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Baxfendy **(baxdrostat) recommended for approval in the EU for the treatment of adults with hypertension**

Based on Phase III results showing statistically significant and clinically meaningful reductions in systolic blood pressure in patients with uncontrolled or resistant hypertension

Baxfendy 2mg lowered office systolic blood pressure by 15.7 mmHg from baseline in BaxHTN trial and 24-hour ambulatory systolic blood pressure by 16.6 mmHg from baseline in Bax24 trial

If approved, Baxfendy will be the first and only aldosterone synthase inhibitor in the EU

AstraZeneca's *Baxfendy* (baxdrostat) has been recommended for approval in the European Union (EU) for the treatment of adults with arterial hypertension insufficiently controlled with at least two antihypertensive medicinal products. If approved, *Baxfendy* will be the first and only aldosterone synthase inhibitor (ASI) in the EU, directly targeting aldosterone to address a key biological driver of elevated blood pressure.

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) based its positive opinion on results from two pivotal Phase III trials in which *Baxfendy* demonstrated statistically significant and clinically meaningful reductions in seated systolic blood pressure (SBP) in patients with uncontrolled or resistant hypertension, and 24-hour average ambulatory SBP in patients with resistant hypertension.[1,2]

There are 1.4 billion people worldwide living with hypertension.[3] Approximately 50% of people already taking two or more antihypertensive medications struggle with persistently uncontrolled hypertension.[4,5] About 70 million adults across Europe have hypertension that remains uncontrolled despite treatment, putting them at increased risk for cardiovascular disease and premature death.[3,6,7] Hypertension is the most prevalent and significant modifiable cardiovascular risk factor worldwide, accounting for more deaths and disability than any other modifiable risk.[8-10] Elevated aldosterone levels play a central role in persistently uncontrolled hypertension and are associated with a decline in kidney function and increased cardiovascular risk.[11-13]

Dr. Bryan Williams, Chair of Medicine at University College London and primary investigator for BaxHTN and Bax24, said: "The strength of the research behind *Baxfendy* is a triumph of science and demonstrates its potential as an important new class of treatment for people in Europe living with persistently uncontrolled hypertension. Epidemiological data indicate that a 10 mmHg decrease in systolic blood pressure is associated with a roughly 20% lower risk of serious cardiovascular events like heart attack and stroke, underscoring why effective blood pressure lowering matters for people living with uncontrolled hypertension."

Ruud Dobber, Executive Vice President and President, BioPharmaceuticals Business Unit, AstraZeneca, said: "Hypertension is often called the 'silent killer' and is a leading risk factor for heart attack, stroke and dementia. This positive CHMP opinion for *Baxfendy* marks a significant step toward bringing this potential first-in-class innovation to patients in Europe. This novel medicine reflects the strength of our pipeline across interconnected cardiovascular, renal and metabolic diseases as we deliver on our 2030 ambition to bring 20 new medicines to the world."

In the BaxHTN Phase III trial,[14] published in the *New England Journal of Medicine*,[1] *Baxfendy* demonstrated statistically significant and clinically meaningful efficacy for the treatment of patients with hypertension on top of standard of care. At week 12, the absolute reduction from

baseline in mean seated SBP was 15.7 mmHg (95% confidence interval [CI], -17.6 to -13.7) and the placebo-adjusted reduction was 9.8 mmHg (95% CI, -12.6 to -7.0; p<0.001) for the 2mg dose.

In the Bax24 Phase III trial,[15] published in *The Lancet*,[2] *Baxfendy* demonstrated statistically significant, clinically meaningful and consistent blood pressure reductions in patients with resistant hypertension who received baxdrostat 2mg or placebo on top of standard of care. At week 12, the absolute reduction from baseline in ambulatory 24-hour average SBP was 16.6 mmHg (95% CI, -18.8 to -14.3) and the placebo-adjusted reduction was 14.0 mmHg (95% CI, -17.2, -10.8; p<0.0001). Efficacy was observed throughout the 24-hour period, including early morning, when patients with hypertension are at a higher risk of cardiovascular events.[16,17]

Baxfendy was generally well-tolerated in the trials, with no unanticipated safety findings.

Baxfendy is approved in the US and other countries as a first-in-class ASI for adults with hypertension not adequately controlled on other therapies, with regulatory filings currently under review in other major regions, including Japan and China.

Baxfendy is a first-in-class, highly selective and potent ASI designed to lower blood pressure in a new way by specifically inhibiting the production of aldosterone,[18] a hormone that raises blood pressure to unhealthy levels and increases the risk of heart and kidney problems.[11-13]

Notes

Persistently uncontrolled hypertension

Hypertension is a medical condition characterised by consistently high blood pressure levels, affecting an estimated 1.4 billion people worldwide.[3,19,20] 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. [19,20]

Treated but uncontrolled patients with hypertension are at a significantly greater risk of all-cause mortality, heart-disease specific mortality, stroke-related mortality, CVD-specific mortality and dementia than patients whose hypertension is controlled. A large meta-analysis found that lowering systolic blood pressure by 10 mmHg can reduce the risk of major adverse cardiovascular events by around 20%,[21] underscoring the urgent need for new treatments that target a key hypertension pathway at its source.

