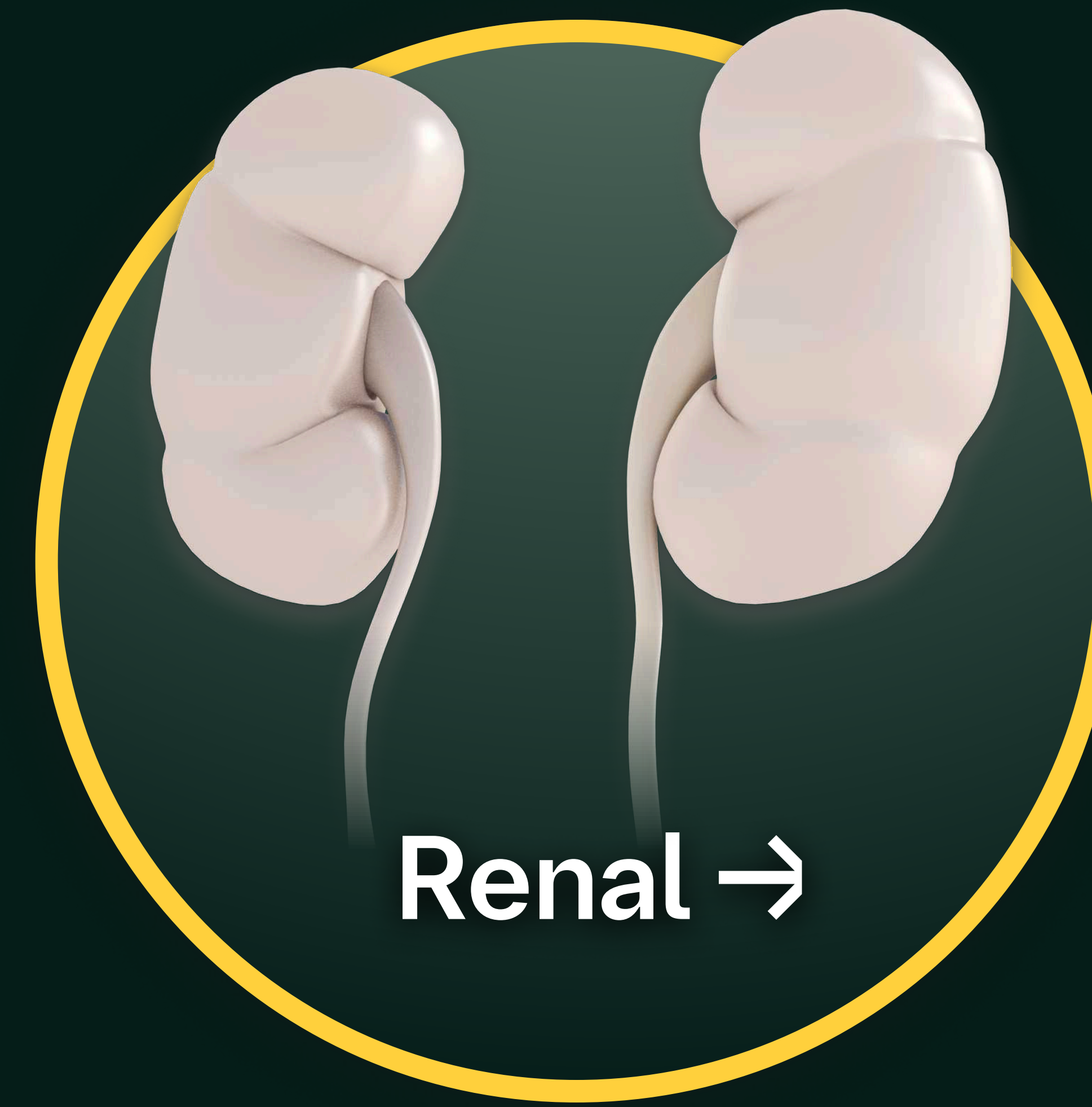
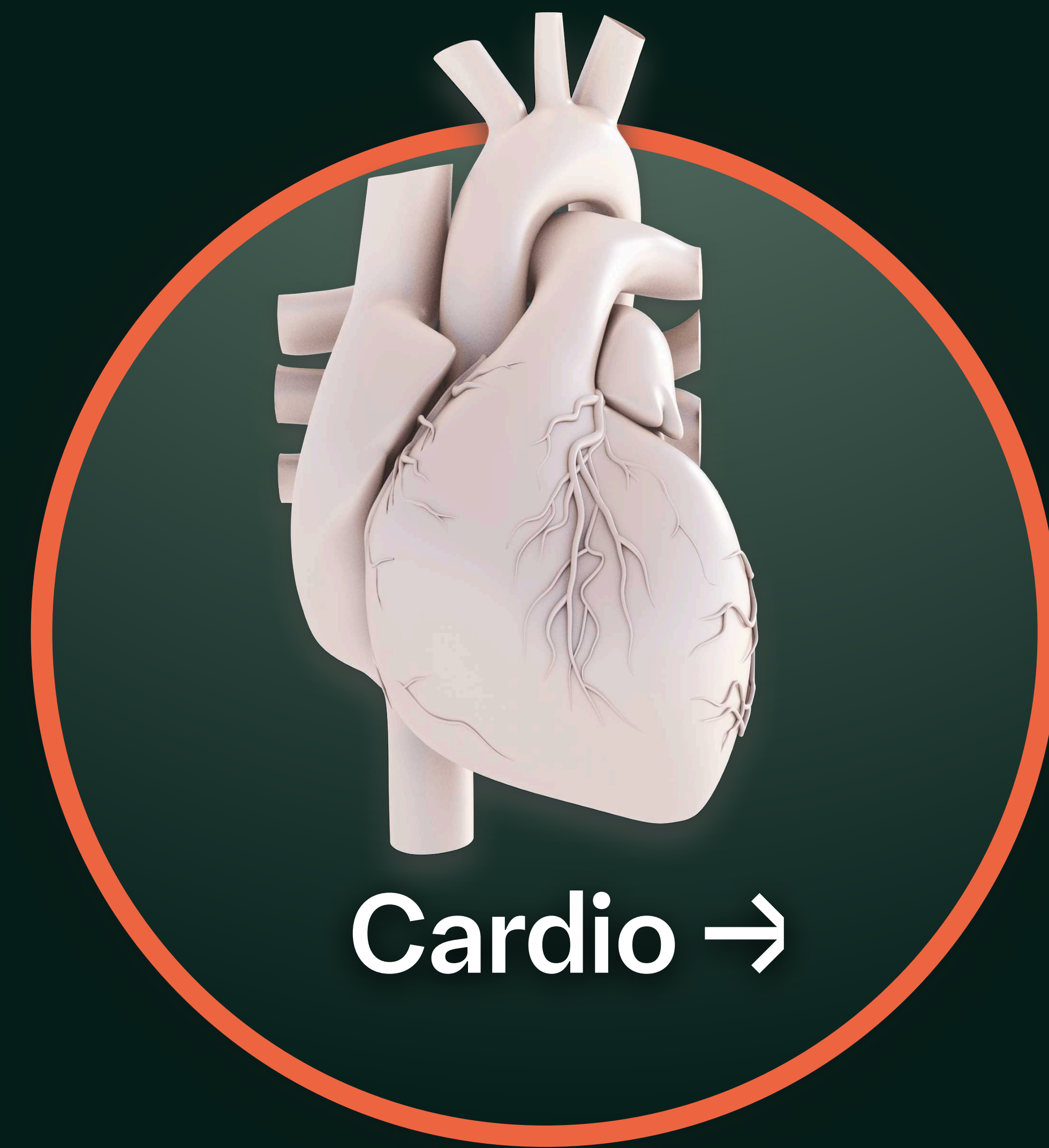
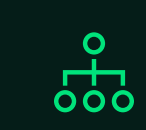


# Cardiovascular- Renal-Metabolic pipeline

We are building on our legacy of innovation for a range of cardiovascular, renal, and metabolic conditions



 [Home](#)

 [Cardiovascular-Renal-Metabolic pipeline](#)

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## Cardiovascular-Renal-Metabolic pipeline

We are building on our legacy of innovation for a range of cardiovascular, renal, and metabolic conditions

### Phase II

Vicadrostat/empagliflozin | SGLT2i/ASi  
**EASI-SYNC™**  
 Chronic kidney disease

[View →](#)

Apecotrep | TRPC6 inhibitor  
**PODOMOUNT-pFSGS**  
 Primary FSGS or genetic FSGS due to a gain-of-function TRPC6 mutation

[View →](#)

### Phase III

Vicadrostat/empagliflozin | SGLT2i/ASi  
**EASI-HF® Preserved**  
 Heart failure with LVEF ≥40%

[View →](#)

Vicadrostat/empagliflozin | SGLT2i/ASi  
**EASI-HF® Reduced**  
 Heart failure with LVEF <40%

[View →](#)

Vicadrostat/empagliflozin | SGLT2i/ASi  
**EASI-PROTKT™**  
 Type 2 diabetes, hypertension, and established cardiovascular disease

[View →](#)

Vicadrostat/empagliflozin | SGLT2i/ASi  
**EASI-KIDNEY®**  
 Chronic kidney disease

[View →](#)

Apecotrep | TRPC6 inhibitor  
**PODOMOUNT-Basket**  
 Proteinuric kidney diseases (secondary FSGS, treatment resistant primary MCD, Alport syndrome, treatment resistant primary MIN)

[View →](#)

Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist  
**SYNCHRONIZE™-1**  
 Overweight or obesity without type 2 diabetes

[View →](#)

Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist  
**SYNCHRONIZE™-2**  
 Overweight or obesity with type 2 diabetes

[View →](#)

Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist  
**SYNCHRONIZE™-CVOT**  
 Overweight or obesity with cardiovascular disease or chronic kidney disease

[View →](#)

Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist  
**SYNCHRONIZE™-MASLD**  
 Overweight or obesity and MASLD/MASH

[View →](#)

Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist  
**LIVERAGE™**  
 Non-cirrhotic MASH and moderate or advanced liver fibrosis

[View →](#)

Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist  
**LIVERAGE™-CIRRHOSIS**  
 Compensated MASH cirrhosis

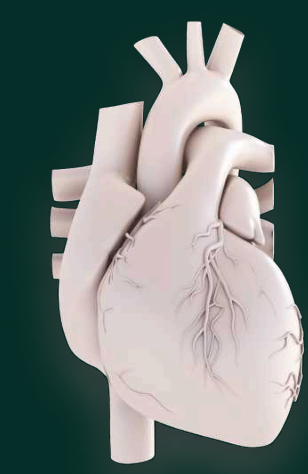
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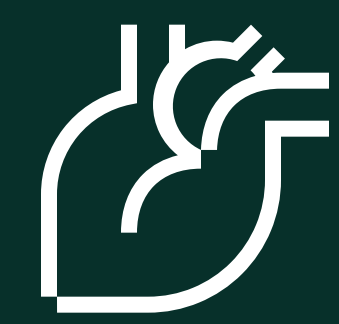
[Cardiovascular-Renal-Metabolic pipeline](#)

# Cardiovascular- Renal-Metabolic pipeline

We are building on our legacy of innovation for a range of cardiovascular, renal, and metabolic conditions



## Cardio

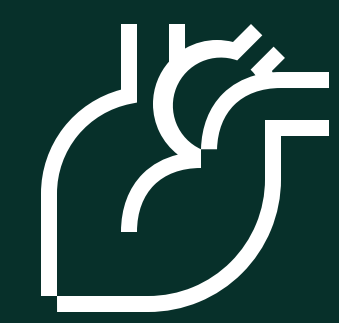


Vicadrostat/empagliflozin | SGLT2i/ASi  
EASi-HF® Preserved  
Heart failure with LVEF  $\geq 40\%$

Phase II

Phase III

View →

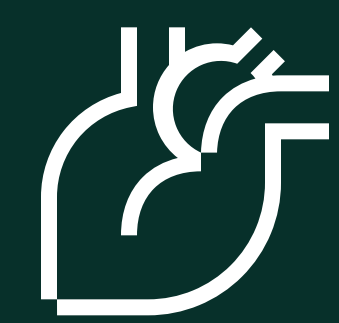


Vicadrostat/empagliflozin | SGLT2i/ASi  
EASi-HF® Reduced  
Heart failure with LVEF  $< 40\%$

Phase II

Phase III

View →



Vicadrostat/empagliflozin | SGLT2i/ASi  
EASi-PROTKT™  
Type 2 diabetes, hypertension, and established cardiovascular disease


Phase II

Phase III

View →

Tap “View →” on a tile to learn more about our research

 Home

 Cardiovascular-Renal-Metabolic pipeline

# Cardiovascular-Renal-Metabolic pipeline

We are building on our legacy of innovation for a range of cardiovascular, renal, and metabolic conditions

Vicadrostat/empagliflozin | SGLT2i/ASi  
**EASi-HF® Preserved**  
**Heart failure with LVEF ≥40%**

**NOW ENROLLING**

Scan the QR code to find out more on EASi-HF® Preserved research and sites



ClinicalTrials.gov ID  
 NCT06424288

Study start  
 June 2024

Study end  
 May 2028 (estimated)

Phase III

## Overview

A Phase III, double-blind, randomized, parallel-group superiority trial to evaluate efficacy and safety of the combined use of oral vicadrostat/empagliflozin compared with empagliflozin in participants with symptomatic HF and LVEF ≥40%.<sup>1</sup>

### Asset description

Vicadrostat/empagliflozin exerts complementary effects on signaling pathways that influence pathomechanisms such as glomerular and systemic hemodynamics, endothelial dysfunction, oxidative stress, inflammation, and fibrosis.<sup>2–15</sup>

Vicadrostat is a potent, selective aldosterone synthase inhibitor which addresses RAAS dysregulation at its center; it can lower aldosterone levels by 50–60%.<sup>2–4,16</sup> Empagliflozin is a sodium-glucose cotransporter 2 inhibitor.<sup>5</sup>

### Intervention

Vicadrostat/empagliflozin compared with empagliflozin.<sup>1</sup>

## Patient population

Chronic HF diagnosed ≥3 months before visit 1, with LVEF ≥40% and NYHA class II–IV at visit 1.<sup>1</sup>

### Key inclusion criteria<sup>1</sup>

- ≥18 years old, or legal age of consent if greater, at the time of consent
- Signed and dated informed consent in accordance with ICH-GCP and local legislation
- Male or female participants; women of childbearing potential must use highly effective contraception
- Diagnosed with chronic HF (NYHA class II–IV) for at least 3 months before visit 1, with LVEF ≥40%
- Presence of structural heart abnormality confirmed by imaging
- Elevated NT-proBNP at Visit 1, with specific thresholds based on BMI and atrial fibrillation/flutter status
- At least 1 of the following:
  - Currently on stable diuretic therapy for at least 1 week prior to visit 1
  - Documented hospitalization for HF within 6 months prior to visit 1
  - Elevated NT-proBNP at visit 1
  - uACR ≥30 mg/g at visit 1
- Treated according to the best standard of care for HF per applicable guidelines

### Key exclusion criteria<sup>1</sup>

- Treatment with MRA or potassium-sparing diuretics within 14 days prior to visit 1, or if needed before randomization or during the trial
- Use of a direct renin inhibitor, or concurrent use of more than one ACE inhibitor, ARB, or ARNI at visit 2
- Acute decompensated HF if received i.v. inotrope, i.v. vasodilating drug, i.v. natriuretic peptide or mechanical support within 24 hours prior to randomization or i.v. diuretic with a dose that has been increased within 6 hours prior to randomization
- Use of systemic mineralocorticoid replacement therapy at visit 2 or ASIs at visit 2 or planned during the trial
- Recent major CV events or surgeries (e.g. myocardial infarction, transient ischemic attack, stroke, coronary artery bypass graft surgery, heart valve surgery) within 90 days prior to visit 1, or scheduled for major elective surgery during the study
- Scheduled or unscheduled percutaneous coronary intervention or any angiography using iodinated contrast agents in the 7 days prior to visit 2
- Heart transplant recipient, awaiting heart transplant, or currently implanted left ventricular assist device
- Known cardiomyopathy due to specific diseases or reversible causes within 12 months prior to visit 1, and until visit 2
- Acute inflammatory heart disease within 90 days prior to visit 1, and until visit 2
- Severe valvular heart disease (obstructive or regurgitant) or planned invasive valvular procedures at visit 1 or during the study

#### Abbreviations:

ACE, angiotensin-converting enzyme; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor–neprilysin inhibitor; ASi, aldosterone synthase inhibitor; BMI, body mass index; CV, cardiovascular; HF, heart failure; ICH-GCP, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use – Good Clinical Practice; i.v., intravenous; LVEF, left ventricular ejection fraction; MRA, mineralocorticoid receptor antagonist; NT-proBNP, N-terminal pro-B-type natriuretic peptide; NYHA, New York Heart Association; RAAS, renin–angiotensin–aldosterone system; SGLT2i, sodium-glucose co-transporter-2 inhibitor; uACR, urine albumin-to-creatinine ratio.

