RNS Number : 9001Q
AstraZeneca PLC
14 July 2025

This announcement contains inside information

14 July 2025

Baxdrostat met the primary and all secondary endpoints in BaxHTN Phase III trial in patients with uncontrolled or treatment resistant hypertension

Baxdrostat demonstrated a statistically significant and clinically meaningful reduction of systolic blood pressure compared with placebo

Positive high-level results from the BaxHTN Phase III trial showed baxdrostat at two doses (2mg and 1mg) demonstrated a statistically significant and clinically meaningful reduction in mean seated systolic blood pressure (SBP) compared with placebo at 12 weeks. The trial also successfully met all secondary endpoints. Patients with uncontrolled or treatment resistant hypertension received baxdrostat or placebo on top of standard of care. Baxdrostat was generally well tolerated with a favourable safety profile.

There are 1.3 billion people worldwide living with hypertension.[1] When uncontrolled, hypertension can lead to a higher risk of heart attack, stroke, heart failure and kidney disease.[2,3] In the US, approximately 50% of hypertensive patients who are on multiple treatments do not have their blood pressure under control.[4] Growing evidence points to aldosterone dysregulation as one of the key biological drivers of hypertension.[5,6]

Dr. Bryan Williams, Chair of Medicine at University College London, primary investigator, said: “Many people continue to struggle with high blood pressure that is hard to control, even when taking multiple medications. The highly promising BaxHTN Phase III results show that once-daily baxdrostat on top of standard of care can meaningfully lower systolic blood pressure and offer a potential new treatment approach for controlling hypertension, the leading risk factor for cardiovascular disease.”

Sharon Barr, Executive Vice President, BioPharmaceuticals R&D, said: “We are very excited with the BaxHTN Phase III results, which show statistically significant and clinically meaningful reductions in systolic blood pressure. These findings provide compelling evidence of baxdrostat’s potential to address a critical unmet need by targeting aldosterone dysregulation, bringing a novel mechanism to a field that has seen little innovation in over two decades.”

BaxHTN is a Phase III, multicentre, randomised, double-blinded, placebo-controlled, parallel group study to evaluate the safety, tolerability and effect of baxdrostat in patients with uncontrolled hypertension being treated with two different antihypertensive medications and patients with resistant hypertension being treated with three or more different antihypertensive medications, one of which is a diuretic.[7]

The data will be shared with regulatory authorities around the world and presented in a late breaking Hot

Line session at the European Society of Cardiology (ESC) Congress in August 2025.

Baxdrostat is a potential first-in-class, highly selective aldosterone synthase inhibitor (ASI) that targets the hormone driving elevated blood pressure and increased cardiovascular and renal risk. It is currently being investigated in clinical trials as a monotherapy for hypertension[8,9] and primary aldosteronism,[10] and in combination with dapagliflozin for chronic kidney disease and the prevention of heart failure in high-risk hypertensive patients.[11-13]

Notes

Hypertension that is hard to control

Hypertension is a medical condition characterised by consistently high blood pressure levels.[2,3] Over time, this can damage blood vessels and vital organs, increasing the risk of serious health problems.[2,3] Hypertension that is hard to control remains a significant public health challenge.[1] Despite lifestyle changes and the use of multiple medications, a significant majority of people with hypertension do not achieve their blood pressure goals.[1,4] Uncontrolled hypertension persists despite treatment with two or more medications, while resistant hypertension, a more severe form, remains elevated despite treatment with three or more medications.[2,4]

A key contributor of hypertension that is hard to control is aldosterone, a hormone that increases blood

A key contributor of hypertension that is hard to control is aldosterone, a hormone that increases blood pressure by promoting sodium and water retention.[5,6] Elevated aldosterone levels, along with factors like obesity, high salt intake and various genetic and secondary conditions,[14] are strongly linked to poor blood pressure control. If left untreated, the condition significantly increases the risk of heart attack, stroke and kidney decline.[2,3]

BaxHTN trial

The BaxHTN Phase III trial[7] had three components to it that support the following endpoints: The primary endpoint was assessed during a 12-week double-blind, placebo-controlled period. A total of 796 patients were randomised in a 1:1:1 ratio to receive baxdrostat 2mg, 1mg or placebo once daily. The primary efficacy endpoint was the difference in mean change from baseline in seated SBP at Week 12 between participants treated with baxdrostat (2mg or 1mg separately) and participants treated with placebo. Persistence of efficacy was assessed during a randomised withdrawal period from week 24 to week 32. Approximately 300 patients treated with baxdrostat 2mg were re-randomised in a 2:1 ratio to either continue receiving baxdrostat 2mg or placebo for the 8 weeks. SBP at the end of the 8 weeks was compared with placebo and the baxdrostat 2mg dose. Long-term safety is assessed at the end of the 52 weeks compared to a standard of care arm.

Additional secondary endpoints include the effect of baxdrostat versus placebo on seated SBP at Week 12 in the resistant hypertension subpopulation, the effect of baxdrostat versus placebo on seated diastolic blood pressure at Week 12, participants achieving seated SBP less than 130 mmHg at Week 12 and occurrence of adverse events.

Baxdrostat

Baxdrostat is a potential first-in-class, highly selective and potent, oral, small molecule that inhibits aldosterone synthase,[15] an enzyme encoded by the CYP11B2 gene, which is responsible for the synthesis of aldosterone in the adrenal gland.[5] In clinical trials, baxdrostat was observed to significantly lower aldosterone levels without affecting cortisol levels across a wide range of doses.[16,17] Baxdrostat is currently being investigated in clinical trials as a monotherapy for hypertension[7-9] and primary aldosteronism,[10] and in combination with dapagliflozin for chronic kidney disease[11,12] and the prevention of heart failure in hypertensive patients.[13]

AstraZeneca acquired baxdrostat through its purchase of CinCor Pharma, Inc. in February 2023.[18] A contingent value right of 10 per share in cash (0.5 billion) is payable to former CinCor shareholders upon the submission of a new drug application either in the US or Europe.[18]

AstraZeneca in CVRM

Cardiovascular, Renal and Metabolism (CVRM), part of BioPharmaceuticals, forms one of AstraZeneca's main disease areas and is a key growth driver for the Company. By following the science to understand more clearly the underlying links between the heart, kidneys, liver and pancreas, AstraZeneca is investing in a portfolio of medicines for organ protection by slowing or stopping disease progression, and ultimately paving the way towards regenerative therapies. The Company's ambition is to improve and save the lives of millions of people, by better understanding the interconnections between CVRM diseases and targeting the mechanisms that drive them, so we can detect, diagnose and treat people earlier and more effectively.

AstraZeneca

AstraZeneca (LSE/STO/Nasdaq: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialisation of prescription medicines in Oncology, Rare Diseases, and BioPharmaceuticals, including Cardiovascular, Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca's innovative medicines are sold in more than 125 countries and used by millions of patients worldwide. Please visit astrazeneca.com and follow the Company on Social Media @AstraZeneca.

Contacts

For details on how to contact the Investor Relations Team, please click here. For Media contacts, click here.

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