLD), plasmablastic lymphoma, and angioimmunoblastic T cell lymphoma. The therapeutic approach is being investigated in a Phase 1b/2 clinical trial of Epstein Barr Virus (EBV)-associated lymphomas, including the ODD granted subtypes.

“We are pleased that the FDA has granted Orphan Drug status to nanatinostat, further validating our therapeutic approach and expediting the development of novel treatments for virally-driven cancers. Importantly, the Orphan Drug designation includes both T cell and B cell lymphomas, which highlights our ability to target cancer cells that contain the EBV genome regardless of tumor type,” said Ivor Royston, MD, Viracta’s CEO. “We look forward to advancing nanatinostat towards registration trials in the U.S. and additional geographies and exploring the potential to treat additional EBV-associated indications.”

The nanatinostat plus valganciclovir combination therapy follows Viracta’s proprietary *Kick & Kill* therapeutic approach, which is being investigated in an ongoing Phase 1b/2 clinical study at clinical sites in the U.S. and Brazil. Nanatinostat (the *Kick*) is designed to activate EBV genes that have been epigenetically suppressed. In combination with valganciclovir (the *Kill*), cancer cells that harbor the virus will be selectively killed. Viracta’s unique treatment approach holds potential to become the first targeted, orally administered epigenetic therapy for EBV-associated cancers.

Drugs that receive ODD by the FDA, such as nanatinostat, obtain seven years of marketing exclusivity, tax credits for clinical trial costs, marketing application filing fee waivers and assistance from the FDA in the drug development process.

About Nanatinostat

Nanatinostat (VRx-3996) is an oral histone deacetylase (HDAC) inhibitor that is being investigated in a range of clinical indications. Nanatinostat is selective for Class 1 HDACs, including isoforms targeted in Viracta’s *Kick & Kill* therapeutic approach. Viracta is investigating nanatinostat in a Phase 1b/2 clinical study in combination with an antiviral valganciclovir for the treatment of EBV-associated cancers.

About EBV-Associated Cancers

Approximately 95% of the world’s adult population is infected with Epstein-Barr Virus (EBV). Infections are commonly asymptomatic or associated with mononucleosis. Following infection, the virus remains latent in a small subset of lymphatic cells for the duration of the patients’ life. Cells containing latent virus are increasingly susceptible to malignant transformation. Patients who are immunocompromised are at an increased risk of developing EBV lymphomas. In addition, EBV is also associated with a variety of solid tumors, including nasopharyngeal carcinoma and gastric cancer.

About The *Kick & Kill* Platform

Viracta’s *Kick & Kill* therapeutic platform is designed to create a pipeline of novel therapies to treat viral-associated cancers and other serious diseases. The “*Kick*” activates genes that have been epigenetically suppressed by a virus or cancer. The “*Kill*” activates a therapeutic that will selectively and directly kill virus-harboring cells or activate suppressed immune response genes. The approach holds the potential for development in combination with other immunotherapies.

About Viracta Therapeutics, Inc.

Viracta is a clinical-stage drug development company focused on advancing novel epigenetic therapeutics derived from its proprietary *Kick & Kill* therapeutic approach to benefit patients with viral-associated cancers and other serious diseases. Viracta has entered into partnerships with Shenzhen Salubris Pharmaceutical Co., Ltd. to bring treatments for EBV-associated cancers to China, and with NantKwest, Inc. to utilize nanatinostat in combination with their clinical-stage Natural Killer (NK) cell immunotherapy. Viracta plans to enter into additional geographic and combination therapy partnerships.

For additional information please visit www.viracta.com.

Investor and Media Contact:

Amy Conrad
Juniper Point
amy@juniper-point.com
858-366-3243

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