

## Viracta Therapeutics Announces FDA Clearance of IND Application for Phase 1b/2 Trial in Epstein-Barr Virus-Positive (EBV+) Solid Tumors

**Third combination trial with nanatinostat and valganciclovir broadens scope beyond EBV+ lymphoproliferative disorders**  
**Trial initiation expected in H2 2021**

SAN DIEGO, July 21, 2021 /PRNewswire/ -- [Viracta](#) Therapeutics, Inc. (Nasdaq: VIRX), a precision oncology company targeting virus-associated malignancies, today announced that the U.S. Food and Drug Administration (FDA) has cleared Viracta's Investigational New Drug (IND) application to proceed into a Phase 1b/2 trial in patients with EBV<sup>+</sup> recurrent or metastatic nasopharyngeal carcinoma (RM-NPC) and other EBV<sup>+</sup> solid tumors. The global Phase 1b/2 trial is designed to evaluate the safety and preliminary efficacy of Viracta's all-oral combination regimen in advanced EBV<sup>+</sup> solid tumors (including EBV<sup>+</sup> RM-NPC), and in combination with the PD-1 inhibitor pembrolizumab in EBV<sup>+</sup> RM-NPC. Initiation of the trial is expected in the second half of 2021.

"Clearance of this IND application is a crucial milestone that underscores the broader applicability of our therapeutic approach to treating patients with EBV-associated malignancies," said Lisa Rojkjaer, M.D., Chief Medical Officer of Viracta. "EBV is the primary etiologic agent for NPC, one of the most commonly reported head and neck cancers worldwide. Patients with RM-NPC have a poor prognosis, with no standard treatment options for second or later lines of therapy, and median overall survival of less than 20 months. PD-L1 is known to be highly expressed by NPC and preliminary response rates of 20%-30% have been reported with PD-1 inhibitors for RM-NPC. Given the encouraging activity seen in our Phase 1b/2 trial of nanatinostat and valganciclovir in patients with EBV<sup>+</sup> recurrent lymphomas, we now turn to evaluating this combination in patients with other EBV<sup>+</sup> malignancies and explore potential synergies with checkpoint inhibition."

Ivor Royston, M.D., President and Chief Executive Officer of Viracta, added, "Expansion into our solid tumor program is an important component of our clinical and corporate strategy, and one that could significantly expand our addressable patient population and unlock significant value to shareholders. Our all-oral combination regimen represents a promising new therapeutic approach to patients with EBV<sup>+</sup> solid tumors, and I'm very pleased that the program is progressing as planned and look forward to its continued advancement."

The Phase 1b dose escalation portion of the trial is designed to evaluate safety, pharmacokinetics, and determine the recommended Phase 2 dosing regimen of nanatinostat and valganciclovir for expansion in patients with EBV<sup>+</sup> solid tumors. In Phase 2, the safety, preliminary efficacy and potential pharmacodynamic markers of nanatinostat and valganciclovir together and in combination with pembrolizumab will be evaluated in EBV<sup>+</sup> RM-NPC patients.

### 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 viral genes that are epigenetically silenced in EBV-associated malignancies. The nanatinostat and valganciclovir combination is being investigated in multiple subtypes of relapsed/refractory EBV<sup>+</sup> lymphoma in two ongoing Phase 2 trials, one of which is 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 [www.viracta.com](http://www.viracta.com).

### 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 Phase 1b/2 solid tumor trial and related expectations; Viracta's ability to expand its pipeline and broaden the impact of its therapeutic approach; the potential synergistic interactions between Viracta's product candidate and pembrolizumab; Viracta's ability to increase shareholder value; 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 manufacture or supply nanatinostat, valganciclovir and pembrolizumab for clinical testing; 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 [www.sec.gov](http://www.sec.gov).

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.

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