Viracta Announces Positive Phase 1b/2 Data Presented at Oral Presentation on Lead Program for Epstein-Barr Virus (EBV)-associated Relapsed/Refractory Lymphomas at the 2019 American Society of Hematology (ASH) Annual Meeting

Phase 1b Overall Objective Response Rate (ORR) of 56% Including 28% Complete Response (CR)

PR Newswire, San Diego, December 8, 2019 - Viracta Therapeutics, Inc. (the "Company"), a precision oncology company targeting virus-associated malignancies, announced today that its lead investigator, Dr. Pierluigi Porcu of the Sidney Kimmel Cancer Center, Thomas Jefferson University, presented new clinical data from the Company's Phase 1b/2a clinical trial of the orally administered combination of nanatinostat (Nstat) in combination with the antiviral valganciclovir for the treatment of EBV-associated relapsed/refractory lymphomas. The data were presented during an oral presentation at the ASH Annual Meeting in Orlando, Florida.

The Phase 1b/2a clinical study [NCT03397706] evaluated the combination across three cohorts. Responses were observed across all doses, and in multiple subtypes of lymphomas, including B-cell, T-cell, NK/T-cell and Hodgkin Lymphoma. The recommended Phase 2 dose of the combination was determined, which enabled the Company to proceed with the Phase 2a dose expansion portion of the study. The overall response rate (ORR) in the Phase 1b portion of the study was 56% (10/18), with 28% (5/18) complete response (CR) and a clinical benefit rate (CBR), the sum of ORR plus stable disease rate, of 78% (14/18), with a median duration of treatment for responders of 6.5 months. Two responders remained on treatment for over 12 months, including one patient who remains in complete response at 17 months, following 12.7 months on treatment. In HIV-negative patients, the ORR was 67% (10/15), with a 33% (5/15) CR and a CBR of 93% (14/15).

The combination regimen was well-tolerated, and the most common serious adverse events were hematologic and resolved without sequalae or bleeding events. Notably, no patients discontinued therapy due to a treatment-related adverse event. In the safety data set, the most frequent treatment related grade 3-4 adverse events prior to establishing a recommended Phase 2 dose (RP2D) were thrombocytopenia 25%, neutropenia 20%, and anemia 10%. All patients dosed at the RP2D including additional Phase 2a patients, had an improved hematologic Grade 3-4 safety profile, with low rates of neutropenia (8%) and anemia (8%) and no thrombocytopenia.

"There is a clear unmet medical need for effective and well-tolerated treatment options for EBV-positive lymphomas, and EBV positivity is very often correlated with poor prognosis. The overall objective response rate, complete response rate, and clinical benefit rate observed for heavily pretreated relapsed/refractory EBV-positive lymphoma patients in this dose ranging Phase 1b study are very encouraging, and represent the first reported evidence of substantial clinical efficacy for an EBV-targeting drug combination in EBV-positive lymphomas," said Pierluigi Porcu, MD, Director, Division of Hematologic Malignancies and Hematopoietic Stem Cell Transplantation, and Professor of Medical Oncology, Dermatology, and Cutaneous Biology, at the Sidney Kimmel Cancer Center – Jefferson Health (SKCC). "The Phase 1b portion of the study also established a recommended Phase 2 dose and schedule, which is associated with a very low rate of Grade 3/4 adverse events. Preliminary results from the ongoing Phase 2 dose expansion appear to be consistent with those observed in the intermittent dose cohort of the Phase 1b study."

"These data underscore the potential for Nstat and valganciclovir as a novel therapeutic approach for the treatment of relapsed/refractory EBV-positive lymphomas. Moreover, while a biomarker diagnostic test for EBV already exists, it has not been routinely used, given the absence of an effective targeted therapy for EBV-positive lymphomas. Our goal is that our therapy will lead to increased screening of relapsed/refractory lymphomas for the presence of EBV," said Ivor Royston, MD, President and Chief Executive Officer of Viracta. "We expect to complete the Phase 2 portion of the Phase 1b/2 study in the first half of 2020, initiate a registration study in the second half of the year, and expand our treatment approach into EBV-positive solid tumor indications."

Details of the ASH presentation are as follows:

- Title: Combination of Oral Nanatinostat (Nstat), a Novel Histone Deacetylase Inhibitor (HDACi), and the Oral Anti-Viral, Valganciclovir (VGCV), Is Active in Relapsed/Refractory (R/R) Epstein-Barr Virus (EBV)-Positive B-Cell, T-Cell, and Hodgkin Lymphoma: Interim Safety and Efficacy Results from a Phase 1b/2a Study (Abstract # 465)
- Presenter: Pierluigi Porcu, MD, Thomas Jefferson University
- Session: Hodgkin Lymphoma and T/NK Cell Lymphoma – Clinical Studies: Novel Therapies in Peripheral T-cell Lymphomas
- Date/Time: Sunday, December 8, 2019, 12:30 PM

- Location: Orange County Convention Center, Orlando, FL, Valencia D (W415D)

The presentation from the 2019 ASH Annual Meeting can be accessed by visiting the “News/Media” section of the Viracta website: http://www.viracta.com/news.html

Viracta has received Fast Track designation from the FDA for its proprietary investigational drug, nanatinostat, in combination with valganciclovir, in relapsed/refractory lymphomas, as well as Orphan Drug Designation for the treatment of post-transplant lymphoproliferative disorder, plasmablastic lymphoma, and angioimmunoblastic T-cell lymphoma.

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 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 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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