#### References:

1. ClinicalTrials.gov. NCT06424288 (accessed February 2026); 2. Tuttle KR, et al. *Lancet*. 2024;403:379–390; 3. Judge PK, et al. *Nephrol Dial Transplant*. 2025;40:1175–1186; 4. Brown NF, et al. Oral presentation at ESAC ADMIRE 2023; 5. Sizar O, et al. Empagliflozin. [Updated 2023 May 29]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK532925/>. (accessed February 2026); 6. Gohari S, et al. *Diabetol Metab Syndr*. 2022;14:170; 7. Janić M, et al. *J Diabetes Res*. 2022;2022:6796470; 8. Hattori S, et al. *Diabetol Metab Syndr*. 2018;10:93; 9. Rykova EY, et al. *Int J Mol Sci*. 2025;26(4):1670; 10. Wang H, et al. *Front Endocrinol (Lausanne)*. 2022;13:917761; 11. Balleza Alejandri LR, et al. *J Cardiovasc Dev Dis*. 2024;11:182; 12. Parksook WW, et al. *Cardiovasc Res*. 2023;119:28–44; 13. Patel SK, et al. *Cardiac Failure Review*. 2025;11:e20; 14. Diez J. *Hypertension*. 2008;52:462–4; 15. Verma S, et al. *Am J Physiol Heart Circ Physiol*. 2024;326:H670; 16. Gashaw IA, et al. *Eur J Endocrinol*. 2026;194(1):46–57.

Overview

Study design

Home

Cardiovascular-Renal-Metabolic pipeline

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← Back to Cardio research

Browse this asset in other indications

HF with LVEF <40% →

T2D, hypertension, and established CVD →

CKD (EASi-SYNC™) →

CKD (EASi-KIDNEY®) →

# Cardiovascular- Renal-Metabolic pipeline

We are building on our legacy of innovation for a range of cardiovascular, renal, and metabolic conditions

Vicadrostat/empagliflozin | SGLT2i/ASi  
**EASi-HF® Preserved**  
**Heart failure with LVEF ≥40%**

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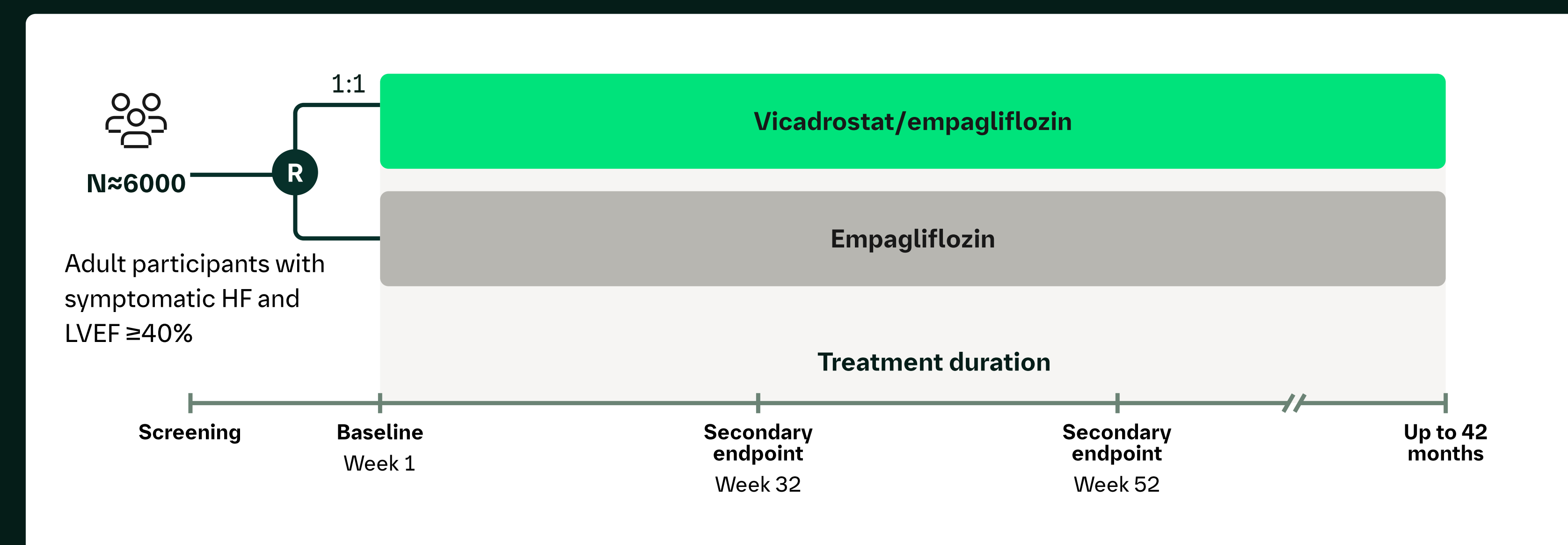
**Phase III**

ClinicalTrials.gov ID  
NCT06424288

Study start  
June 2024

Study end  
May 2028 (estimated)

## Study design



### Primary endpoint

- Time to first event of CV death, HHF, or urgent HF visit

### Key secondary endpoints

- Time to first event of CV death or HHF
- Occurrence of HHF (first and recurrent)
- Absolute change from baseline in KCCQ-TSS at Week 32
- Time to CV death
- Time to all-cause mortality

#### Abbreviations:

ASi, aldosterone synthase inhibitor; CV, cardiovascular; HF, heart failure; HHF, hospitalization for heart failure; KCCQ-TSS, Kansas City Cardiomyopathy Questionnaire Total Symptom Score; LVEF, left ventricular ejection fraction; R, randomization; SGLT2i, sodium-glucose co-transporter-2 inhibitor.

Overview

**Study design**

#### References:

ClinicalTrials.gov. NCT06424288 (accessed February 2026).

[Home](#)

[Cardiovascular-Renal-Metabolic pipeline](#)

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[← Back to Cardio research](#)

[Browse this asset in other indications](#)

[HF with LVEF <40%](#) →

[T2D, hypertension, and established CVD](#) →

[CKD \(EASi-SYNC™\)](#) →

[CKD \(EASi-KIDNEY®\)](#) →

# Cardiovascular-Renal-Metabolic pipeline

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Vicadrostat/empagliflozin | SGLT2i/ASi  
**EASi-HF<sup>®</sup> Reduced Heart failure with LVEF <40%**

**NOW ENROLLING**

Scan the QR code to find out more on EASi-HF<sup>®</sup> Reduced research and sites



ClinicalTrials.gov ID  
NCT06935370

Study start  
May 2025

Study end  
February 2029 (estimated)

Phase III

## Overview

A Phase III double-blind, randomized, parallel-group superiority trial to evaluate efficacy and safety of the combined use of oral vicadrostat/empagliflozin compared with empagliflozin in participants with symptomatic chronic HF and LVEF <40%.<sup>1</sup>

### Asset description

Vicadrostat/empagliflozin exerts complementary effects on signaling pathways that influence pathomechanisms such as glomerular and systemic hemodynamics, endothelial dysfunction, oxidative stress, inflammation, and fibrosis.<sup>2-15</sup>

Vicadrostat is a potent, selective aldosterone synthase inhibitor which addresses RAAS dysregulation at its center; it can lower aldosterone levels by 50–60%.<sup>2-4,16</sup> Empagliflozin is a sodium-glucose cotransporter 2 inhibitor.<sup>5</sup>

### Intervention

Vicadrostat/empagliflozin compared with empagliflozin.<sup>1</sup>

### Patient population

Chronic HF diagnosed  $\geq 3$  months before visit 1, with LVEF <40% and NYHA class II–IV at visit 1.<sup>1</sup>

### Key inclusion criteria<sup>1</sup>

- $\geq 18$  years old, or legal age of consent if greater, at the time of consent
- Signed and dated informed consent in accordance with ICH-GCP and local legislation
- Male or female participants; women of childbearing potential must use highly effective contraception
- Diagnosed with chronic HF (NYHA class II–IV) for at least 3 months before visit 1, with LVEF <40%
- Elevated NT-proBNP at visit 1
- Treated according to best possible SOC (disregarding SGLT2i and MRA) in accordance with applicable HF local/international guidelines and judgement of the investigator

### Key exclusion criteria<sup>1</sup>

- Treatment with MRA or potassium-sparing diuretics within 14 days prior to visit 1, or if needed before randomization or during the trial
- Use of a direct renin inhibitor or concurrent use of more than one ACE inhibitor, ARB, or ARNI at visit 2
- Use of other ASIs or systemic mineralocorticoid replacement therapy at visit 2
- Acute decompensated HF if received i.v. inotrope, i.v. vasodilating drug, i.v. natriuretic peptide, or mechanical support within 24 hours prior to randomization or i.v. diuretic with a dose that has been increased within 6 hours prior to randomization
- Recent major CV events or surgeries (e.g. myocardial infarction, transient ischemic attack, stroke, coronary artery bypass graft surgery, heart valve surgery) within 90 days prior to visit 2, or scheduled for major elective surgery during the study
- Percutaneous coronary intervention or any angiography using iodinated contrast agents in the 7 days prior to visit 2
- Heart transplant recipient, awaiting heart transplant, or currently with implanted left ventricular assist device
- Known cardiomyopathy due to specific diseases or reversible causes within 12 months prior to visit 1 and until visit 2
- Acute inflammatory heart disease within 90 days prior to visit 1, and until visit 2

#### Abbreviations:

ACE, angiotensin-converting enzyme; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor–neprilysin inhibitor; ASi, aldosterone synthase inhibitor; CV, cardiovascular; HF, heart failure; ICH-GCP, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use – Good Clinical Practice; i.v., intravenous; LVEF, left ventricular ejection fraction; MRA, mineralocorticoid receptor antagonist; NT-proBNP, N-terminal pro-B-type natriuretic peptide; NYHA, New York Heart Association; RAAS, renin–angiotensin–aldosterone system; SGLT2i, sodium-glucose co-transporter-2 inhibitor; SOC, standard of care.

#### References:

1. ClinicalTrials.gov. NCT06424288 (accessed February 2026);
2. Tuttle KR, et al. *Lancet*. 2024;403:379–390;
3. Judge PK, et al. *Nephrol Dial Transplant*. 2025;40:1175–1186;
4. Brown NF, et al. Oral presentation at ESAC ADMIRE 2023;
5. Sizar O, et al. Empagliflozin. [Updated 2023 May 29]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK532925/> (accessed February 2026);
6. Gohari S, et al. *Diabetol Metab Syndr*. 2022;14:170;
7. Janić M, et al. *J Diabetes Res*. 2022;2022:6796470;
8. Hattori S, et al. *Diabetol Metab Syndr*. 2018;10:93;
9. Rykova EY, et al. *Int J Mol Sci*. 2025;26(4):1670;
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11. Balleza Alejandri LR, et al. *J Cardiovasc Dev Dis*. 2024;11:182;
12. Parksook WW, et al. *Cardiovasc Res*. 2023;119:28–44;
13. Patel SK, et al. *Cardiac Failure Review*. 2025;11:e20;
14. Diez J. *Hypertension*. 2008;52:462–4;
15. Verma S, et al. *Am J Physiol Heart Circ Physiol*. 2024;326:H670;
16. Gashaw IA, et al. *Eur J Endocrinol*. 2026;194(1):46–57.

Overview

Study design

← Back to Cardio research

Browse this asset in other indications

HF with LVEF  $\geq 40\%$  →

T2D, hypertension, and established CVD →

CKD (EASi-SYNC™) →

CKD (EASi-KIDNEY®) →

# Cardiovascular-Renal-Metabolic pipeline

We are building on our legacy of innovation for a range of cardiovascular, renal, and metabolic conditions

Vicadrostat/empagliflozin | SGLT2i/ASi  
**EASi-HF<sup>®</sup> Reduced Heart failure with LVEF <40%**

**NOW ENROLLING**

Scan the QR code to find out more on EASi-HF<sup>®</sup> Reduced research and sites



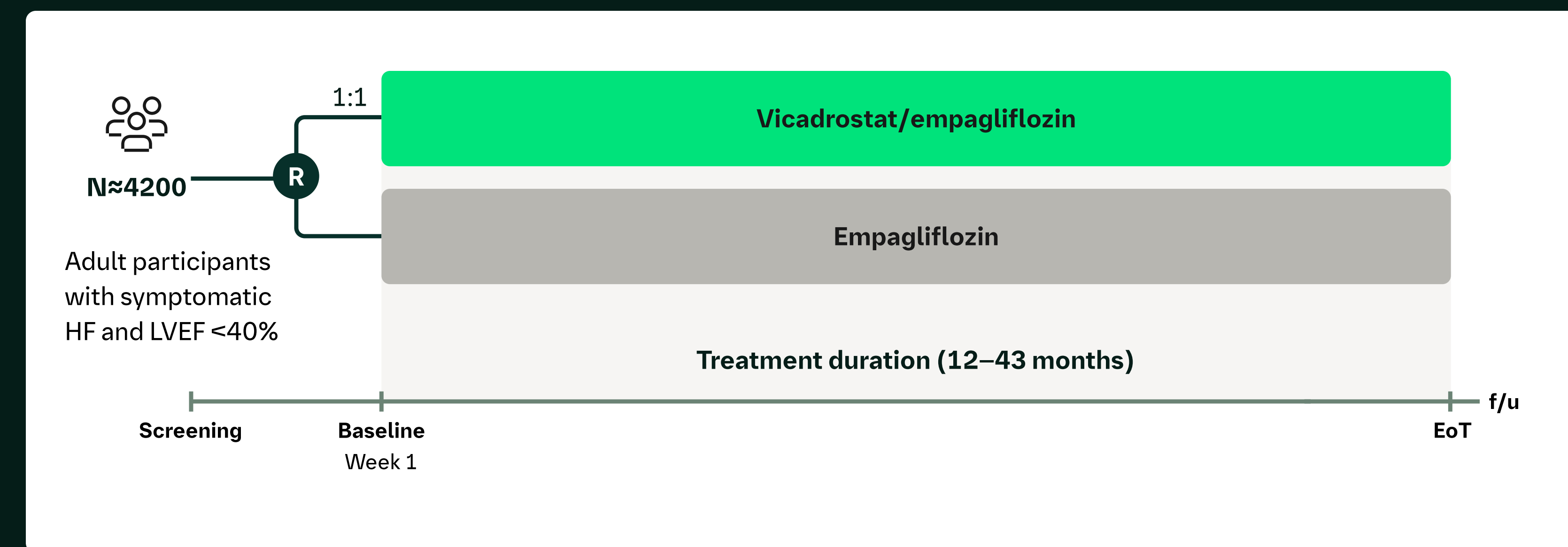
Phase III

ClinicalTrials.gov ID  
NCT06935370

Study start  
May 2025

Study end  
February 2029 (estimated)

## Study design



### Primary endpoint

- Time to first event of CV death, HHF, or urgent HF visit

### Key secondary endpoints

- Time to first event of CV death or HHF
- Occurrence of HHF (first and recurrent)
- Absolute change from baseline in KCCQ-TSS at Week 32
- Time to CV death
- Time to all-cause mortality

#### Abbreviations:

ASi, aldosterone synthase inhibitor; CV, cardiovascular; f/u, follow-up; HF, heart failure; HHF, hospitalization for heart failure; KCCQ-TSS, Kansas City Cardiomyopathy Questionnaire Total Symptom Score; LVEF, left ventricular ejection fraction; R, randomization; SGLT2i, sodium-glucose co-transporter-2 inhibitor.

Overview

Study design

#### References:

ClinicalTrials.gov. NCT06935370 (accessed February 2026).

