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News Release

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Bayer Pharmaceuticals advances next generation of blockbuster medicines

- Latest data for elinzanetant clear the path to submission for regulatory approval
- Acquisition of exclusive European commercialization rights for acoramidis strengthens cardiovascular portfolio
- Prostate cancer drug Nubeqa™ (darolutamide) on track to reach blockbuster status in 2024
- Launch of Eylea™ (aflibercept) 8 mg has the potential to establish next standard of care in retinal diseases
- Replenishment of pipeline in full swing with eight Investigational New Drug Applications in 2023
- Four assets expected to transition to Phase II by end of 2024, all with first-in-class potential
- Advancing seven programs in cell therapy and gene therapy through clinical trials, with those in Parkinson's disease and congestive heart failure furthest ahead
- Investment of more than 3.5 billion Euro to date in the build-up of technology platforms for the discovery and development of cell therapies and gene therapies
- New DSO operating model important lever to drive efficiency and productivity thereby accelerating growth and improving long-term returns

Berlin, March 21, 2024 – At its annual Pharma Media Day 2024, Bayer showcased the latest advancements in the transformation of its Pharma business to fuel long-term, sustainable growth as part of its Pharma strategy.

"We have made significant progress in growing our pipeline value, clearly demonstrating that our revised R&D strategy is bearing fruit," said Stefan Oelrich, Member of the Board of Management, Bayer AG and President of Bayer's Pharmaceuticals Division. "At the

same time, we are further expanding our presence in key therapeutic areas, making important progress in realizing the full potential of our current launch assets."

Specifically, the company has strengthened its innovation engine with a clear research focus on four core therapeutic areas (cardiovascular diseases, oncology, immunology and neurology & rare diseases), extended capabilities through collaborations and acquisitions of platform companies, and increased the quality of its pipeline through rigorous portfolio pruning. As a result, the company advanced its pipeline with eight Investigational New Drug (IND) applications in 2023. In addition, four assets are expected to transition to Phase II by the end of this year, all with first-in-class potential.

"We have been working diligently in Research & Development over the past 24 months and are making important progress in rebuilding a healthy pipeline," said Dr. Christian Rommel, Member of the Executive Committee of Bayer's Pharmaceuticals Division and Head of Research and Development. "We will continue to drive this forward with a great sense of urgency, in particular by sustainably generating more innovative Investigational New Drug applications, by increasing the contributions from our platform companies and by mining for attractive new external partnerships or deals."

Earlier in March, the company acquired the European marketing rights for acoramidis, a highly potent and selective small molecule oral transthyretin stabilizer for transthyretin amyloid cardiomyopathy (ATTR CM), a progressive and fatal heart disease. Acoramidis met all clinical endpoints in a phase III clinical trial and is already being reviewed by European regulators for marketing approval.

Latest data for elinzanetant pave the way for submission

By advancing a portfolio of innovative treatments, Bayer is investing in broadening therapeutic options and raising the standard of care for menopausal women. For its late-stage investigational compound elinzanetant, the first dual neurokinin-1,3 (NK-1,3) receptor antagonist in development as an oral, once-daily non-hormonal treatment of moderate to severe vasomotor symptoms associated with menopause, the company reported consistently positive topline data across three Phase III studies. Given these positive results, Bayer will submit data from the studies OASIS 1, 2 and 3 to health authorities with first launches expected in 2025. The company confirms the blockbuster potential for elinzanetant.

“The results from OASIS 1, 2 and 3 for elinzanetant are very encouraging to the many women worldwide suffering from vasomotor symptoms during their menopausal transition, which, along with sleep disturbances, are common symptoms which can strongly impact quality of life,” said Dr. Cecilia Caetano, Head Global Medical Affairs Women’s Health at Bayer. “We are committed to advance science and break the silence by driving education, awareness and broadening treatment choices to support women across all stages of their lives.”

