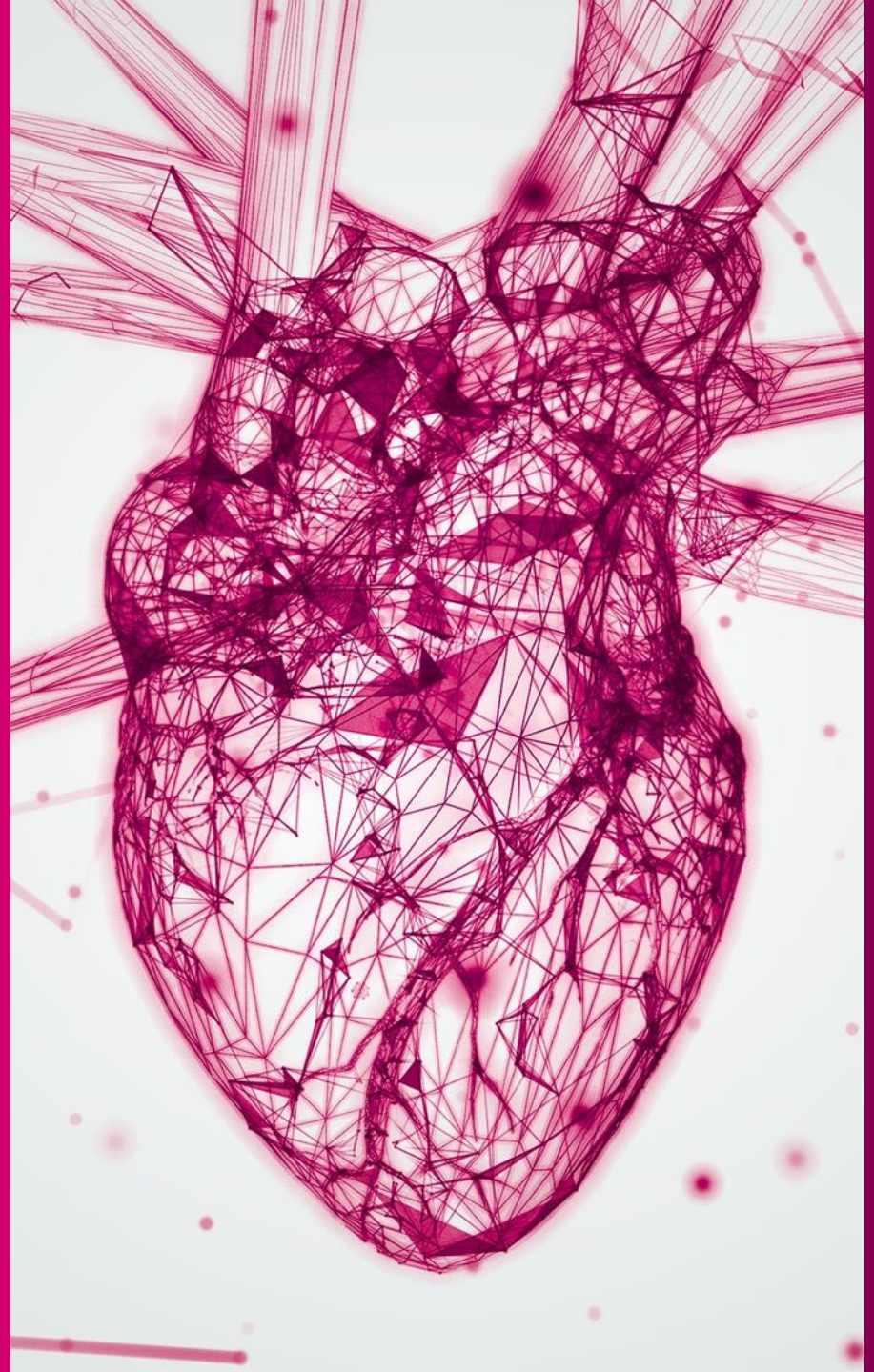

BaxHTN
Baxdrostat Adult Phase 3 Clinical Trial

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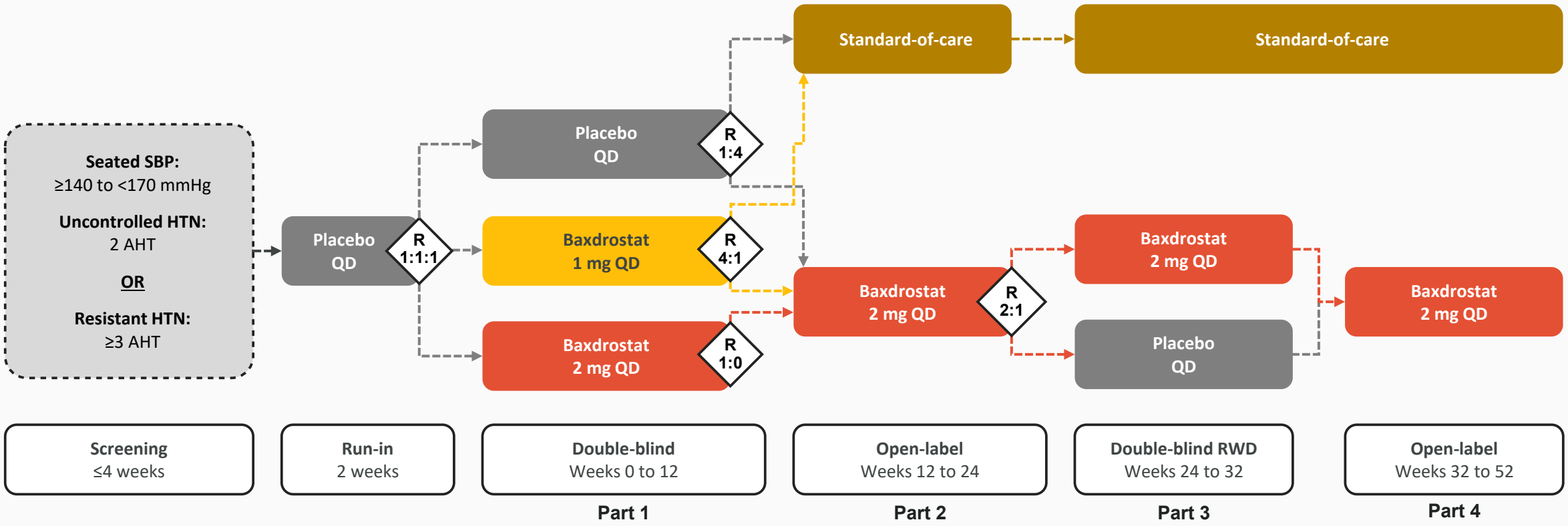
BaxHTN Phase 3 trial design



AHT, antihypertensive medication; HTN, hypertension; QD, once daily; R, randomization; RWD, randomized withdrawal; SBP, systolic blood pressure.

Flack, J.M., Azizi, M., Brown, J.M. et al. Hypertens Res (2025) doi.org/10.1038/s41440-025-02297-7

Study population

Adults ≥18 years of age with uncontrolled or resistant hypertension

Key inclusion criteria

- **Mean seated-SBP ≥140 and <170 mmHg**
- **Despite treatment with maximally tolerated doses of either 2 (uncontrolled HTN) or ≥3 (resistant HTN) antihypertensive medications, including a diuretic, for ≥4 weeks before screening**
- eGFR ≥45 mL/min/1.73m^2
- Serum potassium ≥3.5 and <5 mmol/L

Key exclusion criteria

- Current use of MRAs or potassium-sparing diuretics
- Secondary hypertension (except for obstructive sleep apnea or primary aldosteronism)
- Uncontrolled diabetes (HbA_{1c} >10%)
- Cardiovascular or cerebrovascular events within 6 months, or persistent atrial fibrillation

Seated office systolic BP at randomization ≥135 mmHg

eGFR, estimated glomerular filtration rate; HbA_{1c}, glycated hemoglobin; HTN, hypertension; MRAs, mineralocorticoid receptor antagonists; SBP, systolic blood pressure.