Home

Cardiovascular-Renal-Metabolic pipeline

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← Back to Cardio research

Browse this asset in other indications

HF with LVEF ≥40% →

T2D, hypertension, and established CVD →

CKD (EASi-SYNC<sup>™</sup>) →

CKD (EASi-KIDNEY<sup>®</sup>) →

# Cardiovascular-Renal-Metabolic pipeline

We are building on our legacy of innovation for a range of cardiovascular, renal, and metabolic conditions

Vicadrost/empagliflozin | SGLT2i/ASi

**EASi-PROTKT™**

**Type 2 diabetes, hypertension, and established cardiovascular disease**

Phase III

ClinicalTrials.gov ID  
NCT07064473

Study start  
May 2025

Study end  
December 2029 (estimated)

## Overview

A Phase III double-blind, randomized, parallel-group superiority trial assessing efficacy and safety of oral vicadrost/empagliflozin combined, versus empagliflozin alone, to reduce CV death or HF events (hospitalization or urgent HF visit) in participants with T2D, hypertension, and established CVD.<sup>1</sup>

## Asset description

Vicadrost/empagliflozin exerts complementary effects on signaling pathways that influence pathomechanisms such as glomerular and systemic hemodynamics, endothelial dysfunction, oxidative stress, inflammation, and fibrosis.<sup>3-16</sup>

Vicadrost is a potent, selective aldosterone synthase inhibitor which addresses RAAS dysregulation at its center; it can lower aldosterone levels by 50–60%.<sup>3-5,17</sup> Empagliflozin is a sodium-glucose cotransporter 2 inhibitor.<sup>6</sup>

## Intervention

Vicadrost/empagliflozin compared with empagliflozin.<sup>1</sup>

## Patient population

Type 2 diabetes, hypertension, and established CVD (defined as one of the following: cerebrovascular disease [including prior stroke], coronary artery disease, peripheral artery disease).<sup>1,2</sup>

## Key inclusion criteria<sup>1</sup>

- ≥18 years old
- A medical history of hypertension and on active pharmacological treatment
- Participants with medical history of T2D and on active pharmacological treatment
- Established CVD and on active pharmacological treatment
- At least one additional risk factor for developing HF

## Key exclusion criteria<sup>1</sup>

- History of HF or HHF or treatment of HF
- Atrial fibrillation or atrial flutter with a resting heart rate >110 bpm documented by electrocardiogram at visit 1
- Advanced untreated conduction disease or untreated clinically relevant ventricular arrhythmia at visit 1
- Treatment with an MRA, amiloride, or other potassium-sparing diuretic
- Receiving a direct renin inhibitor, more than one ACEi and/or ARB simultaneously, use of other ASi, systemic MRA therapy

### Abbreviations:

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; ASi, aldosterone synthase inhibitor; BMI, body mass index; CV, cardiovascular; CVD, cardiovascular disease; HF, heart failure; HHF, hospitalization for heart failure; MRA, mineralocorticoid receptor antagonist; RAAS, renin-angiotensin-aldosterone system; SGLT2i, sodium-glucose co-transporter-2 inhibitor; T2D, type 2 diabetes.

### References:

1. ClinicalTrials.gov. NCT06424288 (accessed February 2026); 2. Boehringer Ingelheim. Date on file; 3. Tuttle KR, et al. *Lancet*. 2024;403:379–390; 4. Judge PK, et al. *Nephrol Dial Transplant*. 2025;40:1175–1186; 5. Brown NF, et al. Oral presentation at ESAC ADMIRE 2023; 6. Sizar O, et al. Empagliflozin. [Updated 2023 May 29]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK532925/>. (accessed February 2026); 7. Gohari S, et al. *Diabetol Metab Syndr*. 2022;14:170; 8. Janić M, et al. *J Diabetes Res*. 2022;2022:6796470; 9. Hattori S, et al. *Diabetol Metab Syndr*. 2018;10:93; 10. Rykova EY, et al. *Int J Mol Sci*. 2025;26(4):1670; 11. Wang H, et al. *Front Endocrinol (Lausanne)*. 2022;13:917761; 12. Balleza Alejandri LR, et al. *J Cardiovasc Dev Dis*. 2024;11:182; 13. Parksook WW, et al. *Cardiovasc Res*. 2023;119:28–44; 14. Patel SK, et al. *Cardiac Failure Review*. 2025;11:e20; 15. Díez J. *Hypertension*. 2008;52:462–4; 16. Verma S, et al. *Am J Physiol Heart Circ Physiol*. 2024;326:H670; 17. Gashaw IA, et al. *Eur J Endocrinol*. 2026;194(1):46–57.

Overview

Study design

← Back to Cardio research

Browse this asset in other indications

HF with LVEF ≥40% →

Heart failure with LVEF <40% →

CKD (EASi-SYNC™) →

CKD (EASi-KIDNEY®) →

# Cardiovascular-Renal-Metabolic pipeline

We are building on our legacy of innovation for a range of cardiovascular, renal, and metabolic conditions

Vicadrostat/empagliflozin | SGLT2i/ASi

**EASi-PROTKT™**

Type 2 diabetes, hypertension, and established cardiovascular disease

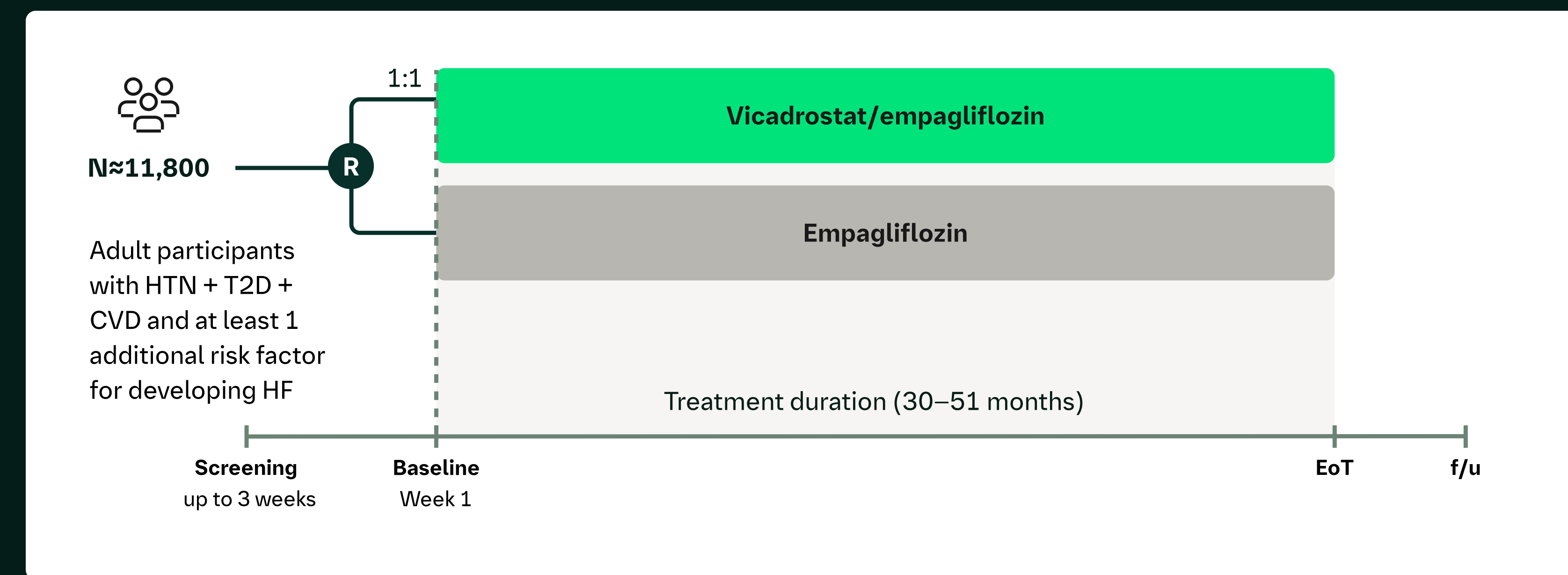
Phase III

ClinicalTrials.gov ID  
NCT07064473

Study start  
May 2026

Study end  
December 2029 (estimated)

## Study design



### Primary endpoint

- Time to first event of CV death or HFE defined as HHF or urgent HF visit

### Secondary endpoints

- Time to first event of CV death or HHF
- Absolute change from baseline in mean SBP at Week 24
- Relative change from baseline in uACR at Week 24
- Time to first occurrence of the composite outcome of kidney disease progression, HHF, or CV death
- Time to first event of CV death, HFE, non-fatal myocardial infarction, or non-fatal stroke (4-point MACE)
- Occurrences of all-cause hospitalizations (first and recurrent)
- Time to first event of new-onset atrial fibrillation or atrial flutter, or CV death
- Time to all-cause death
- Time to CV death
- Time to first HHF
- Time to first event of new-onset HF or CV death
- Occurrences of HHF (first and recurrent)
- Absolute change from baseline in mean DBP at Week 24

#### Abbreviations:

ASi, aldosterone synthase inhibitor; BMI, body mass index; CV, cardiovascular; CVD, cardiovascular disease; DBP, diastolic blood pressure; EoT, end of treatment; f/u, follow-up; HF, heart failure; HFE, heart failure event; HHF, hospitalization for heart failure; HTN, hypertension; MACE, major adverse cardiovascular events; R, randomization; SBP, systolic blood pressure; SGLT2i, sodium-glucose co-transporter-2 inhibitor; T2D, type 2 diabetes; uACR, urine albumin-to-creatinine ratio.

Overview

Study design

#### References:

ClinicalTrials.gov. NCT07064473 (accessed February 2026).

Home

Cardiovascular-Renal-Metabolic pipeline

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← Back to Cardio research

Browse this asset in other indications

HF with LVEF ≥40% →

Heart failure with LVEF <40% →

CKD (EASi-SYNC™) →

CKD (EASi-KIDNEY®) →

# Cardiovascular- Renal-Metabolic pipeline

We are building on our legacy of innovation for a range of cardiovascular, renal, and metabolic conditions



## Renal



Vicadrostat/empagliflozin | SGLT2i/ASi  
**EASi-SYNC™**  
Chronic kidney disease

Phase II

Phase III

[View →](#)



Vicadrostat/empagliflozin | SGLT2i/ASi  
**EASi-KIDNEY®**  
Chronic kidney disease

Phase II

Phase III

[View →](#)



Apecotrep | TRPC6 inhibitor  
**PODOMOUNT-pFSGS**  
Primary FSGS or genetic FSGS due to a gain-of-function TRPC6 mutation

Phase II

Phase III

[View →](#)



Apecotrep | TRPC6 inhibitor  
**PODOMOUNT-Basket**  
Proteinuric kidney diseases (secondary FSGS, treatment resistant primary MCD, Alport syndrome, treatment resistant primary MN)

Phase II

Phase III

[View →](#)

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[Home](#)

[Cardiovascular-Renal-Metabolic pipeline](#)

# Cardiovascular-Renal-Metabolic pipeline

We are building on our legacy of innovation for a range of cardiovascular, renal, and metabolic conditions

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## Renal

Vicadrostat/empagliflozin | SGLT2i/ASi

### EASi-SYNC™ Chronic kidney disease

Phase II

ClinicalTrials.gov ID: NCT06926660 | Study start: July 2025 | Study end: August 2026 (estimated)

#### Overview

A Phase II, randomized, double-blind, parallel-group, multicenter, international trial to investigate the safety and efficacy of vicadrostat/empagliflozin administered with simultaneous vs staggered initiation in participants with CKD at risk of kidney-disease progression.<sup>1</sup>

#### Asset description

Vicadrostat/empagliflozin exerts complementary effects on signaling pathways that influence pathomechanisms such as glomerular and systemic hemodynamics, endothelial dysfunction, oxidative stress, inflammation, and fibrosis.<sup>2-15</sup>

Vicadrostat is a potent, selective aldosterone synthase inhibitor which addresses RAAS dysregulation at its center; it can lower aldosterone levels by 50–60%.<sup>2-4,16</sup> Empagliflozin is a sodium-glucose cotransporter 2 inhibitor.<sup>5</sup>

#### Intervention

Staggered initiation of empagliflozin followed by vicadrostat/empagliflozin compared with simultaneous initiation of vicadrostat/empagliflozin.<sup>1</sup>

#### Abbreviations:

ACEi, angiotensin-converting enzyme inhibitor; ALT, alanine transaminase; ARB, angiotensin receptor blocker; ASi, aldosterone synthase inhibitor; AST, aspartate transaminase; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; ICH-GCP, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use – Good Clinical Practice; MRA, mineralocorticoid receptor antagonist; RAAS, renin–angiotensin–aldosterone system; SGLT2i, sodium-glucose co-transporter-2 inhibitor; uACR, urine albumin-to-creatinine ratio; ULN, upper limit of normal.

#### References:

1. ClinicalTrials.gov. NCT06424288 (accessed February 2026); 2. Tuttle KR, et al. *Lancet*. 2024;403:379–390; 3. Judge PK, et al. *Nephrol Dial Transplant*. 2025;40:1175–1186; 4. Brown NF, et al. Oral presentation at ESAC ADMIRE 2023; 5. Sizar O, et al. Empagliflozin. [Updated 2023 May 29]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK532925/> (accessed February 2026); 6. Gohari S, et al. *Diabetol Metab Syndr*. 2022;14:170; 7. Janić M, et al. *J Diabetes Res*. 2022;2022:6796470; 8. Hattori S, et al. *Diabetol Metab Syndr*. 2018;10:93; 9. Rykova EY, et al. *Int J Mol Sci*. 2025;26(4):1670; 10. Wang H, et al. *Front Endocrinol (Lausanne)*. 2022;13:917761; 11. Balleza Alejandri LR, et al. *J Cardiovasc Dev Dis*. 2024;11:182; 12. Parksook WW, et al. *Cardiovasc Res*. 2023;119:28–44; 13. Patel SK, et al. *Cardiac Failure Review*. 2025;11:e20; 14. Diez J. *Hypertension*. 2008;52:462–4; 15. Verma S, et al. *Am J Physiol Heart Circ Physiol*. 2024;326:H670; 16. Gashaw IA, et al. *Eur J Endocrinol*. 2026;194(1):46–57.

- Overview
- Study design

#### Patient population

CKD at risk of progression.<sup>1</sup>

#### Key inclusion criteria<sup>1</sup>

- ≥18 years old, or legal age of consent if greater, at the time of consent
- Signed and dated informed consent in accordance with ICH-GCP and local legislation
- Male or female participants; women of childbearing potential must use highly effective contraception
- Evidence of CKD at risk of progression based on 2 eGFR measurements recorded recently (within 1 year) and at the time of visit 1, with each eGFR ≥20 and <60 mL/min/1.73 m<sup>2</sup>, irrespective of uACR
- Treatment with a clinically appropriate, stable dose of either ACEi or ARB (but not both together) for ≥4 weeks before visit 1, with no planned changes to the therapy for the duration of the trial

#### Key exclusion criteria<sup>1</sup>

- Treatment with an SGLT2i within 4 weeks before visit 2
- Treatment with MRA, ASi, or potassium-sparing diuretics within 14 days prior to visit 1, or if needed before randomization or planned during the trial
- Blood potassium of >5.2 mmol/L at visit 1
- Blood ALT or AST >3 × ULN at visit 1
- Known severe hepatic impairment
- On dialysis, functioning kidney transplant or scheduled for transplant
- Treated with new immunosuppression therapy for new (or relapse/flare of pre-existing) kidney disease within the last 60 days
- Currently treated with systemic mineralocorticoid replacement therapy

← Back to Renal research

Browse this asset in other indications

HF with LVEF ≥40% →

HF with LVEF <40% →

T2D, hypertension, and established CVD →

CKD (EASi-KIDNEY®) →

# Cardiovascular- Renal-Metabolic pipeline

We are building on our legacy of innovation for a range of cardiovascular, renal, and metabolic conditions

