

News Release

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Vividion Therapeutics Doses First Patient in Phase I Study of RAS-PI3K α Inhibitor for Treatment of Advanced Solid Tumors

- VVD-159642, Vividion's fourth clinical-stage program stemming from its chemoproteomics discovery platform, is designed to improve patient outcomes by inhibiting RAS-PI3K α , a key signaling pathway implicated in solid tumor development and progression
 - Preclinical data support clinical trials with a broad patient population, and may deliver increased efficacy in combination with other RAS/MAPK pathway inhibitors
 - Approximately 20 percent of all cancers are driven by mutations of the RAS family of genes¹
 - Vividion continues to advance the chemoproteomics technology platform with goal to unlock disease-causing, yet traditionally undruggable targets with precision small-molecule therapeutics
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San Diego, CA, USA, Berlin, Germany, April 3, 2025 – Vividion Therapeutics, Inc. (Vividion) today announced that the first patient has been dosed in a Phase I clinical trial evaluating VVD-159642, an investigational oral inhibitor designed to target RAS-driven cancers. Vividion is a clinical-stage biopharmaceutical company, and a wholly owned and independently operated subsidiary of Bayer AG, utilizing innovative discovery technologies to unlock targets with strong disease-link, yet traditionally undruggable and develop small molecule precision therapeutics for devastating cancers and immune disorders.

The new Phase I study ([NCT06804824](https://clinicaltrials.gov/ct2/show/study/NCT06804824)) will evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary anti-tumor activity of VVD-159642 as a single agent and in combination with either sotorasib or trametinib in patients with advanced solid tumors.

“Despite being a major driver in approximately 20% of cancers, the RAS gene has proven exceptionally difficult to target with drugs, largely due to its essential role in the RAS-PI3K α signaling pathway, which is vital for healthy cell function,” said Jenna Goldberg, M.D., Chief Medical Officer of Vividion. “VVD-159642 is designed and being studied to selectively prevent RAS activation of the PI3K α pathway, thus blocking oncogenic signaling without disrupting normal cellular function. Preclinical studies of VVD-159642 give us confidence in its potential to inhibit tumor growth while avoiding the on-target toxicities that have limited prior attempts to drug this important target. In addition to providing a more tolerable alternative to current therapies, we believe that VVD-159642 has potential to treat a broad patient population, including in both RAS-mutant and HER2-overexpressed tumors, and may deliver increased efficacy in combination with other RAS/MAPK pathway inhibitors.”

“We’re excited to bring our fourth innovative oncology asset into the clinic, which not only represents continued validation of Vividion’s covalent-first chemoproteomics platform but also provides a potential new treatment option for patients with RAS-driven cancers,” said Aleksandra Rizo M.D., Ph.D., Chief Executive Officer of Vividion.

“The team at Vividion is rapidly advancing scientific innovations into clinical development that have the potential to address multiple devastating diseases not reachable by current therapies,” said Christian Rommel, Ph.D., Head of Research and Development at Bayer’s Pharmaceuticals Division. “The initiation of this clinical trial marks a significant step forward in leveraging Vividion’s innovative drug discovery approach to target a highly relevant signaling pathway and bring a potential new treatment option to people suffering from difficult-to-treat cancers.”

Vividion also has ongoing Phase I trials evaluating an oral KEAP1 activator in solid tumors and oral STAT3 inhibitor in solid and hematologic malignancies. The company is advancing multiple innovative drug discovery programs toward the clinic and has a rich pipeline of opportunities emerging in early discovery in the fields of oncology and immunology.

About Vividion

Vividion Therapeutics, Inc., a wholly owned and independently operated subsidiary of Bayer AG, is a clinical stage biopharmaceutical company utilizing novel discovery technologies to unlock high value, traditionally undruggable targets with precision

therapeutics for devastating cancers and immune disorders. The company's platform has enabled it to identify hundreds of previously unknown functional pockets on well-validated protein targets implicated in a wide range of diseases, while simultaneously identifying compounds from its proprietary covalent chemistry library that interact in a highly selective manner with those pockets. The company is leveraging its proprietary chemoproteomic platform to advance a diversified pipeline of highly selective small molecule therapeutics targeting high value, traditionally undruggable targets in oncology and immunology. For more information, please visit www.vividion.com.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. In line with its mission, "Health for all, Hunger for none," the company's products and services are designed to help people and the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2024, the Group employed around 93,000 people and had sales of 46.6 billion euros. R&D expenses amounted to 6.2 billion euros. For more information, go to www.bayer.com.

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Reference:

1. Ian A. Prior et al "The Frequency of RAS Mutations in Cancer". Cancer Res (2020) 80 (14): 2969–2974. Available at: <https://aacrjournals.org/cancerres/article/80/14/2969/640657>. Accessed: March 2025.