Volastra Therapeutics Announces First Patient Dosed in Phase I/II Clinical Trial of VLS-1488, One in a Portfolio of Novel and Differentiated KIF18A Inhibitors

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VLS-1488 is a potent oral KIF18A inhibitor with the potential to be the first-ever chromosomal instability-targeted cancer therapy.
Phase Ib trial for sovilnesib, Volastra's second KIF18A inhibitor, is anticipated to open in Q1 2024.

NEW YORK, October 30, 2023– Volastra Therapeutics, a discovery and clinical-stage cancer biotechnology company, today announced the dosing of the first patient in a Phase I/II clinical trial evaluating VLS-1488. VLS-1488 and sovilnesib (formally AMG650) make up Volastra's innovative clinical portfolio of differentiated KIF18A inhibitors specifically designed for the treatment of solid tumors characterized by high levels of chromosomal instability (CIN).

The Phase I/II trial (NCT05902988) evaluates safety, tolerability and preliminary efficacy of VLS-1488 in patients with advanced tumors. The trial is a significant milestone in Volastra's mission to help patients with these hard-to-treat cancers.

"In 2019, our team set out to understand the biology of chromosomal instability and discover new treatment approaches," said Charles Hugh-Jones M.D., FRCP, CEO at Volastra. "The ground-breaking work leading to this study has the potential to define the first-ever CIN-directed therapy."

KIF18A is a protein required by many tumor cells to divide and grow efficiently. It is not required by normal healthy cells to divide, allowing the selective killing of cancer cells. Volastra will deploy multiple exploratory biomarkers that measure CIN, including AI-based tissue imaging developed in partnership with Microsoft.

Dr. Pat LoRusso, D.O., Director of the Phase I Clinical Trial Unit at Yale commented, "Targeting chromosomal instability is a major opportunity for cancer therapy. Inhibiting KIF18A shows impressive data in pre-clinical models with high levels of CIN. We look forward to contributing to the clinical trial of this promising molecule."

Dr. Alexander Starodub, M.D., Ph.D., at The Christ Hospital Cancer Center in Cincinnati, Ohio dosed the first patient in this Phase 1 trial.

About Volastra Therapeutics, Inc.
Volastra Therapeutics is a New York-based clinical-stage biotechnology company pioneering novel

approaches to treating cancer by targeting a tumor vulnerability known as chromosomal instability. The company was founded in 2019 by Lewis Cantley, Ph.D., Samuel Bakhoum, M.D., Ph.D., and Olivier Elemento, Ph.D., and is funded by Polaris Partners, Arch Ventures, Droia Ventures, Vida Ventures, Catalio Capital Management, and Eli Lilly & Company. Volastra is developing new techniques to understand the biology of chromosomal instability and leveraging these insights to drive a pipeline of therapies towards innovative targets. The company leads the field with two differentiated clinical-stage KIF18A inhibitors, VLS-1488 and sovilnesib (AMG-650). A robust discovery pipeline targeting both synthetic lethal and immune activation approaches to chromosomal instability, progresses internally and in collaboration with Bristol Myers Squibb. A transformational imaging partnership with Microsoft supports AI-driven target discovery and identification of novel biomarkers to inform patient selection.

For more information, please visit www.volastratx.com.

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