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News Release

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Bayer initiates Phase II study of investigational GIRK4 inhibitor in patients with atrial fibrillation

- GIRK4 (BAY 3670549) is an investigational highly selective G-protein-coupled inwardly rectifying potassium channel 4 (GIRK4) inhibitor being evaluated as a potential new approach to control the electrical activity of cardiomyocytes in patients with atrial fibrillation (AFib)
 - AFib is the most common type of sustained cardiac arrhythmia (irregular heart rhythm), affecting more than 60 million people worldwide, and a significant risk factor for stroke and heart failure^{1,2,3}
 - Robust data from the Phase I first-in-human, dose-escalation study supports advancing GIRK4 inhibitor to the next phase of development
 - Derived from the strategic research alliance with the Broad Institute of MIT and Harvard, BAY 3670549 further strengthens Bayer's cardiovascular development portfolio
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Berlin, September 9, 2026 – Bayer announced today the initiation of a global Phase II clinical trial ([NCT07625215](#)) evaluating BAY 3670549, an investigational highly selective G-protein-coupled inwardly rectifying potassium channel 4 (GIRK4) inhibitor, which has the potential as a new approach to control the electrical activity of heart cells in patients with atrial fibrillation (AFib). The Phase II single-treatment study in a randomized, double-blind, placebo-controlled, parallel-group, multi-cohort design, will investigate the efficacy, safety and tolerability, as well as pharmacodynamics and pharmacokinetics of BAY 3670549 in adult patients with AFib. BAY 3670549 demonstrated a favorable safety and tolerability profile in healthy participants in the completed first-in-human single-ascending-

¹ Atrial fibrillation: epidemiology, screening and digital health, Linz, Dominik et al., The Lancet Regional Health – Europe, Volume 37, 100786

² American Heart Association, [Why Atrial Fibrillation Matters | American Heart Association](#)

³ Kornej J, Benjamin EJ, Magnani JW, Atrial fibrillation: global burdens and global opportunities, *Heart* 2021;107:516-518.

dose Phase I study, supporting its continued clinical advancement and strengthening Bayer's cardiovascular development portfolio.

"The start of the Phase II marks an important step in our commitment to redefining what may be possible in cardiovascular care, with GIRK4 inhibition carrying the potential to meaningfully advance the treatment of atrial fibrillation, a condition affecting millions of people worldwide," said Dominik Ruettinger, M.D., Ph.D., Head of Research and Early Development at Bayer's Pharmaceuticals Division. "We are advancing this program because patients and physicians need fast-acting and well-tolerated treatment options that can make a real difference."

BAY 3670549, which emerged from Bayer's strategic research alliance with the Broad Institute, is being investigated as a novel approach for rapid cardioversion to normal sinus rhythm. If successful, it could provide a fast-acting and well-tolerated treatment option that may help reduce the burden on both patients and healthcare systems by offering a potential alternative to electrical cardioversion, the current gold standard for AFib, which often requires anesthesia or sedation, external defibrillation and prolonged hospital-based care.

AFib is the most common type of sustained cardiac arrhythmia (irregular heart rhythm), affecting more than 60 million people worldwide, and a significant risk factor for stroke and heart failure.^{4,5,6}

About GIRK4 inhibitor (BAY 3670549)

BAY 3670549 is an investigational highly selective G-protein-coupled inwardly rectifying potassium channel 4 (GIRK4) inhibitor being evaluated as a potential new approach to help control the electrical activity of heart cells in patients with atrial fibrillation (AFib).

GIRK4 channels are specialized proteins that regulate the electrical activity of heart cells by facilitating the flow of potassium ions (K⁺) in response to the neurotransmitter acetylcholine (ACh). This mechanism is particularly crucial during the later phases of the heart's electrical signaling, specifically during the atrial effective refractory period (AERP). Increased activity of these channels shortens the AERP in the atria (the upper chambers

⁴ Atrial fibrillation: epidemiology, screening and digital health, Linz, Dominik et al., The Lancet Regional Health – Europe, Volume 37, 100786

⁵ American Heart Association, [Why Atrial Fibrillation Matters | American Heart Association](#)

⁶ Kornej J, Benjamin EJ, Magnani JW, Atrial fibrillation: global burdens and global opportunities, *Heart* 2021;107:516-518.

of the heart), thereby reducing the recovery time after each heartbeat. This alteration in recovery time can contribute to the onset and persistence of AFib.

