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News Release

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Bayer's Pharma Growth Strategy Progressing Well as Pipeline Advances

- Regulatory filings underway for a third indication for darolutamide in prostate cancer, for finerenone in a common form of heart failure, and acoramidis in transthyretin amyloid cardiomyopathy (ATTR-CM), reinforcing Bayer's leadership in these important therapeutic areas
- Phase III OASIS 4 trial achieves all primary and key secondary endpoints for elinzanetant, an innovative, non-hormonal treatment for vasomotor symptoms associated with menopause or caused by adjuvant endocrine therapy in women with or at high risk of developing hormone receptor positive breast cancer
- Phase III QUANTI program for gadoquatrane, Bayer's investigational MRI contrast agent, successfully met primary and main secondary endpoints, underlining Bayer's leading position in radiology
- Bemdaneprocel, an investigational stem cell-based therapy for Parkinson's disease, advances directly to Phase III clinical development
- First participants randomized in the Phase II REGENERATE-PD study, evaluating gene therapy AB-1005 in patients with moderate-stage Parkinson's disease
- Vividion's precision oncology platform is advancing while further expanding capabilities with the acquisition of Tavros Therapeutics

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San Francisco, CA, USA, January 14, 2025 – On the occasion of the 43rd J.P. Morgan Healthcare Conference in San Francisco, Bayer AG announces further progress in its pharmaceutical growth strategy, with multiple filing submissions underway for key growth drivers darolutamide and finerenone, acoramidis and elinzanetant.

"We are successfully delivering on our ambitious business goals despite significant headwinds. At the same time, the value of our pipeline is growing by accelerating breakthrough innovations," said Stefan Oelrich, Member of the Board of Management,

Bayer AG, and President of Bayer's Pharmaceuticals Division. "Our new operating model is visibly becoming a key enabler to drive growth and efficiency gains."

Topline improved and poised for future growth

Bayer continues to strengthen its leadership position in Prostate Cancer with the anticipated launch of a third indication for darolutamide (marketed under the brand name Nubeqa™) in 2025, which is supported by strong data from the ARANOTE trial. Darolutamide plus ADT now has positive data both with and without chemotherapy (docetaxel) based on two pivotal Phase III studies (ARASENS and ARANOTE) in metastatic hormone-sensitive prostate cancer. Bayer recently submitted an application to the Center of Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) for this third indication for darolutamide, in addition to filings in the EU and the U.S. earlier in 2024. Nubeqa achieved blockbuster status in September 2024 after crossing the threshold of one billion euros in annual sales. Additionally, Nubeqa is now the fastest growing androgen receptor inhibitor in the U.S., with 100,000 patients treated around the world as of the end of 2024.

In Cardiovascular, Bayer also recently submitted a supplemental new drug application (sNDA) to the U.S. Food and Drug Administration (FDA) and to the CDE of China's NMPA for finerenone (Kerendia™) in heart failure, initiating a major step forward in expanding its reach. Further regulatory filings are planned with a potential market launch as early as end of 2025. Filing submissions are supported by data from FINEARTS-HF Phase III trial, where finerenone demonstrated statistically significant cardiovascular benefits in patients with heart failure and a left ventricular ejection fraction of greater than or equal to 40%. The robust data from Kerendia's clinical development program underscore its potential to become an important therapy for both patients with kidney disease and heart failure.

Additionally, in early 2025, EU approval is anticipated for acoramidis, which demonstrated near-complete stabilization (≥90%) of transthyretin (TTR), for the treatment of transthyretin amyloid cardiomyopathy (ATTR-CM). This follows positive Committee for Medicinal Products for Human Use (CHMP) opinion in December 2024.

In the area of Women's Healthcare, elinzanetant marked another significant clinical milestone in early 2025 following three positive Phase III read-outs in 2024 (OASIS 1-3). OASIS 4, the first pivotal international Phase III study evaluating a treatment for

vasomotor symptoms (VMS, also known as hot flashes) caused by adjuvant endocrine therapy in women being treated or at high risk for breast cancer, met all primary and key secondary endpoints with elinzanetant, demonstrating statistically significant reductions in the frequency of moderate to severe VMS compared to placebo. Elinzanetant also reduced the severity of VMS and improved sleep disturbances and quality of life. The detailed results from OASIS 4 are planned to be presented at an upcoming scientific congress. With regulatory submissions under review around the world, Bayer anticipates a potential launch this year, aiming for fast market penetration building on Bayer's strength in women's healthcare. Elinzanetant is the first dual neurokinin-1 and 3 (NK-1 and 3) receptor antagonist with potential to transform the management of menopause, broadening treatment choices, and addressing major unmet needs in women’s health.

In Ophthalmology, Eylea 8mg (aflibercept 8 mg) has the potential to become the new standard of care in the treatment of certain exudative retinal diseases. In the global Phase III QUASAR study evaluating the efficacy and safety of aflibercept 8 mg in patients with macular edema following retinal vein occlusion (RVO), including central, branch, hemi-retinal vein occlusion, the primary endpoint at week 36 was met. Patients receiving aflibercept 8 mg every 8 weeks (after initial monthly doses) achieved non-inferior visual acuity gains compared to those receiving the current standard therapy Eylea 2 mg (aflibercept 2 mg) every four weeks.

In Radiology, Bayer substantially advanced the development of innovative contrast agents for magnetic resonance imaging (MRI), achieving a significant milestone with its Phase III QUANTI clinical development program. The first data from the program show that the investigational gadolinium-based MRI contrast agent gadoquatrane successfully met the primary and main secondary diagnostic efficacy and safety endpoints in patients using a 60% lower gadolinium dose compared to trial comparators. The QUANTI program showcases Bayer's commitment as a leader in radiology, bringing forward innovation in medical imaging.