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.[22] Studies have shown that increased night-time blood pressure is associated with higher cardiovascular risk,[23,24] 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.[16,17] Epidemiological data indicate that a 10 mmHg decrease in SBP is associated with a roughly 20% lower risk of serious cardiovascular events.[21]

Uncontrolled hypertension refers to persistently elevated blood pressure despite the use of two or more medications, while resistant hypertension, a more severe form, remains elevated despite treatment with three or more medications. Guidelines currently recommend that in patients with hypertension, treated BP values should be targeted to 130/80 mmHg or lower in most patients.[19,25]

Aldosterone, a hormone that can raise blood pressure to unhealthy levels by promoting sodium and water retention,[11,12] is a key contributor to persistently uncontrolled hypertension.

Elevated aldosterone levels, along with factors such as obesity, high salt intake and various genetic or secondary conditions,[26] are strongly associated with poor blood pressure control and the progression of heart failure and kidney disease. When left untreated, hypertension significantly increases the risk of cardiovascular and kidney-related complications.[8,19,25]

BaxHTN trial

The BaxHTN Phase III trial[14] had three different evaluation periods that supported 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 *Baxfendy* 2mg, 1mg or placebo once daily on top of standard of care [two antihypertensive agents at baseline, one of which is a diuretic for uncontrolled hypertension and ≥ 3 antihypertensive agents at baseline, one of which is a diuretic for resistant hypertension]. The primary efficacy endpoint was the difference in mean change from baseline in seated SBP at week 12 between participants treated with *Baxfendy* (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 *Baxfendy* 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 between placebo and the *Baxfendy* 2mg dose. Long-term safety was assessed at the end of the study (Week 52 followed by a 2-week safety follow-up visit) compared to a standard-of-care arm and was consistent with that observed during the 12-week double-blind treatment period. In a post-hoc efficacy analysis on the clinically meaningful reductions in seated SBP with *Baxfendy* were sustained over 52 weeks with a placebo-adjusted reduction of 12.6 mmHg (95% CI, -16.7 to -8.5; p<0.001) for the 2 mg dose.[1]

Additional confirmatory secondary endpoints include the effect of *Baxfendy* versus placebo on seated SBP at week 12 in the resistant hypertension subpopulation, the effect of *Baxfendy* versus placebo on seated diastolic blood pressure at week 12, and proportion of participants achieving seated SBP less than 130 mmHg at week 12.

Bax24 trial

The Bax24 Phase III trial[15] was a randomised, double-blind, placebo-controlled, parallel group study to evaluate the effects of 2mg *Baxfendy* versus placebo, administered once a day (QD) orally, on the reduction of ambulatory SBP, as well as safety and tolerability in participants with resistant hypertension. A total of 218 patients were randomised in a 1:1 ratio to receive *Baxfendy* 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.

Consistent 24-hour blood pressure control is an important clinical outcome in patients with persistently uncontrolled hypertension. Multiple studies have demonstrated that 24-hour blood pressure is a more powerful predictor of cardiovascular events than a clinic-based measurement.[22] When 24-hour average systolic blood pressure rises by 9.5 mmHg, the associated risk of all-cause mortality increases by 30%.[22]

Additional secondary endpoints include the effect of baxdrostat versus placebo on change from baseline in ambulatory night-time average SBP, change from baseline in ambulatory daytime average SBP, change from baseline in seated SBP, the number of participants achieving ambulatory 24-hour average SBP of less than 130 mmHg, change from baseline in ambulatory 24-hour average diastolic blood pressure (DBP), change from baseline in ambulatory night-time average DBP, change from baseline in the average ambulatory daytime average DBP, change from baseline on seated DBP and the number of participants achieving

a nocturnal SBP dipping of greater than or equal to 10%, all measured 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.

In a key secondary endpoint, 70.6 percent of patients treated with *Baxfendy* achieved ambulatory 24-hour average SBP of less than 130 mmHg compared to 16.7 percent of patients receiving placebo (Odds ratio 15.2 [95% CI 6.6, 35.2; p<0.0001]),[2] in line with the 2024 ESH guidelines for the management of arterial hypertension.[25] This corresponds to two patients needing treatment (NNT) with *Baxfendy* rather than placebo for one additional patient to achieve this blood pressure threshold at week 12.[27]

Baxfendy and the clinical development programme

Baxfendy is a first-in-class, highly selective and potent, oral, small molecule that inhibits aldosterone synthase,[18] an enzyme encoded by the CYP11B2 gene, which is responsible for the synthesis of aldosterone in the adrenal gland.[12] In clinical trials, *Baxfendy* was observed to significantly lower aldosterone levels without affecting cortisol levels across a wide range of doses.[28,29]

As part of a broad development programme, *Baxfendy* is currently being investigated in clinical trials in other conditions where high aldosterone plays a role in elevating cardiorenal risk, including as a monotherapy for primary aldosteronism,[30] and in combination with dapagliflozin for chronic kidney disease and hypertension,[31,32] and the prevention of heart failure in patients with hypertension.[33]

AstraZeneca acquired *Baxfendy* through its purchase of CinCor Pharma, Inc. in February 2023.[34]

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/NYSE: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialisation of prescription medicines in Oncology, Rare Disease, 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

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