Vicadrostat/empagliflozin | SGLT2i/ASi

## EASi-SYNC™ Chronic kidney disease

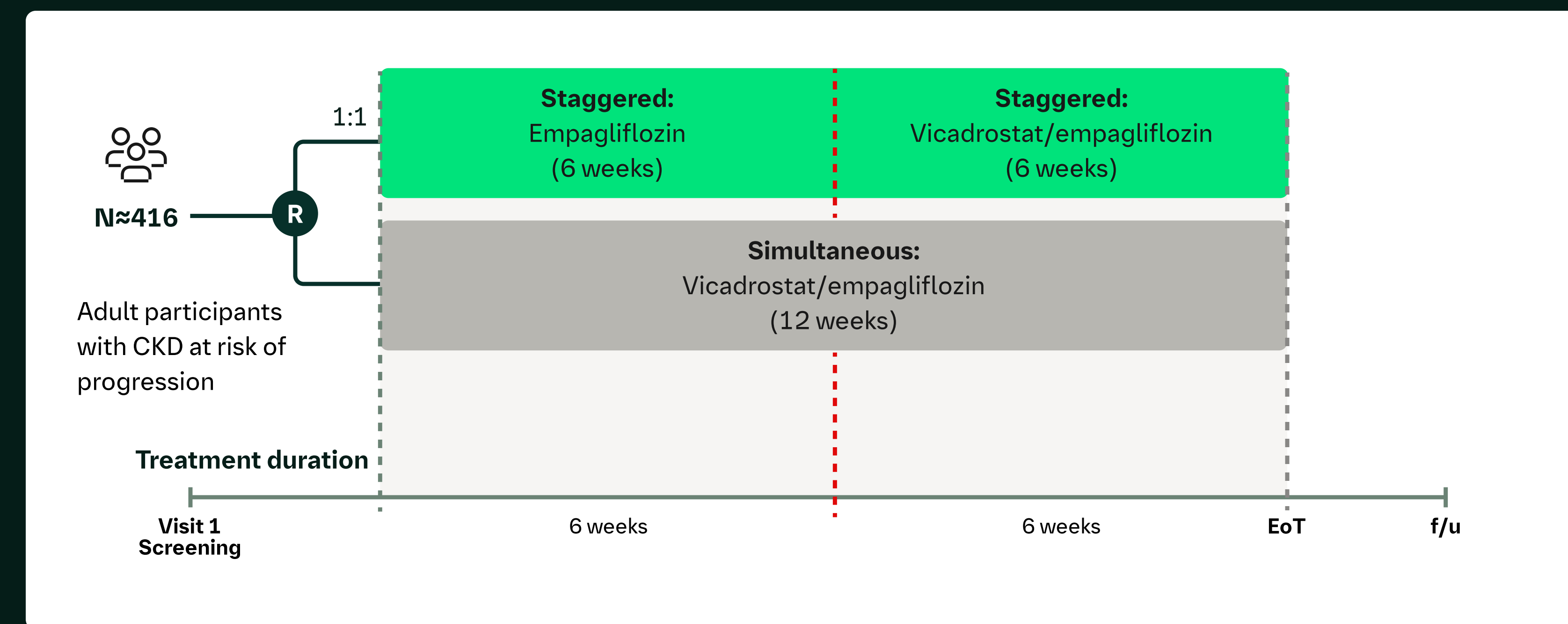
Phase II

ClinicalTrials.gov ID  
NCT06926660

Study start  
July 2025

Study end  
August 2026 (estimated)

### Study design



### Primary endpoint

- Absolute change in eGFR (mL/min/1.73 m<sup>2</sup>) from baseline to Week 14 and Week 16

### Key secondary endpoints

- Absolute change in eGFR (mL/min/1.73 m<sup>2</sup>) from baseline to Week 12
- Absolute change in SBP (mmHg) from baseline to Week 12
- Relative change (ratio) in uACR from baseline to Week 6
- Absolute change in serum potassium (mmol/L) from baseline to Week 12

#### Abbreviations:

ASi, aldosterone synthase inhibitor; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; EoT, end of treatment; f/u, follow-up; R, randomization; SBP, systolic blood pressure; SGLT2i, sodium-glucose co-transporter-2 inhibitor; uACR, urine albumin-to-creatinine ratio.

Overview

Study design

#### Reference:

ClinicalTrials.gov. NCT06926660 (accessed February 2026).

Home

Cardiovascular-Renal-Metabolic pipeline

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← Back to Renal research

Browse this asset in  
other indications

HF with LVEF ≥40% →

HF with LVEF <40% →

T2D, hypertension,  
and established CVD →

CKD (EASi-KIDNEY®) →

# Cardiovascular-Renal-Metabolic pipeline

We are building on our legacy of innovation for a range of cardiovascular, renal, and metabolic conditions

Vicadrostat/empagliflozin | SGLT2i/ASi

## EASi-KIDNEY® Chronic kidney disease

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Scan the QR code to find out more on EASi-KIDNEY® research and sites



ClinicalTrials.gov ID  
NCT06531824

Study start  
August 2024

Study end  
August 2028 (estimated)

Phase III

### Overview

A Phase III, multicenter, international, randomized, double-blind, placebo-controlled clinical trial of vicadrostat/empagliflozin in patients with CKD.<sup>1</sup>

#### Asset description

Vicadrostat/empagliflozin exerts complementary effects on signaling pathways that influence pathomechanisms such as glomerular and systemic hemodynamics, endothelial dysfunction, oxidative stress, inflammation, and fibrosis.<sup>2-15</sup>

Vicadrostat is a potent, selective aldosterone synthase inhibitor which addresses RAAS dysregulation at its center; it can lower aldosterone levels by 50–60%.<sup>2-4,16</sup> Empagliflozin is a sodium-glucose cotransporter 2 inhibitor.<sup>5</sup>

#### Intervention

Vicadrostat/empagliflozin compared with empagliflozin.<sup>1,5</sup>

### Patient population

CKD at risk of progression with or without T2D.<sup>1</sup>

#### Key inclusion criteria<sup>1</sup>

- Male or female aged ≥18 years old
- Evidence of CKD at risk of progression which is defined by local laboratory results recorded at least 3 months before and at the time of the screening visit and requires:
  - CKD-EPI eGFR ≥20 to <45 mL/min/1.73 m<sup>2</sup> or
  - CKD-EPI eGFR ≥45 to <90 mL/min/1.73 m<sup>2</sup> with uACR ≥200 mg/g (or protein-to-creatinine ratio ≥300 mg/g)
- Neither requires an ASi or MRA, nor that such treatment is definitely inappropriate

#### Key exclusion criteria<sup>1</sup>

- Blood potassium of >5.2 mmol/L at screening visit
- Blood ALT or AST >3 × ULN at screening visit
- Known liver cirrhosis
- On dialysis, functioning kidney transplant, or scheduled living donor transplant
- Treated with new immunosuppression therapy for new (or relapse/flare of pre-existing) kidney disease within the last 60 days
- Receiving more than 1 RAAS inhibitor
- Currently treated with an MRA or systemic mineralocorticoid replacement therapy

#### Abbreviations:

ALT, alanine transaminase; ASi, aldosterone synthase inhibitor; AST, aspartate transaminase; CKD, chronic kidney disease; CKD-EPI, Chronic Kidney Disease Epidemiology Collaboration; eGFR, estimated glomerular filtration rate; MRA, mineralocorticoid receptor antagonist; RAAS, renin-angiotensin-aldosterone system; SGLT2i, sodium-glucose co-transporter-2 inhibitor; T2D, type 2 diabetes; uACR, urine albumin-to-creatinine ratio; ULN, upper limit of normal.

#### References:

1. ClinicalTrials.gov. NCT06531824 (accessed February 2026);
2. Tuttle KR, et al. *Lancet*. 2024;403:379–390;
3. Judge PK, et al. *Nephrol Dial Transplant*. 2025;40:1175–1186;
4. Brown NF, et al. Oral presentation at ESAC ADMIRE 2023;
5. Sizar O, et al. Empagliflozin. [Updated 2023 May 29]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK532925/> (accessed February 2026);
6. Gohari S, et al. *Diabetol Metab Syndr*. 2022;14:170;
7. Janić M, et al. *J Diabetes Res*. 2022;2022:6796470;
8. Hattori S, et al. *Diabetol Metab Syndr*. 2018;10:93;
9. Rykova EY, et al. *Int J Mol Sci*. 2025;26(4):1670;
10. Wang H, et al. *Front Endocrinol (Lausanne)*. 2022;13:917761;
11. Balleza Alejandri LR, et al. *J Cardiovasc Dev Dis*. 2024;11:182;
12. Parksook WW, et al. *Cardiovasc Res*. 2023;119:28–44;
13. Patel SK, et al. *Cardiac Failure Review*. 2025;11:e20;
14. Diez J. *Hypertension*. 2008;52:462–4;
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16. Gashaw IA, et al. *Eur J Endocrinol*. 2026;194(1):46–57.

Overview

Study design

Home

Cardiovascular-Renal-Metabolic pipeline

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← Back to Renal research

Browse this asset in other indications

HF with LVEF ≥40% →

HF with LVEF <40% →

T2D, hypertension, and established CVD →

CKD (EASi-SYNC™) →

# Cardiovascular- Renal-Metabolic pipeline

We are building on our legacy of innovation for a range of cardiovascular, renal, and metabolic conditions

Vicadrostat/empagliflozin | SGLT2i/ASi

## EASi-KIDNEY® Chronic kidney disease

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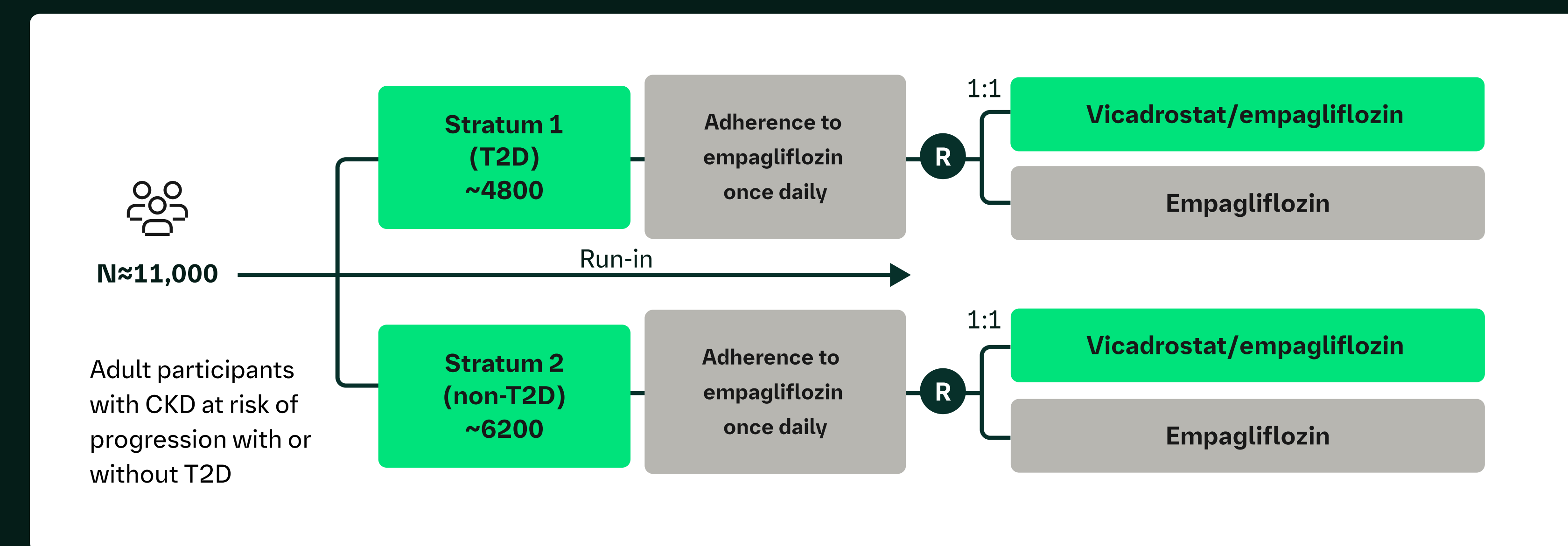
ClinicalTrials.gov ID  
NCT06531824

Study start  
August 2024

Study end  
August 2028 (estimated)

Phase III

### Study design



#### Primary composite outcome

- Kidney disease progression, defined as kidney failure or sustained decline of  $\geq 40\%$  in eGFR or CV death or HHF

#### Key secondary endpoint

- Annual rate of change in eGFR from 3 months until last scheduled visit (i.e. chronic eGFR slope)

#### Abbreviations:

ASi, aldosterone synthase inhibitor; CKD, chronic kidney disease; CV, cardiovascular; eGFR, estimated glomerular filtration rate; HHF, hospitalization for heart failure; R, randomization; SGLT2i, sodium-glucose co-transporter-2 inhibitor; T2D, type 2 diabetes.

Overview

Study design

#### Reference:

ClinicalTrials.gov. NCT06531824 (accessed February 2026).

[Home](#)

[Cardiovascular-Renal-Metabolic pipeline](#)

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[← Back to Renal research](#)

[Browse this asset in other indications](#)

[HF with LVEF  \$\geq 40\%\$](#)  →

[HF with LVEF  \$< 40\%\$](#)  →

[T2D, hypertension, and established CVD](#) →

[CKD \(EASi-SYNC™\)](#) →

# Cardiovascular- Renal-Metabolic pipeline

We are building on our legacy of innovation for a range of cardiovascular, renal, and metabolic conditions

Apecotrep | TRPC6 inhibitor

## PODOMOUNT-pFSGS

Primary FSGS or genetic FSGS due to a gain-of-function TRPC6 mutation

**NOW ENROLLING**

Scan the QR code to find out more on PODOMOUNT-pFSGS and sites



Phase III

ClinicalTrials.gov ID  
NCT07220083

Study start  
February 2026

Study end  
December 2029 (estimated)

### Overview

A multicenter, randomized, double-blind, parallel group, placebo-controlled study to assess effects of oral TRPC6 inhibitor apecotrep taken over a 104-week treatment period in adult and adolescent patients with pFSGS or genetic FSGS related to TRPC6 gene variants.<sup>1</sup>

#### Asset description

Apecotrep is an oral TRPC6 inhibitor differentiated from current SoC by a non-immunosuppressive, podocyte-targeted MoA.<sup>2-4</sup>

#### Intervention

Apecotrep given as an oral tablet once a day + SoC compared with placebo + SoC.<sup>1</sup>

### Patient population

Adults and adolescents with either primary FSGS or genetic FSGS resulting from TRPC6 gain-of-function gene mutations

### Key inclusion criteria<sup>1</sup>

- Male or female patients aged  $\geq 12$  years
- Biopsy-proven pFSGS or documented TRPC6 gene mutation causing FSGS
- Mean UPCR  $\geq 1500$  mg/g based on first morning void urine sample during screening
- Weight  $\geq 40$  kg and BMI  $\leq 40$  kg/m<sup>2</sup> at screening visit
- eGFR  $\geq 25$  mL/min/1.73 m<sup>2</sup> at screening visit

### Key exclusion criteria<sup>1</sup>

- Known monogenic or syndromic causes (except TRPC6 gene mutations) or clinical/histological evidence of secondary FSGS
- FSGS of unknown cause
- History of or planned organ transplantation
- Use of IV immunosuppressive agents (e.g., cyclophosphamide, rituximab, obinutuzumab) in the 6 months prior to screening

#### Abbreviations:

BMI, body mass index; FSGS, focal segmental glomerulosclerosis; IV, intravenous; SoC, standard of care; TRPC6, transient receptor potential cation channel, subfamily C, member 6; UPCR, urine protein-creatinine ratio.

#### References:

1. ClinicalTrials.gov. NCT07220083 (accessed Mar 2026); 2. Boehringer Ingelheim. Press Release. 28 January 2026. Available at: <https://www.boehringer-ingelheim.com/human-health/chronic-kidney-disease/boehringer-announces-phase-2-results-fsgs-rare-kidney-disease>. Last accessed: March 2026; 3. Yonemura T, et al. *Expert Opin Investig Drugs* 2025;34:425-433; 4. Schultz A, et al. *Expert Opin Investig Drugs* 2025;34:415-423.

