

News Release

Not intended for U.S. and UK Media

In the field of precision oncology:

Bayer and Vividion Therapeutics to highlight advancing oncology portfolio at AACR 2025 Annual Meeting

- In “New Drugs on the Horizon” session, Bayer will present preclinical data and results from clinical imaging on its investigational targeted alpha radiopharmaceutical being developed to treat tumors expressing Glypican-3 (GPC3) in patients with advanced hepatocellular carcinoma (HCC)
 - Preclinical data to be presented on the HER2/mEGFR inhibitor sevabertinib (BAY 2927088), an investigational agent developed for patients with non-small cell lung cancer (NSCLC) and other solid tumors with HER2 activating mutations
 - Preclinical data to be presented on investigational SOS1 inhibitor targeting KRAS dependent advanced solid tumors, such as NSCLC, pancreatic cancer and colorectal cancer
 - Translational pharmacokinetic-pharmacodynamic (PK/PD) model framework and preclinical data to be presented on selective, allosteric CyclinE1/CDK2 inhibitors, for treatment of CyclinE1 amplified tumors
 - Vividion Therapeutics will present preclinical data of its innovative Kelch-like ECH-associated protein 1 (KEAP1) activator, VVD-037, being developed to inhibit tumor growth and overcome resistance by allosterically promoting NRF2 degradation
 - Presentations reinforce Bayer’s commitment to develop new medicines that help improve and extend the lives of people living with cancer
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Abstracts: ND09; 4348; 4349; 4373; 5610

Berlin, Germany, and Chicago (IL), USA, April 22, 2025 – Bayer and Vividion Therapeutics, Inc. (Vividion) will present the latest research on their advancing oncology

portfolio at the upcoming [American Association for Cancer Research \(AACR\) 2025 Annual Meeting](#), taking place from April 25-30, 2025, in Chicago, USA. Bayer will present preclinical data as well as clinical imaging results from its evolving portfolio of targeted alpha therapy, an emerging class of targeted radionuclide therapy and a focus of Bayer's precision drug development strategy in oncology. In addition, the company will showcase encouraging preclinical and clinical research data on several compounds targeting intracellular tumor signaling pathways responsible for the development and survival of cancer, potentially offering new treatment opportunities in indications of high medical relevance. Vividion, a wholly owned and independently operating subsidiary of Bayer AG, will provide insights into the development and characterization of its highly selective small molecule KEAP1 activator, being evaluated as a new therapeutic means of blocking the oncogenic pathways.

During the "New Drugs on the Horizon" session, Bayer will introduce its **investigational targeted alpha radiopharmaceutical** (BAY 3547926) being developed to treat tumors expressing Glypican-3 (GPC3) in patients with advanced **hepatocellular carcinoma (HCC)**. GPC3 is an oncofetal protein overexpressed in 70-75 percent of HCC lesions which makes it an attractive target for targeted radionuclide therapy.^{1,2} This investigational radiotherapeutic delivers a highly potent alpha-particles to the GPC3-expressing cancer cells, aiming to induce DNA double-strand breaks and reduce cancer cell viability, which may potentially cause anti-tumor activity. The data presented will include preclinical *in vitro* and *in vivo* characterization, along with the results of a clinical imaging study in patients with advanced HCC.

From its focus area Precision Molecular Oncology, Bayer will present latest research on a novel targeted treatment option for patients with advanced **non-small cell lung cancer (NSCLC)** harboring **HER2-activating mutations**. Derived from its strategic research alliance with the Broad Institute of MIT and Harvard, the investigational **HER2/mEGFR inhibitor** sevabertinib (BAY 2927088) is the first oral, reversible small molecule targeting human epidermal growth factor receptor 2 (HER2). The ongoing Phase I/II SOHO-01 study is evaluating its safety and efficacy. Its potential is underscored by Breakthrough Therapy Designations from both the US FDA and Chinese Centre for Drug Evaluation

¹ Kolluri A and Ho M (2019), The Role of Glypican-3 in Regulating Wnt, YAP, and Hedgehog in Liver Cancer. *Front. Oncol.* 9:708. doi: 10.3389/fonc.2019.00708.

² Yongle Wu, Hui Liu, Huiguo Ding, GPC-3 in hepatocellular carcinoma: current perspectives, *Journal of Hepatocellular Carcinoma* 2016:3, 63-67.

(CDE) of the National Medical Products Administration (NMPA). Beyond the SOHO-01 trial, sevabertinib (BAY 2927088) is also being assessed for its potential as a first-line therapy in patients with advanced non-small cell lung cancer (NSCLC), whose tumors have activating HER2 mutations in the Phase III SOHO-02 trial.