Participant characteristics

794 participants

27% uncontrolled HTN
73% resistant HTN

- Participants were 62% male and 63% White
  - 26% Asian; 7% Black
- Mean (SD) age was 61 (12) years
- Participants were from:
  - The Americas (27%)
  - Europe (43%)
  - Asia Pacific, Middle East, and Africa (30%)

Characteristic	Placebo (n=264)	Baxdrostat, 1 mg (n=264)	Baxdrostat, 2 mg (n=266)
Age, mean ± SD, yrs	61.9 ± 11.6	59.8 ± 11.8	61.8 ± 11.7
Male sex, n (%)	162 (61.4)	169 (64.0)	163 (61.3)
Race, n (%)*			
White	167 (63.3)	165 (62.5)	168 (63.2)
Black	15 (5.7)	23 (8.7)	21 (7.9)
Asian	72 (27.3)	65 (24.6)	72 (27.1)
Native Hawaiian or Pacific Islander	1 (0.4)	1 (0.4)	0 (0.0)
Other	9 (3.4)	10 (3.8)	5 (1.9)

*Reported by the participant.
HTN, hypertension; SD, standard deviation.

Participant characteristics

- Clinical characteristics at baseline were similar across treatment arms
- Baseline BP: 149/87 mmHg
- Median number of background AHT medications: 3 (for each treatment group)
  - Almost all on a diuretic (99.6%)
  - 90% on an ACEi or ARB
  - 70% on a calcium channel blocker
  - 34% on a beta blocker
- 52% had obesity, 38% had diabetes
- Baseline potassium: 4.2 mmol/L
- Baseline eGFR: 85.0 mL/min/1.73m^2

Characteristic	Placebo (n=264)	Baxdrostat, 1 mg (n=264)	Baxdrostat, 2 mg (n=266)
Seated BP, mmHg*			
Systolic, mean ± SD	149.0 ± 8.7	149.7 ± 10.1	149.1 ± 9.1
Diastolic, mean ± SD	85.8 ± 10.5	88.0 ± 10.5	85.8 ± 10.5
eGFR, mL/min/1.73m^2			
Mean	84.1 ± 18.0	86.6 ± 18.5	84.3 ± 17.9
<60, n (%)	29 (11.0)	27 (10.2)	30 (11.3)
Serum sodium, mmol/L			
Mean ± SD	139.6 ± 2.5	139.9 ± 2.6	139.8 ± 2.5
Serum potassium, mmol/L			
Mean ± SD	4.2 ± 0.5	4.2 ± 0.4	4.2 ± 0.4
Serum aldosterone, ng/dL†			
Median (IQR)	7.5 (4.2,10.3)	7.9 (4.7, 10.8)	7.2 (4.5, 10.9)
PRA, ng/mL/h‡			
Median (IQR)	1.4 (0.6, 4.0)	1.8 (0.7, 4.7)	1.5 (0.6, 5.0)

*n=1 placebo had a missing SBP value at baseline; †placebo: n=224; baxdrostat 1 mg: n=228; baxdrostat 2 mg: n=227; ‡placebo: n=178; baxdrostat 1 mg: n=197; baxdrostat 2 mg: n=179.

ACEi, angiotensin-converting enzyme inhibitor; AHT, antihypertensive treatments; ARB angiotensin-receptor blocker; BP, blood pressure; eGFR, estimated glomerular filtration rate; IQR, interquartile range; PRA, plasma renin activity; SD, standard deviation.

Baxfendy US Prescribing Information

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use BAXFENDY safely and effectively. See full prescribing information for BAXFENDY.

BAXFENDY™ (baxdrostat) tablets, for oral use
Initial U.S. Approval: 2026

---------- **INDICATIONS AND USAGE** ----------

BAXFENDY is an aldosterone synthase inhibitor indicated for the treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adults who are not adequately controlled on other agents. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. (1)

The NEW ENGLAND JOURNAL of MEDICINE

Bax HTN

ORIGINAL ARTICLE

Efficacy and Safety of Baxdrostat in Uncontrolled and Resistant Hypertension

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Available now on-line

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