Overview

Study design

[← Back to Renal research](#)

Browse this asset in other indications

PODOMOUNT-Basket [→](#)

[Home](#)

[Cardiovascular-Renal-Metabolic pipeline](#)

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# Cardiovascular- Renal-Metabolic pipeline

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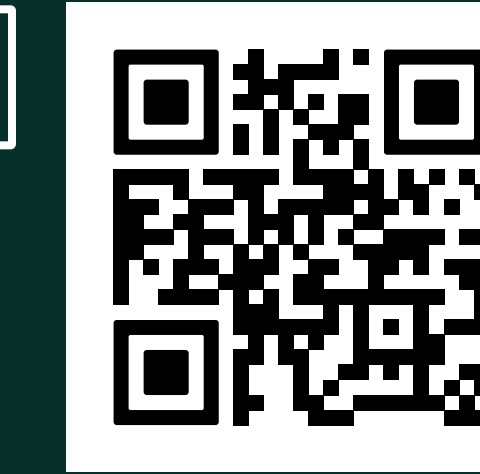
Apecotrep | TRPC6 inhibitor

## PODOMOUNT-pFSGS

Primary FSGS or genetic FSGS due to a gain-of-function TRPC6 mutation

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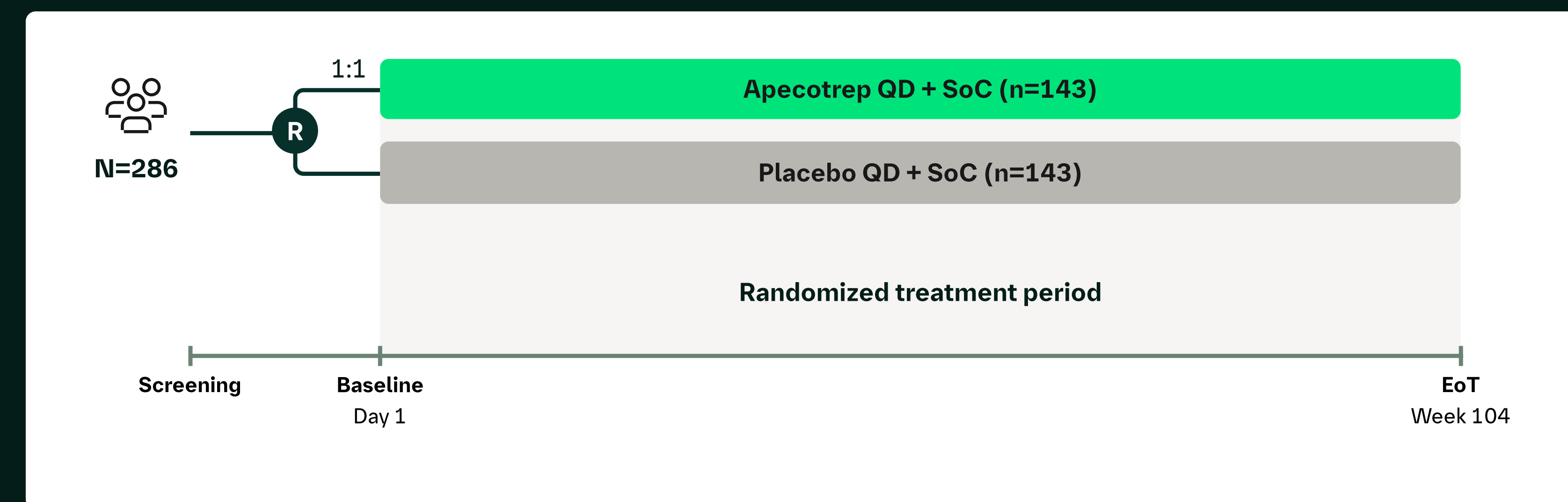
ClinicalTrials.gov ID  
NCT07220083

Study start  
February 2026

Study end  
December 2029 (estimated)

Phase III

### Study design



#### Primary endpoint

- Mean relative change in 24-hour UPCR (mg/g) relative to baseline at Week 104

#### Secondary endpoints

- Absolute change in eGFR<sub>cys</sub> from baseline to Week 104
- Change in 24-hour UPCR (<1000 mg/g) at Week 104 (treatment response)

#### Abbreviations:

eGFR<sub>cys</sub>, estimated glomerular filtration rate based on serum cystatin C; EoT, end of treatment; IV, intravenous; (p)FSGS, (primary) focal segmental glomerulosclerosis; QD, once a day; R, randomized; SoC, standard of care; TRPC6, transient receptor potential cation, subfamily C, member 6; UPCR, urine protein-creatinine ratio; W, week.

Overview

Study design

#### Reference:

ClinicalTrials.gov. NCT07220083 (accessed Mar 2026).

[Home](#)

[Cardiovascular-Renal-Metabolic pipeline](#)

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[← Back to Renal research](#)

[Browse this asset in other indications](#)

[PODOMOUNT-Basket →](#)

# Cardiovascular- Renal-Metabolic pipeline

We are building on our legacy of innovation for a range of cardiovascular, renal, and metabolic conditions

Apecotrep | TRPC6 inhibitor

## PODOMOUNT-Basket Proteinuric kidney diseases (secondary FSGS, treatment-resistant primary MCD, Alport syndrome, treatment-resistant primary MN)

**NOW ENROLLING**

Scan the QR code to find out more on PODOMOUNT-Basket and sites



ClinicalTrials.gov ID  
NCT07355296

Study start  
February 2026<sup>1</sup>

Study end  
January 2028 (estimated)<sup>1</sup>

Phase II

### Overview

A multicenter, randomized, double-blind, parallel group, placebo-controlled basket study to assess safety, tolerability, pharmacokinetics and efficacy of TRPC6 inhibitor apecotrep in four proteinuric kidney diseases.<sup>1</sup>

### Asset description

Apecotrep is an oral TRPC6 inhibitor differentiated from current SoC by a non-immunosuppressive, podocyte-targeted MoA.<sup>2-4</sup>

### Intervention

Apecotrep given as an oral table once a day compared with placebo + SoC.<sup>1</sup>

### Patient population

Adults that have glomerular diseases with pronounced podocyte injury, such as secondary FSGS, primary minimal change disease, Alport syndrome, primary membranous nephropathy.<sup>1</sup>

### Key inclusion criteria<sup>1</sup>

- Male and female patients aged  $\geq 18$  years ( $\geq 12$  years for TR-pMCD)
- Diagnosis confirmed by historical biopsy or for specific cohorts, by clinical features, positive antibody or genetic testing
- Seated blood pressure (mean of 3 values) SBP  $\leq 160$  mmHg (adult participant  $\geq 18$  years) or SBP  $\leq 140$  mmHg (participants  $< 18$  years) at screening
- BMI  $\leq 40$  kg/m<sup>2</sup> at screening visit
- eGFR  $\geq 25$  mL/min/1.73 m<sup>2</sup> at screening visit
- Patients treated with ACE inhibitors, ARBs, MRA, ERA, GLP-1 receptor agonist or SGLT2 inhibitors should be on a stable dose for  $\geq 8$  weeks prior to screening with no plan to change the dose
- Patients treated with oral immunosuppressive therapy (except glucocorticoids) should be on a stable dose for  $\geq 12$  weeks prior to screening with no plan to change the dose
- Patients treated with oral glucocorticoids have to be at a dose  $\leq 10$  mg/d for  $\geq 4$  weeks prior to screening with no plan to change the dose

### Key exclusion criteria<sup>1</sup>

- History of or planned organ transplantation
- Use of (or anticipated use of) IV immunosuppressive agents (e.g., cyclophosphamide, rituximab, obinutuzumab) in the 6 months prior to screening
- Treatment with metformin, dofetilide or strong inhibitors of CYP3A4/5 within 1 week (or 5 half-lives) prior to randomization
- ALT/AST  $> 3 \times$  upper limit of normal at screening
- Clinically significant laboratory abnormalities or medical conditions which pose a safety risk
- History of congenital long QT syndrome or QRcF (QTc intervals  $> 450$  ms in males or  $> 470$  ms in females) at screening

#### Abbreviations:

ACE, angiotensin converting enzyme; ALT, alanine aminotransferase; ARB, angiotensin receptor blocker; AST, aspartate aminotransferase; BMI, body mass index; CYP3A4/5, cytochrome P450 3A4/5; eGFR, estimated glomerular filtration rate; ERA, endothelin receptor antagonists; FSGS, focal segmental glomerulosclerosis; GLP-1, glucagon-like peptide-1; MCD, minimal change disease; MN, membranous nephropathy; MoA, mechanism of action; MRA, mineralocorticoid receptor antagonist; SBP, systolic blood pressure; SoC, standard of care; TRPC6, transient receptor potential cation channel, subfamily C, member 6.

#### References:

1. ClinicalTrials.gov. NCT07355296 (accessed Mar 2026); 2. Boehringer Ingelheim. Press Release. 28 January 2026. Available at: <https://www.boehringer-ingelheim.com/human-health/chronic-kidney-disease/boehringer-announces-phase-2-results-fsgs-rare-kidney-disease>. Last accessed: March 2026; 3. Yonemura T, et al. *Expert Opin Investig Drugs* 2025;34:425-433; 4. Schultz A, et al. *Expert Opin Investig Drugs* 2025;34:415-423.

Overview | Study design

Home

Cardiovascular-Renal-Metabolic pipeline

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← Back to Renal research

Browse this asset in other indications

PODOMOUNT-pFSGS →

# Cardiovascular- Renal-Metabolic pipeline

We are building on our legacy of innovation for a range of cardiovascular, renal, and metabolic conditions

Apecotrep | TRPC6 inhibitor

## PODOMOUNT-Basket Proteinuric kidney diseases (secondary FSGS, treatment-resistant primary MCD, Alport syndrome, treatment-resistant primary MN)

**NOW ENROLLING**

Scan the QR code to find out more on PODOMOUNT-Basket and sites



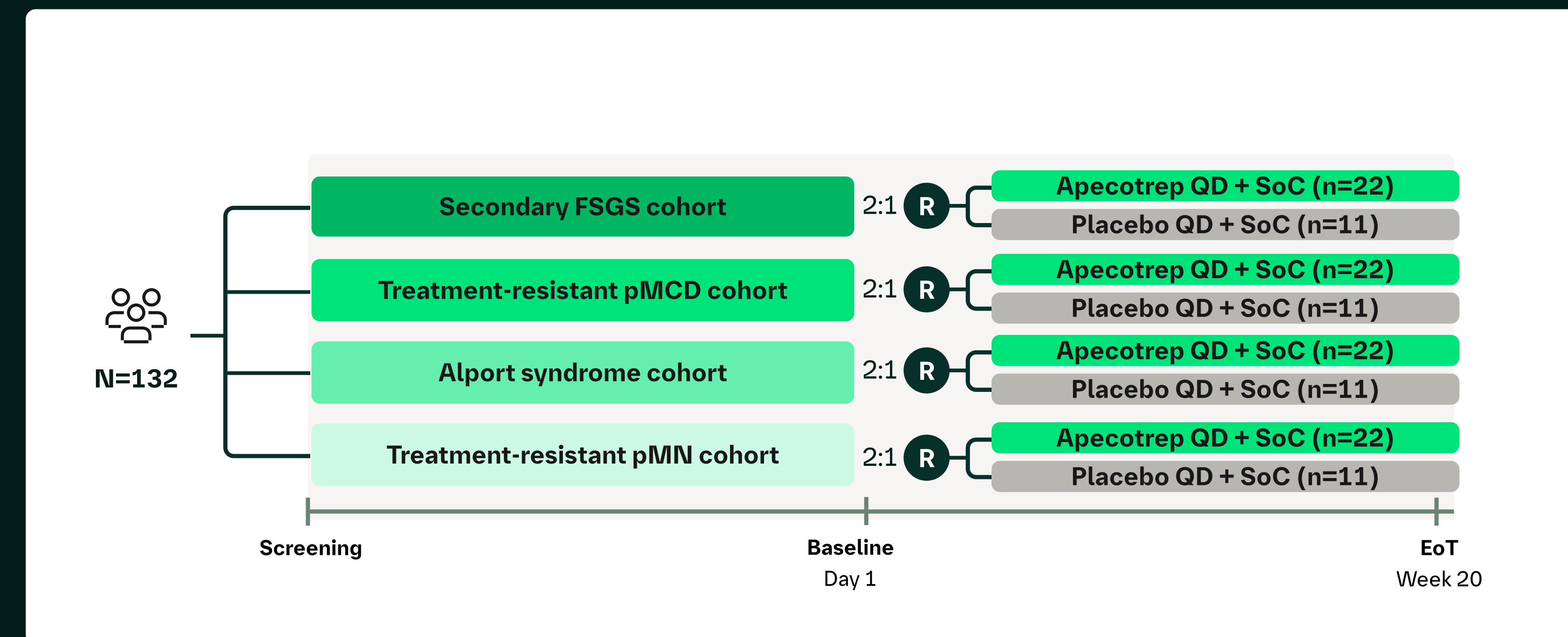
Phase II

ClinicalTrials.gov ID  
NCT07355296

Study start  
February 2026

Study end  
January 2028 (estimated)

### Study design



### Primary endpoint

- Change in 24-hour UPCR (mg/g) relative to baseline at Week 20

### Secondary endpoints

- Number of patients achieving at least 25% reduction in 24-hour UPCR relative to baseline at Week 20
- Number of patients achieving at least 40% reduction in 24-hour UPCR relative to baseline at Week 20
- Absolute change in eGFR<sub>cys</sub> from baseline to Week 20

#### Abbreviations:

eGFR, estimated glomerular filtration rate; eGFR<sub>cys</sub>, estimated glomerular filtration rate based on serum cystatin C; EoT, end of treatment; FSGS, focal segmental glomerulosclerosis; (p)MCD, (primary) minimal change disease; (p)MN, (primary) membranous nephropathy; QD, once a day; R, randomized; SoC, standard of care; TRPC6, transient receptor potential cation, subfamily C, member 6; UPCR, urine protein-creatinine ratio; W, week.

Overview

Study design

#### Reference:

ClinicalTrials.gov. NCT07355296 (accessed Mar 2026).

[← Back to Renal research](#)

[Browse this asset in other indications](#)

[PODOMOUNT-pFSGS →](#)

[Home](#)

[Cardiovascular-Renal-Metabolic pipeline](#)

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# Cardiovascular- Renal-Metabolic pipeline

We are building on our legacy of innovation for a range of cardiovascular, renal, and metabolic conditions



Home



Cardiovascular-Renal-Metabolic pipeline

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## Metabolic



Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist  
**SYNCHRONIZE™-1**  
Overweight or obesity without type 2 diabetes

Phase II

Phase III

View →



Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist  
**SYNCHRONIZE™-2**  
Overweight or obesity with type 2 diabetes

Phase II

Phase III

View →

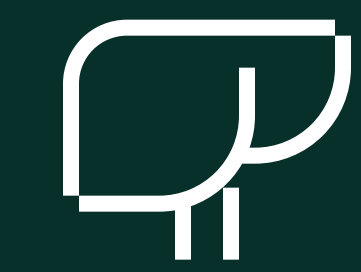


Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist  
**SYNCHRONIZE™-CVOT**  
Overweight or obesity with cardiovascular disease or chronic kidney disease

Phase II

Phase III

View →

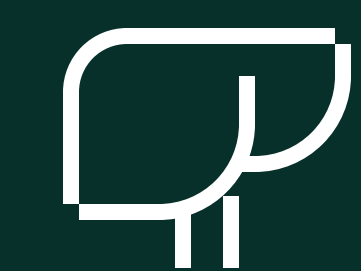


Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist  
**SYNCHRONIZE™-MASLD**  
Overweight or obesity and MASLD/MASH

Phase II

Phase III

View →

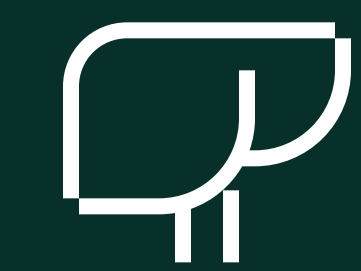


Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist  
**LIVERAGE™**  
Non-cirrhotic MASH and moderate or advanced liver fibrosis

Phase II

Phase III

View →



Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist  
**LIVERAGE™-CIRRHOSIS**  
Compensated MASH cirrhosis

Phase II

Phase III

View →

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# Cardiovascular-Renal-Metabolic pipeline

We are building on our legacy of innovation for a range of cardiovascular, renal, and metabolic conditions

[Home](#)

[Cardiovascular-Renal-Metabolic pipeline](#)

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## Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist SYNCHRONIZE™-1 Overweight or obesity without type 2 diabetes

Phase III

ClinicalTrials.gov ID  
NCT06066515

Study start  
November 2023

Study end  
February 2026

### Overview

A Phase III, randomized, double-blind, multicenter clinical trial evaluating the efficacy and safety of once-weekly survodutide in people living with obesity or overweight who do not have T2D.<sup>1,2</sup>

#### Asset description

**Survodutide** is a dual agonist of the glucagon receptor and GLP-1 receptor. Survodutide has the potential to induce weight loss and improve glycemic control while directly clearing liver fat, resolving inflammation, and reversing fibrosis.<sup>3-5</sup>

#### Intervention

Survodutide subcutaneous injection (6.0 mg or 3.6 mg) once per week compared with placebo.<sup>1,2</sup>

#### Patient population

Adults with overweight or obesity without T2D.<sup>1,2</sup>

#### Key inclusion criteria<sup>1,2</sup>

- Adults aged  $\geq 18$  years
- BMI  $\geq 30$  kg/m<sup>2</sup>, OR BMI  $\geq 27$  kg/m<sup>2</sup> and  $\geq 1$  obesity-related comorbidities (e.g. hypertension, dyslipidemia, or obstructive sleep apnea)
- History of  $\geq 1$  self-reported unsuccessful dietary effort to lose weight

#### Key exclusion criteria<sup>1,2</sup>

- Body weight change of  $>5\%$  within 3 months before screening
- Treatment with any medication for obesity within 3 months before screening
- HbA1c  $\geq 6.5\%$  ( $\geq 48$  mmol/mol) at screening
- History of T1D, T2D, or treatment with glucose-lowering agent started  $<3$  months before screening
- HF with NYHA functional class IV
- Known clinically significant gastric emptying abnormality
- History of chronic or acute pancreatitis or elevation of serum lipase or serum pancreatic amylase  $>2 \times$  ULN measured at screening
- Personal or family history of MTC or MEN 2

#### Abbreviations:

BMI, body mass index; GLP-1, glucagon-like peptide-1; HbA1c, glycated hemoglobin; MEN 2, multiple endocrine neoplasia syndrome type 2; MTC, medullary thyroid carcinoma; NYHA, New York Heart Association; T1D, type 1 diabetes; T2D, type 2 diabetes; ULN, upper limit of normal.

