



Bayer AG
Communications
51368 Leverkusen
Germany
Phone +49 214 30-1
www.bayer.com/en/media

News Release

Not intended for U.S. and UK Media

Bayer Accelerates Pharma Growth on High-Value Portfolio

- Bayer plans to submit asundexian, its investigational once-daily oral Factor XIa inhibitor, for approval to health authorities, following demonstration of superiority in stroke prevention when combined with antiplatelet therapy. Phase III study topline results underscore its blockbuster potential
 - Bayer extends market reach of its high-value cardiology products through regulatory approvals, further accelerating revenue growth: finerenone in heart failure and heart drug acoramidis in transthyretin amyloid cardiomyopathy (ATTR-CM)
 - Accelerated growth of darolutamide drives further market penetration following its third prostate cancer approval
 - Bayer expands its leading position in precision oncology with sevabertinib's FDA approval in previously treated patients and Breakthrough Therapy Designation in the U.S. and China as a first-line treatment for patients with *HER2*-mutant non-small cell lung cancer
 - Elinzanetant approvals represent a big step forward in women's health, launching the company's first hormone-free therapy for moderate to severe vasomotor symptoms associated with menopause, opening a substantial market opportunity
 - Bayer's rapidly maturing cell and gene therapy Parkinson's Disease pipeline is progressing with a pivotal Phase III study underway for bemdaneprocel, an investigational pluripotent stem cell-derived therapy, and a Phase II gene therapy trial with ametefgene parvec (AB-1005) with a first patient randomized in Germany
 - AB-1002, an investigational one-time gene therapy for congestive heart failure, and OpCT-001, an investigational induced pluripotent stem cell (iPSC)-derived cell therapy for the treatment of primary photoreceptor diseases, are advancing through clinical development and have received priority designations from regulatory authorities
 - Strategic expansion of Radiology portfolio through acquisition of diagnostic tracers AT-01 and AT-05 for cardiac amyloidosis, reinforcing the company's ambition in molecular imaging and bolstering its precision cardiology strategy
-

San Francisco, January 13, 2026 – On the occasion of the 44th J.P. Morgan Healthcare Conference in San Francisco, Bayer AG today unveiled the strategic focus for its Pharmaceuticals Division in 2026. Capitalizing on new launch momentum the company will drive significant global regulatory expansions and market penetration across its pharmaceutical portfolio. High-value commercial products and an accelerating modality-rich pipeline across oncology, cardiology, neurology and immunology have firmly cemented the Pharmaceuticals Division's growth for the coming years. Five pivotal approvals in 2025 underscore a landmark year of strategic execution, validating the successful advancement of Bayer's ambitious pharmaceutical growth strategy.

"We are now clearly seeing the success of our strategy. We have fundamentally accelerated Bayer Pharmaceutical's growth runway with multiple high-impact launches across oncology, cardiology, and women's health," said Stefan Oelrich, Member of the Board of Management, Bayer AG, and President of Bayer's Pharmaceuticals Division. "Our strategic focus remains on delivering transformative medicines to patients faster, powered by our cutting-edge R&D expertise, dynamic operating model, partnership-driven innovation, AI-enabled development, and commitment to commercial excellence. Our Pharmaceuticals Division is poised for sustainable growth over the coming years."

Innovating to capture additional market opportunity in cardiovascular and cerebrovascular medicine

Bayer is advancing its global leadership in cardiovascular disease management through world-class science, strategic partnerships, and a high-value pipeline.

Asundexian, an investigational, once-daily, oral Factor XIa inhibitor, has been investigated as a potential treatment for secondary stroke prevention, an area of high unmet need. Strokes are the second leading cause of death globally, with an estimated ~1 in 10 ischemic stroke survivors having another stroke within the first year, and secondary strokes are often more disabling, costly, or fatal than the first stroke. Topline data from the Phase III OCEANIC-STROKE study demonstrated the superiority of asundexian 50 mg by showing a significant reduction in the risk of ischemic stroke without increasing ISTH major bleeding rate compared to placebo in non-cardioembolic stroke or high-risk transient ischemic attack patients receiving antiplatelet therapy. OCEANIC-STROKE is the first successfully completed Phase III study of a Factor XIa inhibitor and these results underscore the blockbuster potential of asundexian in secondary stroke prevention.

Asundexian has been granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) as a potential treatment for stroke prevention in patients after a non-cardioembolic ischemic stroke.