By 2030, the world population of women experiencing menopause is projected to increase to 1.2 billion, with 47 million new women entering this phase each year. Over one-third of menopausal women report severe symptoms, which can last 10 years or more after the last menstrual period, with relevant impact on their quality of life. Yet around 30% of women consulting a healthcare professional due to moderate to severe symptoms were not prescribed any treatment.

Nubeqa set for continued growth

Bayer is making important progress on its journey towards becoming a leading oncology company. Bayer’s key brand in this field is Nubeqa™, which is set for continued growth in prostate cancer and is on track to reach blockbuster status this year – only five years after first indication launch. Nubeqa is the fastest-growing androgen receptor inhibitor in the US, with many more approvals accomplished outside the U.S. The next important data read-out, the ARANOTE study, is expected already this year. Further trial data from ARASTEP and DASL-HiCAP may offer the potential for further label expansions into earlier disease stages, increasing the annual number of patients that could benefit from Nubeqa.

“In addition to the lifecycle activities for our existing oncology portfolio, we have ramped up our precision oncology development capabilities to unlock the next generation of breakthrough therapies and build a strong, sustainable pipeline across the areas of tumor intrinsic pathways, immuno-oncology, and targeted radiotherapies,” said Dominik Ruettinger, M.D., Ph.D., Head of Research and Early Development for Oncology at Bayer. “Addressing high unmet medical needs in cancer care, we are striving to push the boundaries of innovation to provide patients with impactful medicines fitted to their personal needs.”

Next to cardiovascular diseases, cancer remains the leading cause of death worldwide. Despite all progress, the numbers are set to rise. Observations indicate that the patient population with cancer is changing, with more patients being younger at first diagnosis and more patients being diagnosed at an earlier stage of their disease. These patients require both efficacious and “kinder”, better tolerated medicines, as well as therapies that are designed to overcome drug resistance.

Bayer has invested significantly in innovation targeted to these fields, focusing on expanding the pool of druggable targets representing a true cancer vulnerability and accelerating the drug development process. With the acquisition of Vividion and its industry-leading chemoproteomics platform, Bayer has strengthened its pharmaceutical research and pipeline in the field of small molecules and precision therapeutics. Vividion’s innovative technology allows identification of previously unknown binding pockets on undruggable targets to generate novel drug candidates in indications with high unmet medical need. In the last six months, Vividion advanced the first two high-profile cancer programs, a KEAP 1 activator and STAT3 inhibitor, into Phase I development.

In February, the U.S. FDA granted Breakthrough Therapy designation for Bayer’s investigational drug BAY 2927088 for the treatment of adult patients with unresectable or metastatic non-small cell lung cancer (NSCLC) harboring activating HER2 (ERBB2) mutations. The program, which is currently in Phase I/II development, was derived from Bayer’s longstanding research collaboration with the renowned Broad Institute of MIT and Harvard, MA, USA.

On March 20, Bayer AG and Thermo Fisher Scientific Inc. announced a collaboration to co-develop next-generation sequencing-based companion diagnostic assays for Bayer’s growing precision oncology portfolio.

Rapidly advancing cell therapy and gene therapy pipeline

Cell therapies and gene therapies bring new, potentially transformative treatment approaches that could ultimately stop or reverse diseases with a once-in-a-lifetime intervention. Bayer’s continuous investments in the area – from early research through to enabling access through manufacturing capacities and platforms – emphasize the

therapies' significance as a key future growth driver for the company and confirm the commitment to translate their promise into tangible treatments for patients.

Bayer, together with its subsidiaries BlueRock and AskBio, is advancing a competitive preclinical and clinical cell therapy and gene therapy portfolio. The development portfolio comprises seven cell therapy and gene therapy programs in different stages of clinical development and focuses on areas of the highest unmet medical need.