[Overview](#)

[Study design](#)

#### References:

1. ClinicalTrials.gov. NCT06066515 (accessed February 2026);
2. Wharton S et al. *Obesity (Silver Spring)* 2025;33:67–77;
3. Blüher M et al. *Diabetologia* 2024;67:470–482;
4. Sanyal AJ et al. *N Engl J Med* 2024;391:311–319;
5. Zimmermann T et al. *Mol Metab* 2022;66:101633.

[← Back to Metabolic research](#)

Browse this asset in other indications

[Overweight or obesity with T2D →](#)

[Overweight or obesity with CVD or CKD →](#)

[Overweight or obesity and MASLD/MASH →](#)

[Non-cirrhotic MASH and moderate or advanced liver fibrosis →](#)

[Compensated MASH cirrhosis →](#)

# Cardiovascular-Renal-Metabolic pipeline

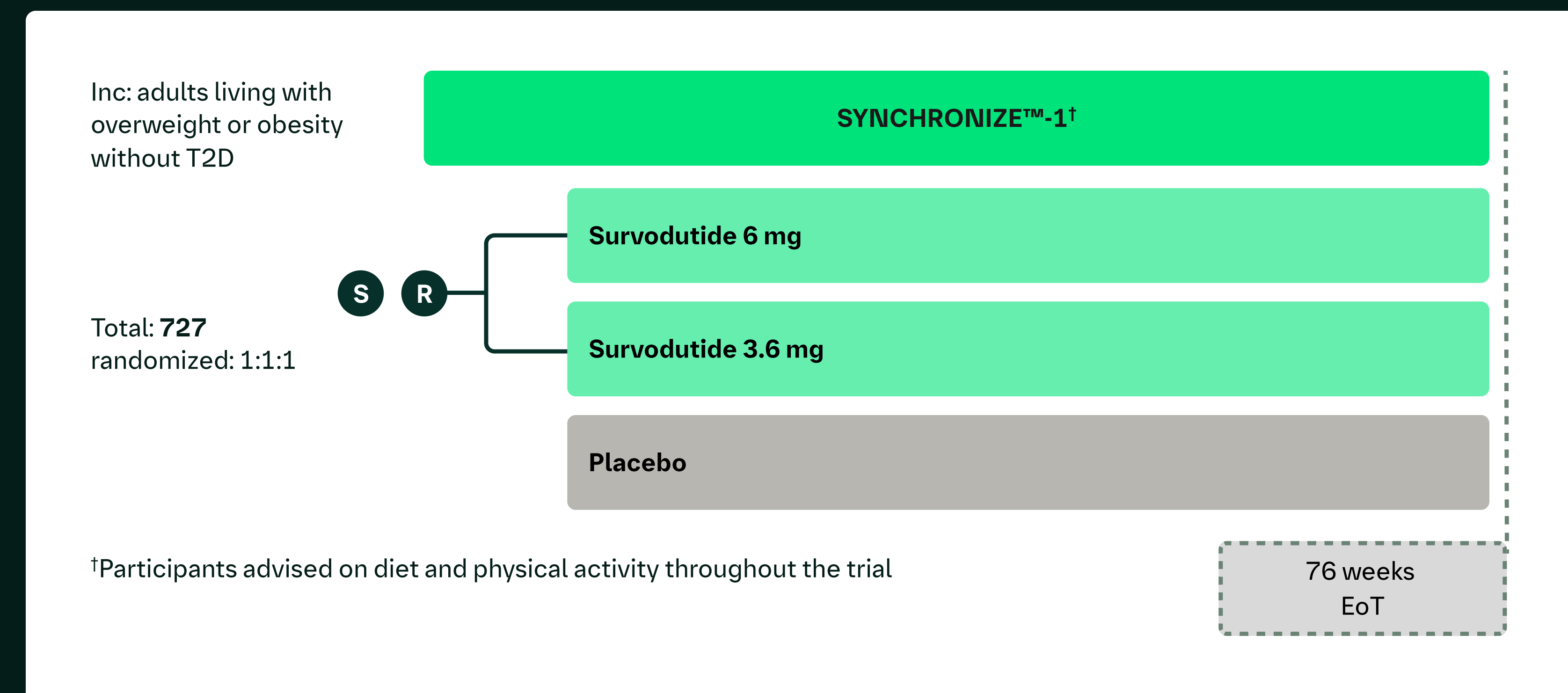
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Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist  
**SYNCHRONIZE™-1**  
 Overweight or obesity without type 2 diabetes

Phase III

ClinicalTrials.gov ID: NCT06066515 | Study start: November 2023 | Study end: February 2026

## Study design



### Primary endpoints<sup>1,2</sup>

- Percentage change from baseline to Week 76 in body weight
- $\geq 5\%$  body weight reduction from baseline to Week 76

### Secondary endpoints<sup>1,2</sup>

- $\geq 10\%$  body weight reduction from baseline to Week 76
- $\geq 15\%$  body weight reduction from baseline to Week 76
- $\geq 20\%$  body weight reduction from baseline to Week 76
- Absolute change from baseline to Week 76 in:
  - Body weight
  - BMI
  - Waist circumference
  - SBP and DBP
  - 'Capacity to Resist' domain and total score of Eating Behavior PRO
  - Eating Behavior PRO total score

**Abbreviations:** BMI, body mass index; DBP, diastolic blood pressure; EoT, end of treatment; GLP-1, glucagon-like peptide 1; PRO, patient-reported outcome; R, randomization; S, screening; SBP, systolic blood pressure.

Overview | **Study design**

**References:**  
 1. ClinicalTrials.gov. NCT06066515 (accessed February 2026); 2. Wharton S et al. Obesity (Silver Spring) 2025;33:67–77.

Home

Cardiovascular-Renal-Metabolic pipeline

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← Back to Metabolic research

Browse this asset in other indications

Overweight or obesity with T2D →

Overweight or obesity with CVD or CKD →

Overweight or obesity and MASLD/MASH →

Non-cirrhotic MASH and moderate or advanced liver fibrosis →

Compensated MASH cirrhosis →

# Cardiovascular-Renal-Metabolic pipeline

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[Home](#)

[Cardiovascular-Renal-Metabolic pipeline](#)

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Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist

## SYNCHRONIZE™-2 Overweight or obesity with type 2 diabetes

Phase III

ClinicalTrials.gov ID  
NCT06066528

Study start  
November 2023

Study end  
April 2026 (estimated)

### Overview

A Phase III, randomized, double-blind clinical trial evaluating the efficacy and safety of once-weekly survodutide in people living with obesity or overweight and T2D.<sup>1,2</sup>

#### Asset description

**Survodutide** is a dual agonist of the glucagon receptor and GLP-1 receptor. Survodutide has the potential to induce weight loss and improve glycemic control while directly clearing liver fat, resolving inflammation, and reversing fibrosis.<sup>3-5</sup>

#### Intervention

Survodutide subcutaneous injection (6.0 mg or 3.6 mg) once per week compared with placebo.<sup>1,2</sup>

#### Patient population

Adults with overweight or obesity and T2D.<sup>1,2</sup>

#### Key inclusion criteria<sup>1,2</sup>

- Adults aged  $\geq 18$  years
- BMI  $\geq 27$  kg/m<sup>2</sup>
- Diagnosis of T2D; HbA1c  $\geq 6.5\%$  ( $\geq 48$  mmol/mol) and  $< 10\%$  ( $< 86$  mmol/mol) at screening
- Currently treated for T2D with either diet and exercise alone or stable treatment (for at least 3 months prior to screening)
- History of  $\geq 1$  self-reported unsuccessful dietary effort to lose body weight

#### Key exclusion criteria<sup>1,2</sup>

- Body weight change of  $> 5\%$  within 3 months before screening
- Treatment with any medication for obesity within 3 months before screening
- Treatment with any medication for T2D other than stated in the inclusion criteria and GLP-1 receptor agonists and DPP-4 inhibitor
- Known clinically significant gastric emptying abnormality
- History of chronic or acute pancreatitis or elevation of serum lipase or amylase  $> 2 \times$  ULN at screening
- Personal or family history of MTC or MEN 2

#### Abbreviations:

BMI, body mass index; DPP-4, dipeptidyl peptidase-4; GLP-1, glucagon-like peptide 1; HbA1c, glycated hemoglobin; MEN 2, multiple endocrine neoplasia syndrome type 2; MTC, medullary thyroid carcinoma; T2D, type 2 diabetes; ULN, upper limit of normal.

[Overview](#)

[Study design](#)

#### References:

1. ClinicalTrials.gov. NCT06066528 (accessed February 2026);
2. Wharton S et al. *Obesity (Silver Spring)* 2025;33:67–77;
3. Blüher M et al. *Diabetologia* 2024;67:470–482;
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5. Zimmermann T et al. *Mol Metab* 2022;66:101633.

[← Back to Metabolic research](#)

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[Overweight or obesity without T2D →](#)

[Overweight or obesity with CVD or CKD →](#)

[Overweight or obesity and MASLD/MASH →](#)

[Non-cirrhotic MASH and moderate or advanced liver fibrosis →](#)

[Compensated MASH cirrhosis →](#)

# Cardiovascular-Renal-Metabolic pipeline

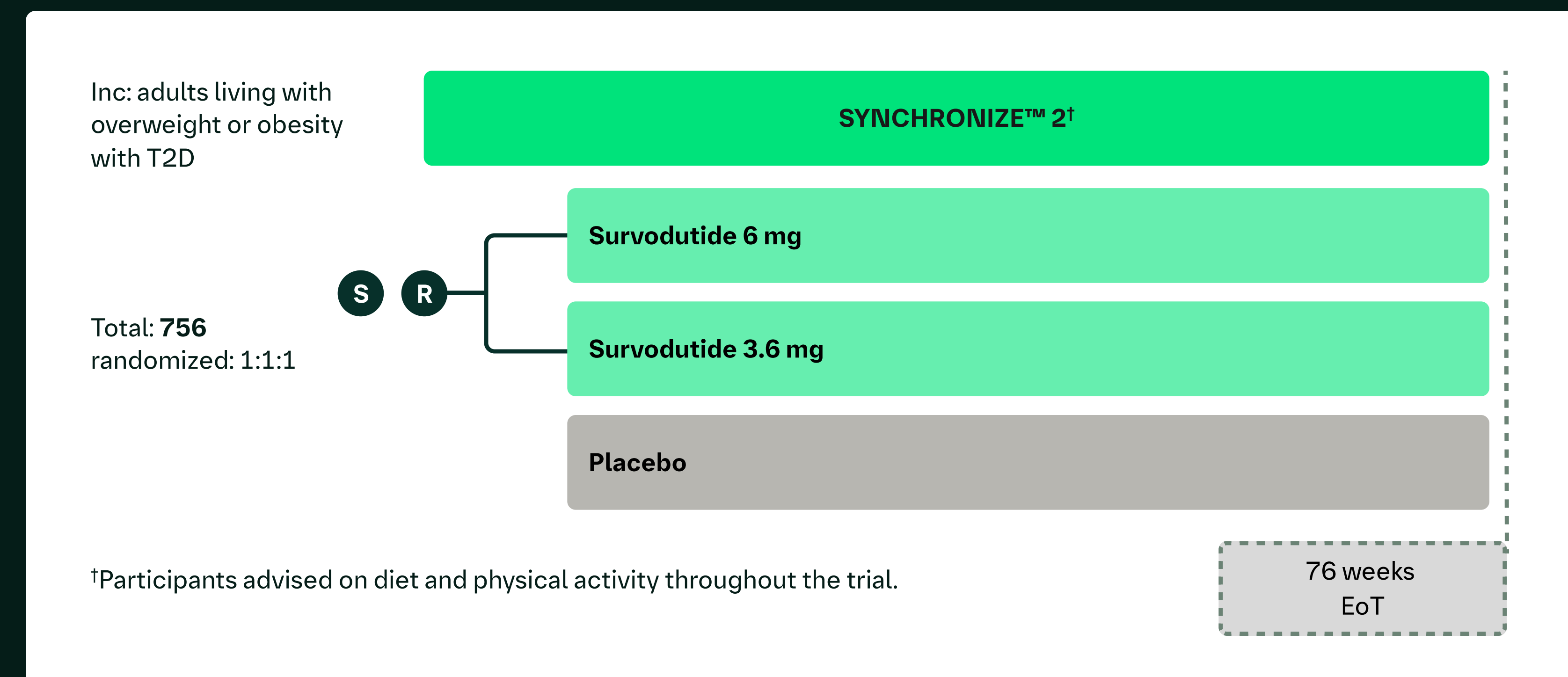
We are building on our legacy of innovation for a range of cardiovascular, renal, and metabolic conditions

Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist  
**SYNCHRONIZE™-2**  
 Overweight or obesity with type 2 diabetes

Phase III

ClinicalTrials.gov ID: NCT06066528 | Study start: November 2023 | Study end: April 2026 (estimated)

## Study design



### Primary endpoints<sup>1,2</sup>

- Percentage change from baseline to Week 76 in body weight
- ≥5% body weight reduction from baseline to Week 76

### Secondary endpoints<sup>1,2</sup>

- ≥10% body weight reduction from baseline to Week 76
- ≥15% body weight reduction from baseline to Week 76
- ≥20% body weight reduction from baseline to Week 76
- Absolute change from baseline to Week 76 in:
  - Body weight
  - BMI
  - HbA1c
  - Waist circumference
  - SBP and DBP
  - 'Capacity to Resist' domain and total score of Eating Behavior PRO
  - Eating Behavior PRO total score

**Abbreviations:** BMI, body mass index; DBP, diastolic blood pressure; EoT, end of treatment; GLP-1, glucagon-like peptide-1; HbA1c, glycated hemoglobin; PRO, patient-reported outcome; R, randomization; S, screening; SBP, systolic blood pressure; T2D, type 2 diabetes.

Overview | **Study design**

**References:**  
 1. ClinicalTrials.gov. NCT06066528 (accessed February 2026); 2. Wharton S et al. *Obesity (Silver Spring)* 2025;33:67–77.