Additionally, Bayer is driving forward its global leadership in cardiovascular and renal disease, leveraging integrated capabilities and robust partnerships to unlock new value streams. Amongst other regulatory authorities, the U.S. FDA and Japan's Ministry of Health, Labour and Welfare (MHLW) have approved finerenone (Kerendia™), a non-steroidal mineralocorticoid receptor antagonist (nsMRA) for patients with heart failure with left ventricular ejection fraction (LVEF) of $\geq 40\%$, based on the positive results from the pivotal Phase III study FINEARTS-HF, further building on its established efficacy in chronic kidney disease (CKD) associated with type 2 diabetes. Applications in HF with LVEF $\geq 40\%$ in additional markets, including the EU and China, are under review. Ongoing dedicated heart failure and chronic kidney disease Phase III programs (MOONRAKER and THUNDERBALL) continue to evaluate Kerendia's potential across a broad spectrum of patients and clinical settings of Cardiovascular-Kidney-Metabolic (CKM) conditions. Late-breaking data from the Phase III study FINE-ONE presented at ASN Kidney Week showed that compared to placebo, finerenone significantly reduced urine albumin-to-creatinine ratio (UACR) in adults with CKD associated with type 1 diabetes who are receiving standard of care.

Furthermore, the European Commission granted marketing authorization for Beyonttra™ (acoramidis) to treat wild-type or variant transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM). Beyonttra slows the amyloidogenic process that results in ATTR-CM.

Beyond current successes, Bayer is actively shaping the future of cardiology with a robust and diversified pipeline, strategically positioned to address critical unmet needs and drive significant long-term value. This includes AB-1002, an investigational single-dose gene therapy in development for congestive heart failure (CHF) developed together with AskBio Inc., a wholly owned subsidiary of Bayer. AB-1002 is progressing well in Phase II. Its Phase I results were published in *Nature Medicine* and it has been granted Pioneering Regenerative Medical Product designation (SAKIGAKE) by Japan's MHLW.

Additionally, Bayer has initiated the Phase II SIRIUS study of BAY-3018250, a first-in-class anti- α -2 antiplasmin (α 2AP) antibody designed to enable targeted thrombolysis

in deep vein thrombosis (DVT), and a Phase I clinical study of BAY-3670549, an investigational, highly selective G-protein-coupled inwardly rectifying potassium channel 4 (GIRK4) inhibitor, with the potential to help control the electrical activity of heart cells in patients with atrial fibrillation. Bayer's commitment to cutting-edge science is further underscored by the company's licensed dilated cardiomyopathy program with Dewpoint Therapeutics. Concurrently, securing exclusive rights in Japan to aficamten from Cytokinetics – a cardiac myosin inhibitor in development for hypertrophic cardiomyopathy – strengthens Bayer's precision cardiology footprint and expands its strategic market access.

Oncology growth engine: Leveraging blockbuster assets and precision pipeline for future leading position

Bayer's oncology portfolio is delivering significant patient benefit and commercial success, with blockbuster Nubeqa™ (darolutamide) continuing its exceptional global uptake, progressing towards a market-leading position. With over 200,000 patients treated worldwide, and a third approval in prostate cancer in both the U.S. and Europe, Nubeqa continues its strong growth trajectory. Total global sales are on the rise in all markets. Third approval in China is anticipated in 2026. Its comprehensive clinical development program is exploring Nubeqa's potential in earlier prostate cancer settings, with two additional Phase III readouts expected in 2027 and 2028. Darolutamide, under the brand name Nubeqa™, is approved in many countries for the treatment of patients with mHSPC in combination with ADT, with or without chemotherapy, and with ADT alone in non-metastatic castration-resistant prostate cancer (nmCRPC) in patients who are at high risk of developing metastatic disease.

Adding to this momentum in oncology, the U.S. FDA granted accelerated approval for Bayer's Hyrnuo™ (sevabertinib) for adult patients with locally advanced or metastatic non-squamous *HER2*-mutant non-small cell lung cancer (NSCLC), who have received prior systemic therapy. Approval followed Breakthrough Therapy Designations from both the U.S. FDA and China's CDE and was based on results from the SOHO-01 study. Bayer received Breakthrough Therapy Designation in the U.S. and China for sevabertinib as a first-line treatment for patients with *HER2*-mutant non-small cell lung cancer. The Breakthrough Therapy Designations are supported by preliminary clinical evidence from cohort F (patients who had not previously received treatment) of the ongoing Phase I/II SOHO-01 study. Sevabertinib addresses unmet needs for a patient population with limited

treatment options. In addition to SOHO-01 the clinical program for sevabertinib includes ongoing trials evaluating its effectiveness as a first-line treatment for *HER2*-mutant NSCLC and in patients with metastatic solid tumors harboring *HER2* activating mutations, excluding advanced NSCLC.

