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News Release

Not intended for UK Media

Bayer starts Phase IIa study for treatment of patients with Alport Syndrome

- BAY 3401016 is an investigational monoclonal antibody with potential to block a protein called Semaphorin 3A (Sema3A), which is thought to be involved in the progression of kidney damage in Alport Syndrome (AS), a rare genetic disorder
- Bayer explores opportunity to address high unmet medical need of patients suffering from AS and advances research efforts through close cooperation with AS patient organizations
- Derived from the strategic research cooperation with Evotec, advancement of BAY 3401016 into ASSESS Phase IIa clinical study is further strengthening Bayer's development portfolio
- The program has received Fast Track Designation and Orphan Drug Designation from the U.S. Food and Drug Administration (FDA)

Berlin, December 4, 2025 – Bayer announced today initiation of a Phase IIa clinical trial with BAY 3401016, an investigational monoclonal antibody with potential to block a protein called Semaphorin 3A (Sema3A), which is thought to be involved in the progression of kidney damage in Alport Syndrome (AS), a rare genetic disorder. The first-in-patient study, ASSESS, is a randomized, double-blind, placebo-controlled, group-comparison trial (NCT07211685), with an extension phase, which will investigate the efficacy and safety of BAY 3401016 in adult participants with Alport Syndrome.

"The initiation of the ASSESS trial represents an important milestone for our investigational BAY 3401016 program," said Andrea Haegebarth, Ph.D., Global Head of Research and Early Development for Cardiovascular, Renal, and Immunology at Bayer's Pharmaceuticals Division. "We are collaborating closely with the patient organization community to gain a deeper understanding of the real challenges faced by people living with Alport Syndrome. We believe BAY 3401016 holds promise as a potential therapeutic

approach, and we look forward to assessing its efficacy and safety profile as we advance this important program in our pipeline."

Alport Syndrome is caused by genetic mutations that affect the type IV collagen found in the kidneys, ears, and eyes. It leads to progressive severe proteinuria, loss of kidney function, and early onset of end-stage renal disease. Diagnosis typically occurs in childhood or adulthood (depending on mutation type) via urine tests, kidney biopsy or genetic testing. Both men and women are affected by Alport Syndrome. Many women may initially have milder symptoms and experience a later onset of disease progression.[1] Currently, there is no specific treatment approved for Alport Syndrome and, despite guideline-recommended therapy, patients still experience progressive decline of kidney function resulting in end-stage kidney disease around their fourth decade of life or even earlier.[2,3] The main goal of the ongoing study is to learn how well BAY 3401016 works in slowing down the loss in kidney function in adults with rapidly progressing AS.

Investigational BAY 3401016 is derived from Bayer's strategic research collaboration with Evotec. The program has received Fast Track Designation and Orphan Drug Designation from the U.S. Food and Drug Administration (FDA).

About Alport Syndrome

Alport Syndrome (AS) is a rare genetic condition that causes kidney disease, hearing loss, and eye abnormalities that occur due to changes in specific genes (COL4A3, COL4A4, and COL4A5) that affect the protein type IV collagen. Type IV collagens are an important component of basement membranes in the kidney, but also other organs, and mutations in these genes result in functional impairment.

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[1] Chavez E, Goncalves S, Rheault MN, Fornoni A. Alport Syndrome. Adv Kidney Dis Health. 2024 May;31(3):170-179. doi: 10.1053/j.akdh.2024.02.004. PMID: 39004457.

[2] Torra R, Lipska-Zietkiewicz B, Acke F, Antignac C, Becker JU, Cornec-Le Gall E, van Eerde AM, Feltgen N, Ferrari R, Gale DP, Gear S, Gross O, Haeberle S, Heidet L, Lennon R, Massella L, Pfau K, Pizarro MDPV, Topaloglu R, Wlodkowski T, Zealey H; ERKNet, ERA Genes&Kidney and ESPN Inherited renal disorders working group. Diagnosis, management and treatment of the Alport syndrome - 2024 guideline on behalf of ERKNet, ERA and ESPN. Nephrol Dial Transplant. 2025 May 30;40(6):1091-1106. doi: 10.1093/ndt/gfae265. PMID: 39673454; PMCID: PMC12209846.

[3] Temme J, Peters F, Lange K, Pirson Y, Heidet L, Torra R, Grunfeld JP, Weber M, Licht C, Müller GA, Gross O. Incidence of renal failure and nephroprotection by RAAS inhibition in heterozygous carriers of X-chromosomal and autosomal recessive Alport mutations. Kidney Int. 2012 Apr;81(8):779-83. doi: 10.1038/ki.2011.452. Epub 2012 Jan 11. PMID: 22237748.

People with AS have a high risk of developing chronic kidney disease (CKD), a condition in which there is progressive loss in kidney function over time resulting in end-stage kidney disease. As a consequence, kidneys have lost their ability to remove waste products from the body properly, leading to the need for kidney replacement therapy, which involves either dialysis or a kidney transplant. A common sign of impaired kidney function is the presence of excess of the protein albumin in the urine that is not usually found with healthy kidneys. This condition is known as albuminuria.[4]

About BAY 3401016

The study drug BAY 3401016 is a monoclonal antibody that blocks a protein called Semaphorin 3A (Sema3A), which is thought to be involved in the progression of kidney damage in Alport Syndrome (AS). By blocking the action of the Sema3A protein, BAY 3401016 may reduce proteinuria and slow down the loss in kidney function due to AS.

About the ASSESS study

The **A**lport **S**yndrome **S**ema3A **E**fficacy & **S**afety **S**tudy (ASSESS) is a Phase IIa clinical trial with an investigational drug (BAY 3401016) for patients with Alport Syndrome. The main goal of the ASSESS study is to learn more about how well BAY 3401016 works in slowing down the progression of kidney damage in patients with Alport Syndrome with increased albuminuria. The study will also evaluate the safety of the BAY 3401016 and record any side effects experienced by participants. Further details of the trial can be found at www.clinicaltrials.gov (NCT07211685).

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.

[4] Chavez E, Goncalves S, Rheault MN, Fornoni A. Alport Syndrome. Adv Kidney Dis Health. 2024 May;31(3):170-179. doi: 10.1053/j.akdh.2024.02.004. PMID: 39004457.

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Forward-Looking Statements
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