AskBio's gene therapy candidate for the treatment of congestive heart failure (CHF), AB-1002, just recently moved to Phase II to evaluate the efficacy and safety of the one-time administration of AB-1002. CHF affects approximately 26 million people worldwide. Most recently, BlueRock Therapeutics released 18-month data from the stem cell derived investigational therapy bemdaneprocel (BRT-DA01) in patients with Parkinson's disease. These data continued to show positive trends in the ongoing Phase I clinical trial and confirm the plans to initiate a Phase II study in 2024. An additional gene therapy candidate is expected to start Phase II in patients with Parkinson's disease later this year.

"Since 2020, Bayer has invested more than 3.5 billion Euro in the build-up of technology platforms for the discovery and development of cell therapies and gene therapies – two of the fastest growing and competitive fields in modern healthcare," said Dr. Christian Rommel, Member of the Executive Committee of Bayer's Pharmaceuticals Division and Head of Research and Development. "We are excited about the critical progress we are making with our diverse and state-of-the-art therapeutic modality platforms. While these programs are still at an earlier stage, we are confident that we will be able to translate them into meaningful benefit for patients in the future."

Expanding presence in key therapeutic areas

With its portfolio of innovative products, Bayer is expanding its presence in key therapeutic areas such as cardiovascular, oncology, women's health, radiology and ophthalmology.

Following the approval of Eylea™ (aflibercept) 8 mg in key markets such as the European Union, Japan, Canada, and the UK earlier this year, Bayer is confident to continue its market leadership in the retinal disease space and establish Eylea 8 mg as the next standard of care in retinal diseases given its unparalleled clinical profile. As the only drug

with unprecedented treatment intervals of up to 5 months, Eylea 8 mg addresses the high unmet need of patients and ophthalmologists for longer treatment intervals with fewer injections and clinic visits compared to Eylea 2 mg at 8-weekly dosing, thereby also freeing up scarce clinic capacities for better patient care.

Another key growth driver is Kerendia™ / Firialta™ (finerenone), which is approved for the treatment of chronic kidney disease associated with type 2 diabetes in more than 85 countries worldwide. Finerenone has the potential to become the foundational treatment option for even broader groups of patients with kidney disease and/or heart failure. The product is demonstrating continued good launch uptake in chronic kidney disease associated with type 2 diabetes, particularly driven by the US, China and Mexico. With additional data read-outs from the ongoing development program, FINEOVATE, over the next four years, the company confirms the blockbuster potential for Kerendia.

Building on its legacy of innovation in the cardiovascular space, Bayer has the ambition to further transform cardiovascular (CV) care for patients. In this regard, the OCEANIC Phase III trial for asundexian in secondary stroke prevention is progressing rapidly. In addition, Bayer is committed to precision cardiology with the clear goal of addressing the high disease burden in the CV space. One example is the investigational anti-alpha2 antiplasmin antibody, which is currently being evaluated in Phase II in patients with deep vein thrombosis as a treatment option in indications of high medical relevance.

In radiology, Bayer is advancing the Phase III clinical development program QUANTI with gadoquatrane, Bayer's novel investigational macrocyclic gadolinium-based contrast agent (GBCA), ahead of schedule. Compared to standard dosing of established macrocyclic GBCAs, gadoquatrane has the potential to enable a substantially lower gadolinium (Gd) dose for patients undergoing a contrast-enhanced MRI.

New operating model driving efficiency and productivity to accelerate growth

With its new company-wide operating model, called Dynamic Shared Ownership (DSO), the company is becoming more mission-centric and value-focused. Guided by customer needs and empowered for rapid decision-making, small cross-functional teams with expertise from all relevant parts of the value chain drive product and customer excellence.

“The introduction of Dynamic Shared Ownership could not come at a better time for us in Pharma, as it will help us to identify business opportunities earlier and realize them faster while making more efficient use of our resources, thereby ultimately improving our long-term returns,” said Stefan Oelrich, Member of the Board of Management, Bayer AG and President of Bayer’s Pharmaceuticals Division. “This is not only good news for us as a company, but also for the patients we serve as we hope to bring future innovations to life more efficiently and effectively moving forward.”

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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