As pioneers in Targeted Radionuclide Therapy (TRT), Bayer established Targeted Alpha Therapies (TATs) as a standard of care for patients with metastatic castration resistant prostate cancer (mCRPC) with bone metastases. The EORTC PEACE III study evaluating radium-223 dichloride (Xofigo™) in combination with enzalutamide met its primary endpoint of improved and demonstrated overall survival (OS). Two additional pivotal trials with radium-223 dichloride are ongoing and will guide decisions regarding future regulatory steps. Radium-223 dichloride has over 12 years of real-world clinical experience and remains the only approved TAT shown to extend OS and delay symptomatic skeletal events in mCRPC. Radium-223 dichloride is approved under the brand name Xofigo™ in over 50 countries for mCRPC patients with symptomatic bone metastases and no known visceral metastatic disease.

Bayer's oncology pipeline is advancing precision-driven therapies, making pivotal progress by targeting challenging tumor types and previously undruggable mechanisms. This includes multiple investigational agents for KRAS-mutant cancers (an internal SOS1 inhibitor, and a partnership with Kumquat for a KRAS G12D inhibitor), next-generation TATs (225Ac-GPC3 for advanced hepatocellular carcinoma), and a PRMT5 inhibitor (from Suzhou Puhe BioPharma) for MTAP-deleted tumors, all of which have entered Phase I. Further strengthening its discovery engine, Bayer secured worldwide rights to the clinical-stage Werner helicase inhibitor (VVD 214) via Vividion, whose R&D capabilities were expanded through new facilities and the acquisition of Tavros Therapeutics. These strategic investments underscore Bayer's commitment to driving groundbreaking innovation and securing long-term growth in oncology.

Menopause management: Advancing care for women with diverse needs

Bayer achieved a big step forward in women's health with the recent regulatory approvals of Lynkuet™ (elinzanetan for the treatment of moderate to severe vasomotor symptoms (VMS) due to menopause (U.S.) and the only hormone-free therapy approved in the EU for both moderate to severe VMS associated with menopause or caused by adjuvant endocrine therapy for breast cancer). These milestones follow consistent positive results

across all four Phase III clinical studies (OASIS 1- 4). Additionally, first results from the exploratory Phase II NIRVANA study in women experiencing sleep disturbances associated with menopause are indicating its broader potential.

Developing a comprehensive cell and gene therapy (CGT) portfolio

Multiple regulatory priority designations granted by authorities in the U.S., Europe and Japan and across Bayer's CGT portfolio reflect the potential of these programs to deliver transformative patient impact. Bemdaneprocel, an investigational cell therapy designed to replace the dopamine producing neurons that are lost in Parkinson's disease, developed with Bayer's wholly owned subsidiary BlueRock Therapeutics, entered pivotal evaluation in a Phase III study. AskBio's ametefgene parvec (AB-1005), an investigational gene therapy, is being assessed in a Phase II study in moderate stage Parkinson's disease. A first participant has been randomized in Germany. In parallel recruitments in the U.S., the U.K. and Poland are still ongoing. In ophthalmology, BlueRock's OpCT-001, an iPSC-derived photoreceptor cell therapy for primary photoreceptor diseases, received U.S. FDA Fast Track designation and is progressing in its Phase I/IIa study.

Radiology: Advancing innovation and expanding into Molecular Imaging

Bayer continues to advance innovation in medical imaging with gadoquatrane, its investigational low-dose magnetic resonance imaging (MRI) contrast designed to reduce the gadolinium dose by up to 60 percent compared to other macrocyclic MRI contrast agents. Building on positive Phase III results, Bayer has submitted marketing authorization applications in key markets worldwide, including the U.S., EU, Japan, and China. Complementing progress in its existing portfolio, Bayer announced the strategic acquisition of two investigational radiotracers – AT-01 (a Positron Emission Tomography or PET tracer in Phase III of clinical development) and AT-05 (a tracer for Single Photon Emission Computed Tomography or SPECT, currently in Phase I) – for the diagnosis of cardiac amyloidosis. This step marks Bayer's entry into diagnostic tracers and underscores its ambition to expand in molecular imaging, aiming to broaden diagnostic options and enhance patient outcomes.

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.

Contact for media inquiries:

Heidi Sylvester, phone +49 173 1069282

Email: heidi.sylvester@bayer.com

Contact for investor inquiries:

Bayer Investor Relations Team, phone +49 214 30-72704

Email: ir@bayer.com

www.bayer.com/de/investoren/ir-team

Find more information at <https://pharma.bayer.com/>

Follow us on Facebook: <http://www.facebook.com/bayer>

syl (2026-0008E)

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.