[Home](#)

[Cardiovascular-Renal-Metabolic pipeline](#)

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[← Back to Metabolic research](#)

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[Overweight or obesity without T2D →](#)

[Overweight or obesity with CVD or CKD →](#)

[Overweight or obesity and MASLD/MASH →](#)

[Non-cirrhotic MASH and moderate or advanced liver fibrosis →](#)

[Compensated MASH cirrhosis →](#)

# Cardiovascular-Renal-Metabolic pipeline

We are building on our legacy of innovation for a range of cardiovascular, renal, and metabolic conditions

Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist

## SYNCHRONIZE™-CVOT

Overweight or obesity with cardiovascular disease or chronic kidney disease

Phase III

ClinicalTrials.gov ID  
NCT06077864

Study start  
November 2023

Study end  
July 2026 (estimated)

### Overview

A Phase III, randomized, double-blind, event-driven clinical trial evaluating the CV safety of survodutide in people living with overweight or obesity with established CVD or CKD, and/or at high risk of CVD.<sup>1,2</sup>

#### Asset description

**Survodutide** is a dual agonist of the glucagon receptor and GLP-1 receptor. Survodutide has the potential to induce weight loss and improve glycemic control while directly clearing liver fat, resolving inflammation, and reversing fibrosis.<sup>3-5</sup>

#### Intervention

Survodutide subcutaneous injection (6.0 mg or 3.6 mg) once per week compared with placebo.<sup>1,2</sup>

#### Patient population

Adults living with overweight or obesity with established CVD or CKD, and/or at least 2 weight-related complications/risk factors for CVD.<sup>1,2</sup>

#### Key inclusion criteria<sup>1,2</sup>

- Adults aged  $\geq 18$  years
- BMI  $\geq 27$  kg/m<sup>2</sup> with established CVD and/or  $\geq 2$  weight-related complications or risk factors for CVD or BMI  $\geq 30$  kg/m<sup>2</sup> at screening with established CVD or CKD, and/or  $\geq 2$  weight-related complications or risk factors for CVD

#### Key exclusion criteria<sup>1,2</sup>

- Previous treatment with GLP-1 receptor agonists  $< 3$  months before screening or  $< 3$  months between last dose of GLP-1 receptor agonists and GLP-1 receptor agonist/insulin/GIP combinations and screening
- T1D
- Known clinically significant gastric emptying abnormality
- History of either chronic or acute pancreatitis or elevation of serum lipase or amylase  $\geq 2 \times$  ULN at screening
- HF with NYHA functional class IV
- Impaired renal function
- Personal or family history of MTC or MEN 2

#### Abbreviations:

BMI, body mass index; CKD, chronic kidney disease; CV, cardiovascular; CVD, cardiovascular disease; CVOT, cardiovascular outcome trial; GIP, glucose-dependent insulinotropic polypeptide; GLP-1, glucagon-like peptide-1; HF, heart failure; MEN 2, multiple endocrine neoplasia syndrome type 2; MTC, medullary thyroid carcinoma; NYHA, New York Heart Association; T1D, type 1 diabetes; ULN, upper limit of normal.

#### References:

1. ClinicalTrials.gov. NCT06077864 (accessed February 2026);
2. Kosiborod MN *et al. JACC Heart Fail* 2024;12:2101–2109;
3. Blüher M *et al. Diabetologia* 2024;67:470–482;
4. Sanyal AJ *et al. N Engl J Med* 2024;391:311–319;
5. Zimmermann T *et al. Mol Metab* 2022;66:101633.

Overview

Study design

Home

Cardiovascular-Renal-Metabolic pipeline

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← Back to Metabolic research

Browse this asset in other indications

Overweight or obesity with T2D →

Overweight or obesity without T2D →

Overweight or obesity and MASLD/MASH →

Non-cirrhotic MASH and moderate or advanced liver fibrosis →

Compensated MASH cirrhosis →

# Cardiovascular-Renal-Metabolic pipeline

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Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist

## SYNCHRONIZE™-CVOT

Overweight or obesity with cardiovascular disease or chronic kidney disease

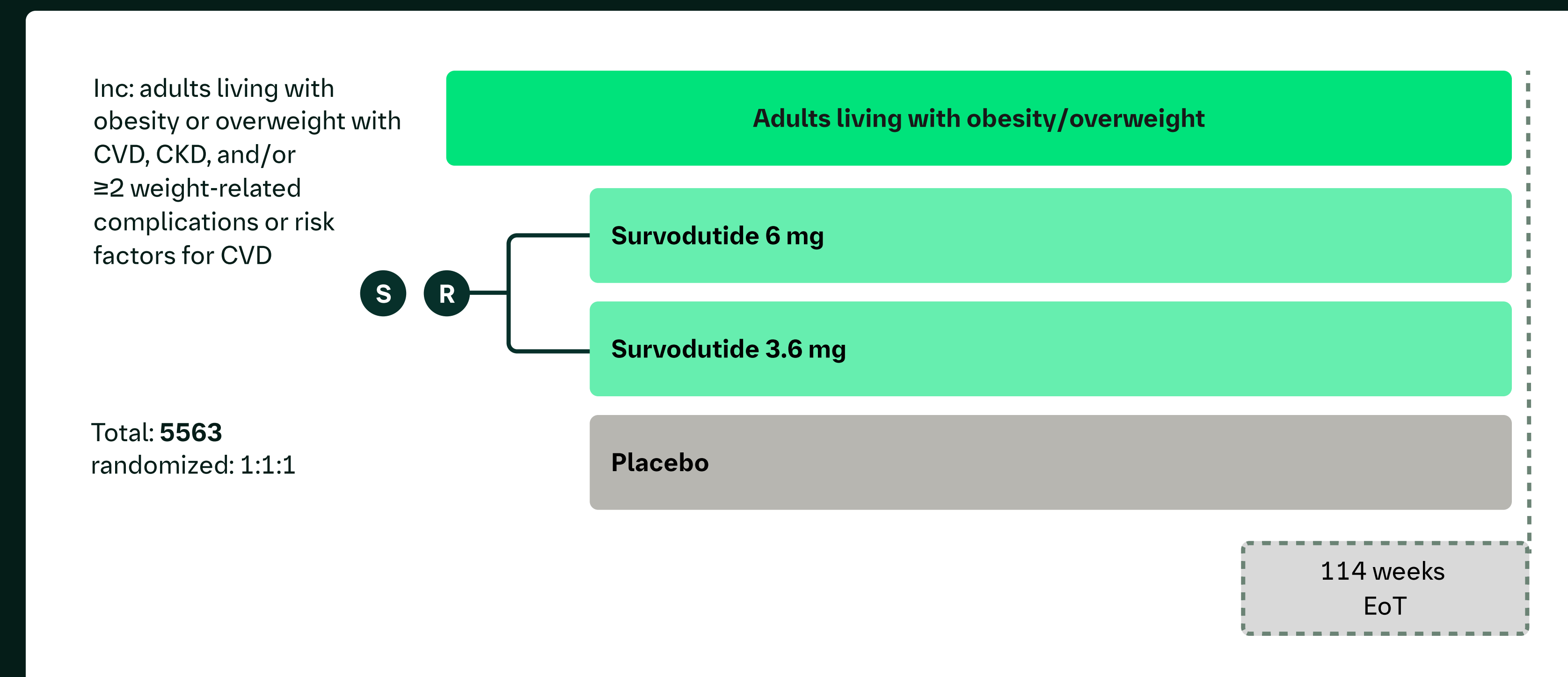
Phase III

ClinicalTrials.gov ID  
NCT06077864

Study start  
November 2023

Study end  
July 2026 (estimated)

### Study design



#### Primary endpoints<sup>1,2</sup>

- Time to first occurrence up to Week 114 of any of the adjudicated components of the composite endpoint consisting of:
  - CV death
  - Non-fatal stroke
  - Non-fatal MI
  - Ischemia-related coronary revascularization
  - HF event<sup>†</sup>

<sup>†</sup>Includes HHF, emergency room visit, urgent care visit, or urgent outpatient HF visit (5P-MACE).

#### Secondary endpoints<sup>1,2</sup>

- Time to first occurrence of any of the adjusted components of the composite endpoint consisting of CV death, non-fatal stroke, or non-fatal MI (3P-MACE) (to demonstrate non-inferiority)
- Absolute change from baseline to Week 72 in SBP
- Absolute change from baseline to Week 72 in waist circumference
- Absolute change from baseline to Week 72 in KCCQ-TSS in participants with HF
- Time to first occurrence of any of the adjudicated components of the composite endpoint consisting of CV death, non-fatal stroke, non-fatal MI, ischemia-related coronary revascularization, or HF event<sup>‡</sup> (5P-MACE) (to demonstrate superiority)

<sup>‡</sup>Includes HHF, emergency department visit, urgent care visit, or urgent outpatient HF visit.

#### Abbreviations:

3P/5P-MACE, 3-point/5-point major adverse cardiovascular events; BMI, body mass index; CKD, chronic kidney disease; CV, cardiovascular; CVD, cardiovascular disease; CVOT, cardiovascular outcome trial; EoT, end of treatment; GLP-1, glucagon-like peptide-1; HF, heart failure; HHF, hospitalization for heart failure; KCCQ-TSS, Kansas City Cardiomyopathy Questionnaire total symptom score; MI, myocardial infarction; R, randomization; S, screening; SBP, systolic blood pressure.

Overview

Study design

#### References:

1. ClinicalTrials.gov. NCT06077864 (accessed February 2026); 2. Kosiborod MN et al. *JACC Heart Fail* 2024;12:2101–2109.

Home

Cardiovascular-Renal-Metabolic pipeline

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← Back to Metabolic research

Browse this asset in other indications

Overweight or obesity with T2D →

Overweight or obesity without T2D →

Overweight or obesity and MASLD/MASH →

Non-cirrhotic MASH and moderate or advanced liver fibrosis →

Compensated MASH cirrhosis →

# Cardiovascular-Renal-Metabolic pipeline

We are building on our legacy of innovation for a range of cardiovascular, renal, and metabolic conditions

Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist

### SYNCHRONIZE™-MASLD Overweight or obesity and MASLD/MASH

Phase III

ClinicalTrials.gov ID: NCT06309992 | Study start: April 2024 | Study end: November 2025 (estimated)

#### Overview

A Phase III, double-blind, randomized, placebo-controlled, multicenter clinical trial evaluating the effect of once-weekly survodutide on liver fat and body weight in people living with obesity or overweight and with presumed or confirmed MASLD/MASH.<sup>1</sup>

#### Asset description

**Survodutide** is a dual agonist of the glucagon receptor and GLP-1 receptor. Survodutide has the potential to directly clear liver fat, resolve inflammation, and reverse fibrosis while inducing weight loss and improving glycemic control.<sup>2-4</sup>

#### Intervention

Survodutide subcutaneous injection once per week compared with placebo.<sup>1</sup>

#### Patient population

Adults living with obesity or overweight and confirmed or presumed MASLD/MASH.<sup>1</sup>

#### Key inclusion criteria<sup>1</sup>

- Adults aged  $\geq 18$  years with confirmed/presumed MASLD/MASH
- BMI  $\geq 30$  kg/m<sup>2</sup>, or BMI  $\geq 27$  kg/m<sup>2</sup> and  $\geq 1$  obesity-related comorbidity (including hypertension, dyslipidemia, obstructive sleep apnea, CVD, or T2D)
- History of  $\geq 1$  self-reported unsuccessful dietary effort to lose body weight

#### Key exclusion criteria<sup>1</sup>

- Current or history ( $< 5$  years) of significant alcohol consumption (females  $> 140$  g/week, males  $> 210$  g/week)
- Intake of medications associated with liver injury, hepatic steatosis, and steatohepatitis
- History of other chronic liver diseases
- Cirrhosis
- Current decompensated liver disease or previous hepatic decompensation
- Evidence of portal hypertension

#### Abbreviations:

BMI, body mass index; CVD, cardiovascular disease; GLP-1, glucagon-like peptide-1; MASH, metabolic dysfunction-associated steatohepatitis; MASLD, metabolic dysfunction-associated steatotic liver disease; T2D, type 2 diabetes.

#### References:

1. ClinicalTrials.gov. NCT06309992 (accessed February 2026); 2. Blüher M et al. *Diabetologia* 2024;67:470–482; 3. Sanyal AJ et al. *N Engl J Med* 2024;391:311–319; 4. Zimmermann T et al. *Mol Metab* 2022;66:101633.

Home

Cardiovascular-Renal-Metabolic pipeline

Overview

Study design

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← Back to Metabolic research

Browse this asset in other indications

Overweight or obesity with T2D →

Overweight or obesity without T2D →

Overweight or obesity with CVD or CKD →

Non-cirrhotic MASH and moderate or advanced liver fibrosis →

Compensated MASH cirrhosis →

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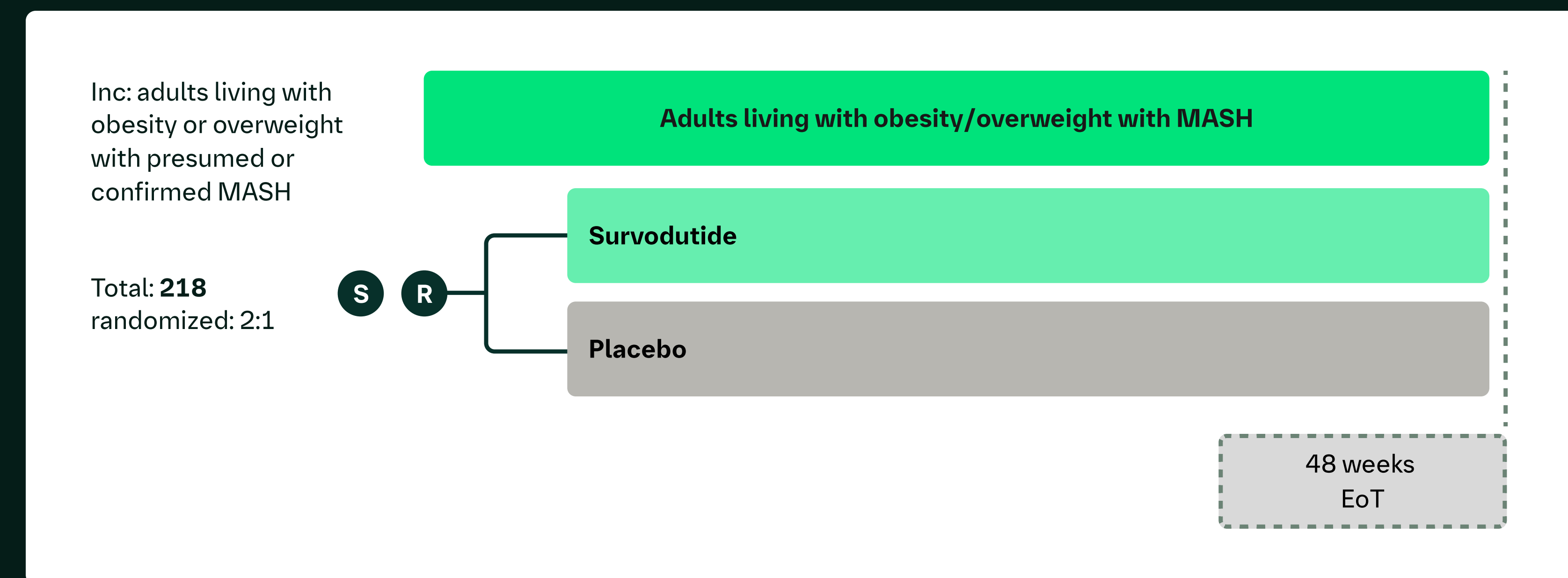
Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist

## SYNCHRONIZE™-MASLD Overweight or obesity and MASLD/MASH

Phase III

ClinicalTrials.gov ID: NCT06309992 | Study start: April 2024 | Study end: November 2025 (estimated)

### Study design



### Primary endpoints

- Reduction in liver fat content of  $\geq 30\%$  from baseline to Week 48 (assessed by MRI-PDFF)
- Percentage change from baseline to Week 48 in body weight

### Secondary endpoints

- Absolute and percentage changes from baseline to Week 48 in:
  - Liver fat content (MRI-PDFF)
  - ALT levels
  - Waist circumference
  - Liver stiffness (assessed by MRE)
  - Liver volume (assessed by MRI)
- Reduction from baseline to Week 48 in iron-corrected T1 levels of  $\geq 80$  ms
- Absolute change from baseline to Week 48 in HOMA-IR

#### Abbreviations:

ALT, alanine transaminase; EoT, end of treatment; HOMA-IR, homeostatic model assessment for insulin resistance; MASH, metabolic dysfunction-associated steatohepatitis; MASLD, metabolic dysfunction-associated steatotic liver disease; MRE, magnetic resonance elastography; MRI, magnetic resonance imaging; MRI-PDFF, magnetic resonance imaging proton density fat fraction; R, randomization; S, screening; T1, longitudinal relaxation time.

Overview

Study design

#### Reference:

ClinicalTrials.gov. NCT06309992 (accessed February 2026).