Pipeline value improved and early lead positions strengthened

Bayer is making significant progress with its cell and gene therapy platform, achieving important clinical trial milestones, especially in the field of Parkinson’s disease.

Bemdaneprocel will directly advance to Phase III clinical development in Parkinson’s disease, based on positive data from the Phase I exPDite trial. Bemdaneprocel is an investigational stem cell-based therapy that surgically implants dopamine-generating nerve cell precursors into the brain. The FDA granted bemdaneprocel Regenerative Medicine Advanced Therapy (RMAT) designation for its innovative potential in treating Parkinson's disease.

AB-1005 is advancing in Phase II, with the randomization of participants in the REGENERATE-PD clinical trial focusing on patients with moderate-stage Parkinson's disease. AB-1005 is an investigational AAV-based gene therapy that delivers the human glial cell line-derived neurotrophic factor (GDNF) transgene to the brain to potentially protect and restore dopamine-generating neurons. AB-1005 has received U.S. FDA Fast Track and UK Medicines and Healthcare products Regulatory Agency (MHRA) Innovation Passport designations, highlighting its potential to address significant unmet medical needs.

As part of its transformation, Bayer has sharpened its focus in R&D to build a highly differentiated pipeline for long-term growth in oncology, cardiology and renal diseases, neurology and rare diseases, and immunology. Through rigorous assessment and prioritization, Bayer Pharmaceuticals is now fully focused on the areas of greatest unmet need and highest value potential.

Targeted investments in R&D and platform companies in recent years are already strengthening Bayer’s early and late pipeline. With Vividion’s acquisition of the precision oncology platform company Tavros Therapeutics, Bayer continues to leverage its chemoproteomics platform technology to unlock traditionally undruggable targets with precision small-molecule therapeutics. It has initiated Phase I trials with oral KEAP1 activator in solid tumors and oral STAT3 inhibitor in solid and hematologic malignancies, and also has IND-enabling programs including a RAS-PIK3CA program for RAS-driven cancers.

Additionally in the field of precision oncology, investigational BAY 2927088, an oral, small molecule, tyrosine kinase inhibitor as a potential new targeted therapy for patients with non-small cell lung cancer (NSCLC) harboring HER2 activating mutations, showed promising results as a second line therapy in the ongoing Phase I/II SOHO-01 study evaluating safety and efficacy. Its potential is underscored by Breakthrough Therapy

Designations from both the FDA and Chinese Centre for Drug Evaluation (CDE). Beyond the SOHO-01 trial, 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 SOHO-02 trial. Further, a Phase I clinical trial with BAY3498264, an investigational oral selective Son of Sevenless Homologue 1 (SOS1) inhibitor, has recently been initiated. The open-label, first-in-human, dose escalation study will evaluate patients with KRAS G12C-mutated metastatic cancer. This innovative approach has the potential to enhance the treatment options available for patients, offering the possibility to reduce or stop tumor progression.

Targeted Radionuclide Therapy (TRT) is a strategic area of focus in Oncology precision drug development at Bayer, building on more than 10 years of real-world experience with Xofigo™ as the first and only targeted alpha therapy for patients with metastatic castration-resistant prostate cancer. Bayer´s evolving TRT portfolio includes new targeting approaches which combine alpha radionuclides such as actinium-225 with different targeting moieties, including antibodies, small molecules or peptide-based molecules. ^{225}Ac-pelgifatamab (BAY 3546828) and ^{225}Ac-PSMA-Trillium (BAY 3563254), two candidates targeting PSMA (prostate specific membrane antigen), are currently in Phase I clinical trials in patients with advanced metastatic castration resistant prostate cancer (mCRPC).

In the field of cardiovascular diseases, Bayer is making progress with its Phase II assets. With BAY3283142, an investigational soluble guanylate cyclase (sGC) activator in patients with chronic kidney disease (CKD), Bayer has entered into a Phase II clinical study. By modulating sGC via a heme-independent pathway, the investigational sGC activator now represents a new class of potential future drugs that could offer an advantage in conditions of high oxidative stress such as in diabetic nephropathy.

With the anti-alpha2 antiplasmin antibody program, Bayer is developing a new modality and mechanism of action-based thrombolytic agent. This antibody specifically blocks the endogenous plasmin inhibitor α2AP leading to the lysis of acute embolic or thrombotic clots without an increase in bleeding. The investigational antibody is currently being evaluated in Phase II in patients with deep vein thrombosis and will potentially be suitable for treatment in indications of high medical relevance.

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 2023, the Group employed around 100,000 people and had sales of 47.6 billion euros. R&D expenses before special items amounted to 5.8 billion euros. For more information, go to www.bayer.com.

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Link to live webcast presentation of Bayer AG at J.P. Morgan’s 43rd Annual Healthcare Conference:
Stefan Oelrich, Member of the Board of Management, Bayer AG, and President of Bayer’s Pharmaceuticals Division will present updates on the company’s pharmaceutical growth strategy and pipeline advancements on Tuesday, January 14, 2025, from 10:30 – 11:10am PST.

Investors, analysts, media professionals and members of the life sciences industry are invited to join the live webcast of the presentation via this link:
https://jpmorgan.metameetings.net/events/healthcare25/sessions/58226-bayer/webcast?gpu_only=true&kiosk=true

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Forward-Looking Statements
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