Bayer will provide insights into the discovery and characterization of its investigational oral selective **Son of Sevenless Homologue 1 (SOS1)** inhibitor BAY 3498264, which is currently being evaluated in a Phase I clinical trial in patients with **advanced KRAS-mutated tumors**, such as non-small cell lung cancer (NSCLC), pancreatic cancer and colorectal cancer. This innovative clinical candidate with promising therapeutic potential across several tumor types, addresses the unmet medical need of improving efficacy of treatment targeting the mitogen-activated protein kinase (MAPK) signaling pathway which regulates cell proliferation and plays a critical role in tumor growth and carcinogenesis.

Another abstract will present a translational pharmacokinetic-pharmacodynamic (PK/PD) modeling framework of novel, highly selective, next-generation **allosteric cyclin-dependent kinase 2 (CDK2) inhibitors**. The amplification and overexpression of the CDK2 binding partner Cyclin E1 (CCNE1) is a key mechanism in various cancers, and selective CDK2/CCNE1 inhibition potentially offers a promising treatment for patients with CCNE1 overexpressing tumors. The use of state-of-the-art PKPD models is a valuable method for integrating multi-scale data to investigate the causal chain between dose and response. Consequently, the development of a model framework based on preclinical *in vitro* and *in vivo* data is of significant interest for the support of preclinical and clinical phases. Model evaluation and refinements based on clinical data will be key for further use during clinical development.

Vividion will be presenting a poster outlining translational pharmacokinetic / pharmacodynamic (PK/PD) modeling for its innovative covalent small molecule **Kelch-like ECH-associated protein 1 (KEAP1) activator, VVD-037**. KEAP1 is an E3 ligase that degrades NRF2, a master regulatory transcription factor that coordinates antioxidant, detoxification, and cytoprotective gene programs. NRF2 pathway hyper activation promotes malignant tumor growth and resistance to many standard-of-care therapies and is frequently detected in solid cancers such as non-small cell lung cancer, esophageal squamous cell carcinoma, and head and neck squamous cell carcinoma. VVD-037 is being evaluated in a Phase I clinical trial as a single agent and in combination.

Information on the registration as well as the virtual scientific program can be found [here](#). Key presentations on Bayer and Vividion research to be presented at AACR 2025 are listed below.

Oral presentation:

BAY 3547926: Novel targeted radionuclide therapy for hepatocellular carcinoma

- o Abstract ND09, Session: DDT03 – New Drugs on the Horizon: Part 3
- o Monday, April 28, 10:15 AM – 11:45 AM (AM), Room S406 (Vista Ballroom) – McCormick Place South (Level 4), Convention Center

Poster presentations:

A translational pharmacokinetic-pharmacodynamic (PKPD) modeling framework of novel, highly selective, next-generation allosteric cyclin-dependent kinase 2 (CDK2) inhibitors

- o Abstract #4348 / Session: Experimental and Molecular Therapeutics / Pharmacokinetics and Pharmacodynamics of Cancer Therapeutics
- o Tuesday, April 29, 9:00 AM – 12:00 PM (PT), Section 20, Poster #13, Convention Center

Translational pharmacokinetic/pharmacodynamic (PK/PD) modeling for VVD-130037, an innovative covalent small molecule Kelch-like ECH-associated protein 1 (KEAP1) activator

- o Abstract #4349 / Session: Experimental and Molecular Therapeutics / Pharmacokinetics and Pharmacodynamics of Cancer Therapeutics
- o Tuesday, April 29, 9:00 AM - 12:00 PM, Section 20, Poster #14, Convention Center

Discovery and characterization of BAY 3498264: a small molecule inhibitor targeting the RAS-SOS1 interaction

- o Abstract #4373 / Session: Experimental and Molecular Therapeutics / RAS Inhibitors
- o Tuesday, April 29, 9:00 AM – 12:00 PM (PT), Section 21, Poster #8, Convention Center

BAY 2927088: a novel treatment option for patients with NSCLC with HER2 mutations

- o Abstract #5610 / Session: Experimental and Molecular Therapeutics / Kinase and Phosphatase Inhibitors 3
- o Tuesday, April 29, 2:00 PM – 5:00 PM (PT), Section 20, Poster #20, Convention Center

About Oncology at Bayer

Bayer is committed to delivering science for a better life by advancing a portfolio of innovative treatments. The company has the passion and determination to develop new medicines that help improve and extend the lives of people living with cancer. The oncology franchise at Bayer includes several marketed products across diverse indications and multiple compounds in different stages of clinical development. We have a wealth of expertise in areas including Tumor Cell Intrinsic Pathways, Targeted Radionuclide Therapies, and selective Next-Generation Immuno-Oncology. With our portfolio we are advancing cancer treatments from early to metastatic stage, with the goal of extending survival while limiting side effects for the cancer patients we serve.

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.

About Vividion Therapeutics

Vividion Therapeutics, Inc., a wholly owned and independently operated subsidiary of Bayer AG, is a 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.

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Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.