Home

Cardiovascular-Renal-Metabolic pipeline

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← Back to Metabolic research

Browse this asset in other indications

Overweight or obesity with T2D →

Overweight or obesity without T2D →

Overweight or obesity with CVD or CKD →

Non-cirrhotic MASH and moderate or advanced liver fibrosis →

Compensated MASH cirrhosis →

# Cardiovascular-Renal-Metabolic pipeline

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[Home](#)

[Cardiovascular-Renal-Metabolic pipeline](#)

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Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist  
**LIVERAGE™**  
Non-cirrhotic MASH and moderate or advanced liver fibrosis

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Phase III

ClinicalTrials.gov ID  
NCT06632444

Study start  
October 2024

Study end  
December 2031 (estimated)

## Overview

A Phase III, double-blind, randomized, placebo-controlled multicenter trial evaluating the long-term efficacy and safety of once-weekly survodutide in people living with non-cirrhotic MASH and moderate or advanced liver fibrosis (F2–F3).<sup>1</sup>

### Asset description

**Survodutide** is a dual agonist of the glucagon receptor and GLP-1 receptor. Survodutide has the potential to directly clear liver fat, resolve inflammation, and reverse fibrosis while inducing weight loss and improving glycaemic control.<sup>2-4</sup>

### Intervention

Survodutide subcutaneous injection once per week compared with placebo.<sup>1</sup>

## Patient population

Adults with non-cirrhotic MASH and moderate or advanced liver fibrosis (F2–F3).<sup>1</sup>

### Key inclusion criteria<sup>1</sup>

- Adults aged ≥18 years with a diagnosis of MASH (NAS ≥4)
- Stable body weight<sup>†</sup> and a willingness to maintain a stable diet and physical activity levels throughout the trial

<sup>†</sup>Defined as <5% change in body weight 3 months prior to the screening or during the period between the historical biopsy and randomization.

### Key exclusion criteria<sup>1</sup>

- Any of the following liver laboratory test abnormalities at screening:
  - Serum AST and/or ALT elevation ≥5× ULN
  - Platelet count <140,000/mm<sup>3</sup> (<140 G/L)
  - Alkaline phosphatase >2× ULN
  - Abnormal synthetic liver function, defined as:
    - Albumin <3.5 g/dL (35.0 g/L)
    - Or INR of prothrombin time >1.3
    - Or total serum bilirubin concentration ≥1.5× ULN
- Current evidence/history of liver disease other than MASH
- Histologically documented liver cirrhosis (fibrosis stage F4), either at screening or in a historical biopsy
- History of/current diagnosis of HCC
- History of/planned liver transplant
- Inability/unwillingness to undergo a liver biopsy
- History of portal hypertension or presence of decompensated liver disease
- MELD score ≥12

#### Abbreviations:

ALT alanine transaminase; AST, aspartate transaminase; F, fibrosis stage; GLP-1, glucagon-like peptide-1; HCC, hepatocellular carcinoma; INR, international normalized ratio; MASH, metabolic dysfunction–associated steatohepatitis; MELD, model for end-stage liver disease; NAS, non-alcoholic fatty liver disease activity score; ULN, upper limit of normal.

[Overview](#)

[Study design](#)

#### References:

1. ClinicalTrials.gov. NCT06632444 (accessed February 2026); 2. Blüher M *et al. Diabetologia* 2024;67:470–482; 3. Sanyal AJ *et al. N Engl J Med* 2024;391:311–319; 4. Zimmermann T *et al. Mol Metab* 2022;66:101633.

[← Back to Metabolic research](#)

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[Overweight or obesity with T2D →](#)

[Overweight or obesity without T2D →](#)

[Overweight or obesity with CVD or CKD →](#)

[Overweight or obesity and MASLD/MASH →](#)

[Compensated MASH cirrhosis →](#)

# Cardiovascular-Renal-Metabolic pipeline

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Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist  
**LIVERAGE™**  
 Non-cirrhotic MASH and moderate or advanced liver fibrosis

**NOW ENROLLING**

Scan the QR code to find out more on LIVERAGE research and sites



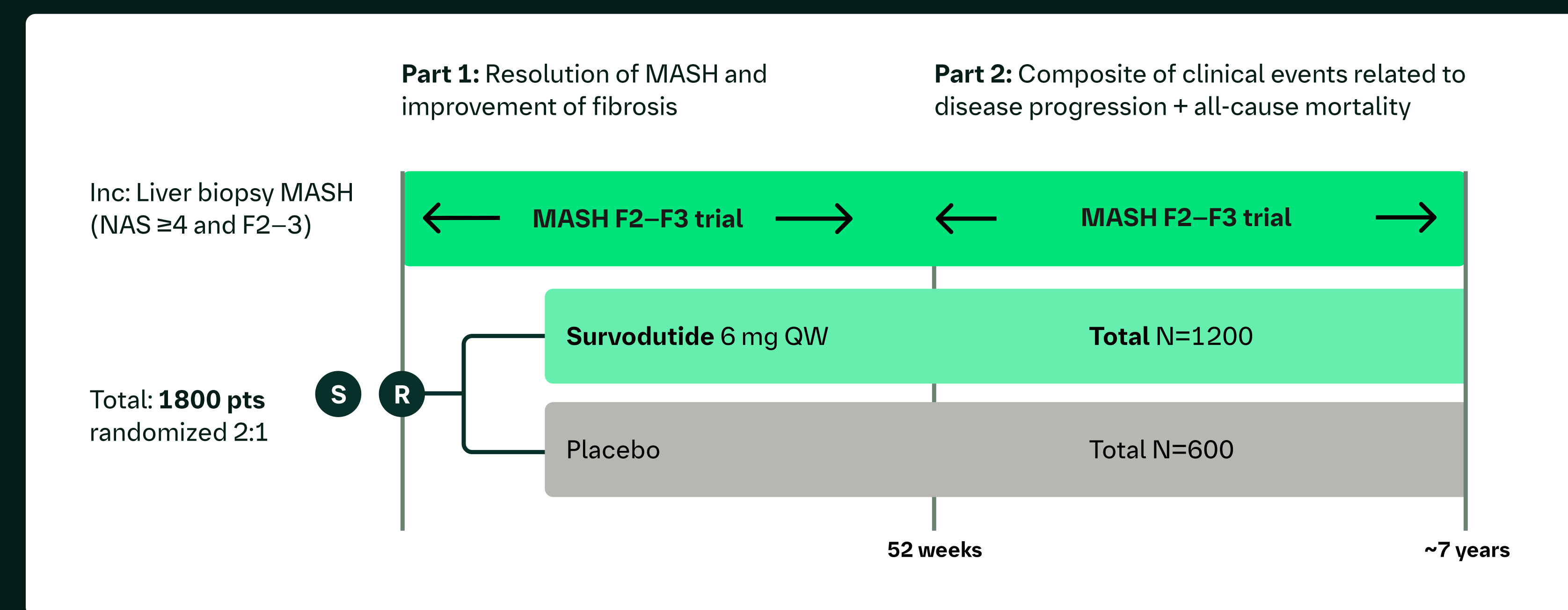
Phase III

ClinicalTrials.gov ID  
NCT06632444

Study start  
October 2024

Study end  
December 2031 (estimated)

## Study design



### Primary endpoints

#### Part 1 (Week 52):

- Resolution of MASH without worsening of liver fibrosis on the MASH CRN fibrosis score
- $\geq$ 1-point improvement in fibrosis stage with no worsening of MASH

#### Part 2 (up to 7 years):

- Time to first occurrence of any of the following components of the composite endpoint:
  - Progression to cirrhosis (F4)
  - All-cause mortality
  - Liver transplant
  - Hepatic decompensation event(s)
  - Worsening of MELD score to  $\geq$ 15
  - Progression to CSPH

### Secondary endpoints

#### Part 1 (Week 52)

- Percentage change from baseline in body weight
- Absolute change from baseline in HbA1c (T2D only)
- Absolute change from baseline in ELF score
- Absolute change from baseline in liver stiffness (assessed by VCTE)

#### Part 2:

- No progression of fibrosis (assessed by histology)
- Percentage change from baseline to Week 114 in body weight
- Absolute change from baseline to Week 114 in HbA1c
- Absolute change from baseline to Week 114 in ELF score
- Absolute change from baseline to Week 114 in liver stiffness (assessed by VCTE)
- No progression of fibrosis (assessed by histology) at 7 years
- Occurrence of all-cause hospitalization (first and recurrent) up to 7 years
- Time to first occurrence of any of the adjudicated components of the composite endpoint 5P-MACE up to 7 years

#### Abbreviations:

5P-MACE, 5-point major adverse cardiovascular events; CRN, Clinical Research Network; CSPH, clinically significant portal hypertension; ELF, enhanced liver fibrosis; F, fibrosis stage; GLP-1, glucagon-like peptide-1; HbA1c, glycated hemoglobin; MASH, metabolic dysfunction-associated steatohepatitis; MELD, model for end-stage liver disease; NAS, non-alcoholic fatty liver disease activity score; QW, once weekly; R, randomized; S, screening; T2D, type 2 diabetes; VCTE, vibration-controlled transient elastography.

Overview

Study design

#### Reference:

ClinicalTrials.gov. NCT06632444 (accessed February 2026).

[Home](#)

[Cardiovascular-Renal-Metabolic pipeline](#)

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[Overweight or obesity without T2D →](#)

[Overweight or obesity with CVD or CKD →](#)

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[Compensated MASH cirrhosis →](#)

# Cardiovascular-Renal-Metabolic pipeline

We are building on our legacy of innovation for a range of cardiovascular, renal, and metabolic conditions

Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist

## LIVERAGE™-CIRRHOSIS Compensated MASH cirrhosis

NOW ENROLLING

Scan the QR code to find out more on LIVERAGE research and sites



ClinicalTrials.gov ID  
NCT06632457

Study start  
December 2024

Study end  
June 2029 (estimated)

Phase III

### Overview

A Phase III, double-blind, randomized, placebo-controlled, multicenter clinical trial evaluating liver-related clinical outcomes and safety of once-weekly survodutide in people living with compensated MASH cirrhosis (F4).<sup>1</sup>

#### Asset description

**Survodutide** is a dual agonist of the glucagon receptor and GLP-1 receptor. Survodutide has the potential to directly clear liver fat, resolve inflammation, and reverse fibrosis while inducing weight loss and improving glycemic control.<sup>2-4</sup>

#### Intervention

Survodutide subcutaneous injection once per week compared with placebo.<sup>1</sup>

### Patient population

Adults with compensated MASH cirrhosis and BMI  $\geq 27$  kg/m<sup>2</sup> ( $\geq 25$  kg/m<sup>2</sup> in Asian participants).<sup>1</sup>

#### Key inclusion criteria<sup>1</sup>

- Adults aged  $\geq 18$  years with compensated MASH cirrhosis<sup>†</sup>
- BMI  $\geq 27$  kg/m<sup>2</sup> (or 25 kg/m<sup>2</sup> for Asian participants)

<sup>†</sup>Confirmed by historical biopsy ( $\leq 5$  years) or non-invasive tests and metabolic comorbidities.

#### Key exclusion criteria<sup>1</sup>

- Current or history ( $\leq 5$  years) of significant alcohol consumption (females  $>140$  g/week, males  $>210$  g/week)
- MELD score  $>12$
- Current or history of hepatic decompensation event<sup>‡</sup>
- Albumin  $<3.5$  g/dL ( $<35.0$  g/L)
- International normalized ratio  $>1.3$  (unless due to therapeutic anticoagulants)
- Total bilirubin  $>1.2 \times$  ULN
- Alkaline phosphatase  $>1.5 \times$  ULN
- Platelets  $<90,000/\mu\text{L}$  ( $<90$  GI/L)
- Chronic liver diseases other than MASH
- Viral hepatitis B or C
- Serum AST and/or ALT  $\geq 5 \times$  ULN
- Alcoholic or drug-induced liver disease
- History of/planned liver transplantation
- Procedures for portal hypertension

<sup>‡</sup>Including portal hypertension–related upper gastrointestinal bleeding, ascites, or hepatic encephalopathy  $\geq$  Grade 1 according to the West Haven criteria.

#### Abbreviations:

ALT, alanine transaminase; AST, aspartate transaminase; BMI, body mass index; F, fibrosis stage; GLP-1, glucagon-like peptide-1; MASH, metabolic dysfunction–associated steatohepatitis; MELD, model for end-stage liver disease; ULN, upper limit of normal.

Overview

Study design

#### References:

1. ClinicalTrials.gov. NCT06632457 (accessed February 2026); 2. Blüher M et al. *Diabetologia* 2024;67:470–482; 3. Sanyal AJ et al. *N Engl J Med* 2024;391:311–319; 4. Zimmermann T et al. *Mol Metab* 2022;66:101633.

Home

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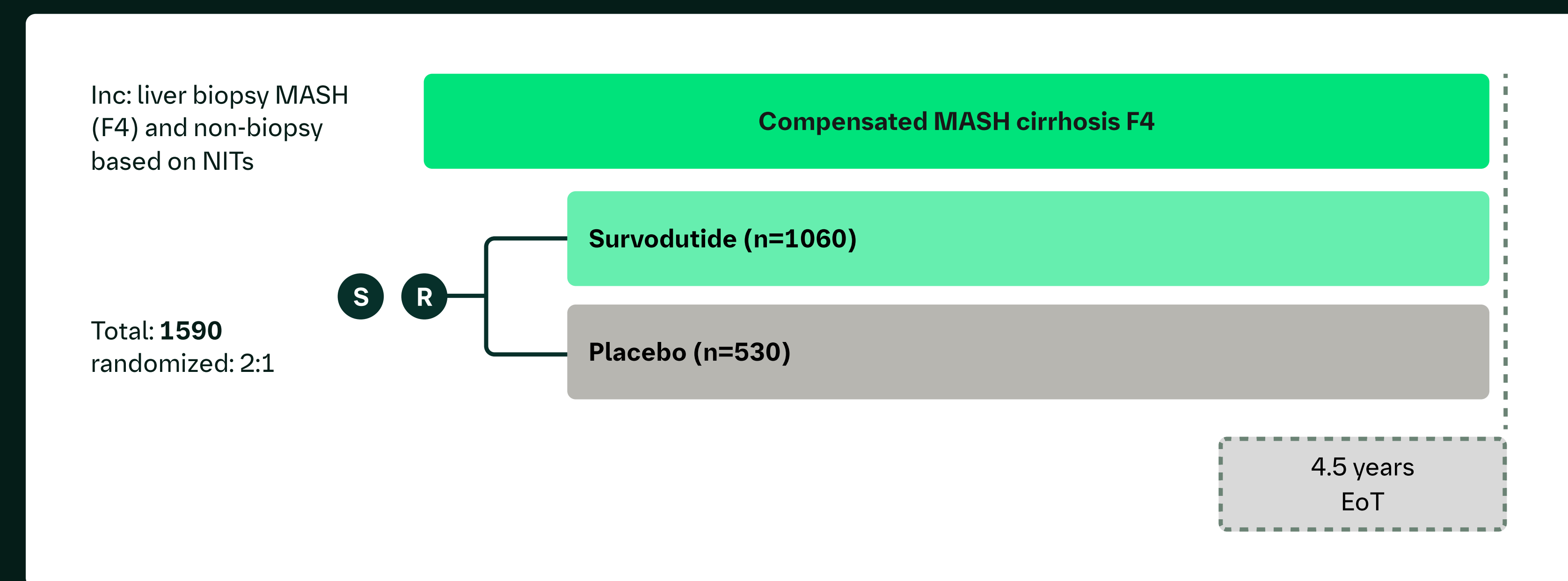
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June 2029 (estimated)

Phase III

## Study design



### Primary endpoint

- Time to first occurrence of any of the following components of the composite endpoint up to 4.5 years:
  - All-cause mortality
  - Liver transplant
  - Hepatic decompensation events
  - Worsening of MELD score to  $\geq 15$
  - Progression to CSPH

### Secondary endpoints

- Absolute change from baseline to Week 76 in ELF score
- Percentage change from baseline to Week 76 in body weight
- Absolute change from baseline to Week 76 in HbA1c (T2D only)
- Absolute change from baseline to Week 76 in liver stiffness (assessed by VCTE/FibroScan®)

#### Abbreviations:

CSPH, clinically significant portal hypertension; ELF, enhanced liver fibrosis; EoT, end of treatment; F, fibrosis stage; GLP-1, glucagon-like peptide-1; HbA1c, glycated hemoglobin; MASH, metabolic dysfunction-associated steatohepatitis; MELD, model for end-stage liver disease; NIT, non-invasive test; R, randomization; S, screening; T2D, type 2 diabetes; VCTE, vibration-controlled transient elastography.

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Home

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← Back to Metabolic research

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Overweight or obesity with T2D →

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