About the study ([NCT07625215](#))

A placebo-controlled, parallel-group, double blind, randomized, multi-cohort Phase II study will investigate efficacy, safety, tolerability, pharmacodynamics and pharmacokinetics of BAY 3670549 in adult participants with AFib.

The study will compare BAY 3670549 to a placebo in patients with AFib who need a treatment called electrical cardioversion. Electrical cardioversion is a procedure that helps the heart return to a normal rhythm.

In the Phase I study, BAY 3670549 was proven to be well-tolerated in healthy male and female participants.

About Atrial fibrillation

AFib is one of the most common sustained cardiac rhythm disorders (arrhythmias). It results from rapid, disorganized electrical signals in the upper chambers (atria) of the heart, causing them to quiver and contract quickly and irregularly. As a result, the atria do not empty efficiently, leading to impaired blood flow and an increased risk of blood clot formation. These clots can break loose, travel to the brain, and cause a stroke. In addition, AFib disrupts the coordinated function of the upper and lower chambers of the heart, impairing overall cardiac performance and leading to symptoms such as palpitations, shortness of breath, fatigue, and a reduced quality of life in many patients. The prevalence of AFib continues to increase globally. Projection studies show that the number of people with AFib will rise to 15.9 million in 2050 in America and 17.9 million in 2060 in Europe.⁷ People with AFib are 5 times more likely to suffer a stroke than people without AFib.⁸ AFib-related strokes are also associated with a 50% likelihood of death within one year.⁹

⁷ Atrial fibrillation: epidemiology, screening and digital health, Linz, Dominik et al., The Lancet Regional Health – Europe, Volume 37, 100786

⁸ Singleton MJ, Imtiaz-Ahmad M, Kamel H, O'Neal WT, Judd SE, Howard VJ, Howard G, Soliman EZ, Bhavne PD. Association of atrial fibrillation without cardiovascular comorbidities and stroke risk: from the REGARDS study. Journal of the American Heart Association. 2020 Jun 16;9(12):e016380.

⁹ Alberts M, Chen YW, Lin JH, Kogan E, Twyman K, Milentijevic D. Risks of Stroke and Mortality in Atrial Fibrillation Patients Treated With Rivaroxaban and Warfarin. Stroke. 2020 Feb;51(2):549-555. doi: 10.1161/STROKEAHA.119.025554. Epub 2019 Dec 31. PMID: 31888412; PMCID: PMC7004448.

The current gold standard to treat acute AFib episodes is electric cardioversion (ECV). This is an effective but resource-intensive and logistically challenging procedure, which is normally scheduled in advance and typically requires sedation or even anesthesia to safely deliver an electrical shock to the patient and restore the heart to its normal sinus rhythm.^{10,11} On the other hand, currently available anti-arrhythmic drugs (AADs), which are commonly used for the management of symptomatic AFib, can't be applied to broad patient populations due to a number of contraindications (such as for patients with structural heart disease) and safety risks, including abnormal heart rhythms and sudden death. Additionally, they show limited, short-term efficacy, require close monitoring and bear the risk of serious side effects.^{12,13}

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 2025, the Group employed around 88,000 people and had sales of 45.6 billion euros. R&D expenses amounted to 5.8 billion euros. For more information, go to www.bayer.com.

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¹⁰ Nusair M, Flaker GC, Chockalingam A. Electric cardioversion of atrial fibrillation. *Mo Med*. 2010 Jan-Feb;107(1):59-64. PMID: 20222298; PMCID: PMC6192814.

¹¹ [Why Atrial Fibrillation Matters | American Heart Association](#)

¹² Andrade JG. Ablation or drug therapy for initial atrial fibrillation. *Ann Cardiothorac Surg* 2024;13(1):71-76. doi: 10.21037/acs-2023-afm-0159

¹³ Journal Article, Zimetbaum, Peter, Antiarrhythmic Drug Therapy for Atrial Fibrillation 2012, *Circulation* 381-389, 125, N 2 doi:10.1161/CIRCULATIONAHA.111.019927, <https://www.ahajournals.org/doi/abs/10.1161/CIRCULATIONAHA.111.019927>

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Forward-Looking Statements

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