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Baxdrostat met the primary endpoint in Bax24 Phase III trial in patients with resistant hypertension

Baxdrostat demonstrated a statistically significant and highly clinically meaningful reduction in 24-hour ambulatory systolic blood pressure compared with placebo

Positive high-level results from the Bax24 Phase III trial showed baxdrostat demonstrated a statistically significant and highly clinically meaningful reduction in ambulatory 24-hour average systolic blood pressure (SBP) compared with placebo at 12 weeks. Efficacy was observed throughout the 24-hour period, including early morning, when patients with hypertension are at a higher risk of cardiovascular events.[1-3]

Patients with treatment-resistant hypertension (rHTN) received baxdrostat 2mg or placebo on top of standard of care. Baxdrostat was generally well tolerated, with a safety profile consistent with the BaxHTN trial.[4]

There are 1.4 billion people worldwide living with hypertension.[5] In the US, approximately 50% of patients living with hypertension on multiple treatments do not have their blood pressure under control.[6] Consistent 24-hour blood pressure control is an important clinical outcome in patients with hard-to-control hypertension.[7-9] Multiple studies have demonstrated that 24-hour blood pressure is a more powerful predictor of cardiovascular events than a clinic-based measurement.[3,10] When 24-hour average systolic blood pressure rises by 9.5 mmHg, the risk of all-cause mortality increases by 30%.[3]

Dr. Bryan Williams, Chair of Medicine at University College London, primary investigator, said: "The Bax24 results show that a once-daily baxdrostat regimen can deliver highly clinically meaningful reductions in 24-hour systolic blood pressure, including in the morning when patients are at greater risk of heart attack and stroke. These results are groundbreaking and together with the BaxHTN results mean we have the potential to change our treatment approach for the many patients whose hypertension remains uncontrolled despite current therapies."

Sharon Barr, Executive Vice President, BioPharmaceuticals R&D, said: "This second Phase III trial of baxdrostat shows substantial improvement in blood pressure, which reflects its durable half-life of up to 30 hours and highly selective inhibition of aldosterone synthase. Too many patients today have hypertension that remains hard-to-control throughout the day and night, making them especially vulnerable to cardiac events. We are advancing our regulatory filings and rapidly progressing our robust clinical development programme for baxdrostat, as both a mono- and combination-therapy, across additional conditions where aldosterone plays a key role, including primary aldosteronism, chronic kidney disease and heart failure prevention."

The data will be shared with regulatory authorities around the world and presented in a late breaking session at the American Heart Association (AHA) Scientific Sessions in November 2025.

Baxdrostat is designed to lower blood pressure by specifically inhibiting aldosterone, a key hormone that raises blood pressure and increases the risk of heart and kidney problems. Phase I studies show baxdrostat reached peak levels in the blood within 2 to 4 hours and had a half-life of about 26 to 30 hours.[11,12] Baxdrostat is currently being investigated as a monotherapy for hypertension[13-15] and primary aldosteronism,[16] and in combination with dapagliflozin for chronic kidney disease[17,18] and the prevention of heart failure in high-risk patients.[19]

Notes

Hard-to-control hypertension
Hypertension is a medical condition characterised by consistently high blood pressure levels, affecting an estimated 1.4 billion people worldwide.[4,20,21] Over time, this can damage blood vessels and vital organs, increasing the risk of serious health problems such as heart attack, stroke, heart failure and kidney disease.[20,21] An observational study of nearly 60,000 patients studied over a median of 9.7 years showed that a 9.5 mmHg increase in SBP was associated with a 30% increase in risk of all-cause mortality and 41% increase in risk of cardiovascular death.[10]Studies have shown that increased night-time blood pressure is associated with higher cardiovascular risk,[7,10] and patients with hypertension have a higher risk of cardiovascular events like heart attack, stroke and death around the time of their morning blood pressure surge.[1,2]

Hard-to-control (uncontrolled and resistant) hypertension remains a major public health challenge.[22] Despite lifestyle changes and the use of multiple medications, approximately 50% of patients in the US who are being treated for hypertension still do not have their blood pressure under control.[5] Uncontrolled hypertension refers to persistently elevated blood pressure despite the use of two or more medications, while rHTN, a more severe form, remains elevated despite treatment with three or more medications.[5,20]

A key contributor to hard-to-control hypertension is aldosterone, a hormone that raises blood pressure by promoting sodium and water retention.[23,24] Elevated aldosterone levels, along with factors such as obesity, high salt intake, and various genetic or secondary conditions,[25] are strongly associated with poor blood pressure control. When left untreated, hypertension significantly increases the risk of cardiovascular and kidney-related complications.[20,21]

Bax24 trial
The Phase III Bax24 trial[15] is a randomised, double-blind, placebo-controlled, parallel group study to evaluate the safety, tolerability and the effect of 2mg baxdrostat versus placebo, administered once a day (QD) orally, on the reduction of ambulatory SBP in participants with rHTN. A total of 218 patients were randomised in a 1:1 ratio to receive baxdrostat 2mg or placebo once daily during a 12-week double blind period. The primary efficacy endpoint was the change from baseline in ambulatory 24-hour average SBP at Week 12.

Additional secondary endpoints include the effect of baxdrostat versus placebo on change from baseline in ambulatory night-time average SBP at Week 12, change from baseline in ambulatory daytime average SBP at Week 12, change from baseline in seated SBP at Week 12, the number of participants achieving ambulatory 24-hour average SBP of less than 130 mmHg at Week 12 and the number of participants achieving a nocturnal SBP dipping of greater than 10% at Week 12. Occurrence of adverse events was evaluated during the 12-week treatment period as well as during a 2-week safety follow-up period.

Baxdrostat
Baxdrostat is a potential first-in-class, highly selective and potent, oral, small molecule that inhibits aldosterone synthase,[11] an enzyme encoded by the CYP11B2 gene, which is responsible for the synthesis of aldosterone in the adrenal gland.[23] In clinical trials, baxdrostat was observed to significantly lower aldosterone levels without affecting cortisol levels across a wide range of doses.[12,26] Baxdrostat is currently being investigated in clinical trials as a monotherapy for hypertension[13-15] and primary aldosteronism,[16] and in combination with dapagliflozin for chronic kidney disease and hypertension,[17,18] and the prevention of heart failure in patients with hypertension.[19]

AstraZeneca acquired baxdrostat through its purchase of CinCor Pharma, Inc. in February 2023.[27]

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
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Contacts
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