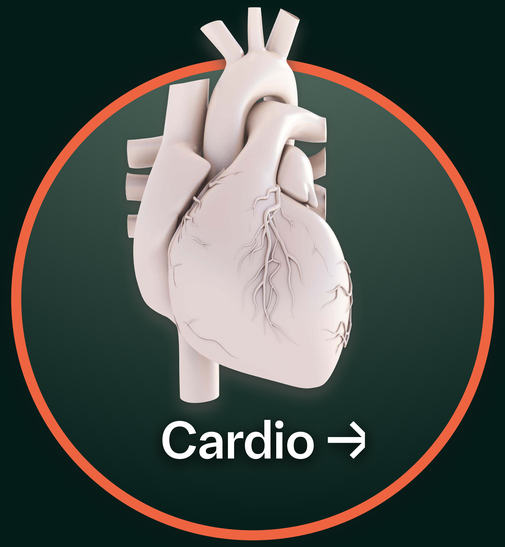
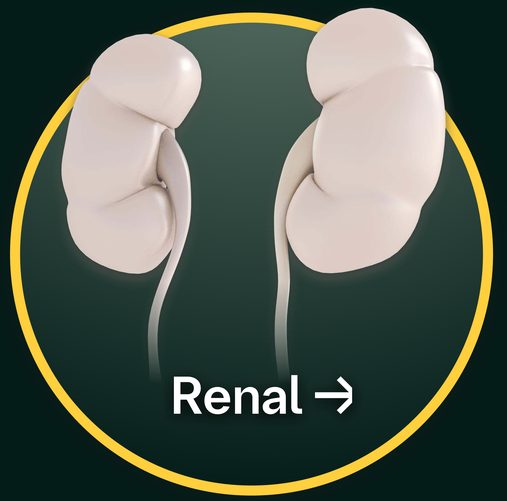
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Cardiovascular-Renal-Metabolic pipeline

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







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Cardiovascular-Renal-Metabolic pipeline

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Cardiovascular-Renal-Metabolic pipeline

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 MN)
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
View →

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Cardio

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

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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)

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%.[1]

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.[2–15]

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

Intervention

Vicadrostat/empagliflozin compared with empagliflozin.[1]

Patient population

Chronic HF diagnosed ≥3 months before visit 1, with LVEF ≥40% and NYHA class II–IV at visit 1.[1]

Key inclusion criteria[1]

- ≥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[1]

- 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.

Overview | Study design

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.

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HF with LVEF <40% →

T2D, hypertension, and established CVD →

CKD (EASi-SYNC™) →

CKD (EASi-KIDNEY®) →

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Vicadrostat/empagliflozin | SGLT2i/ASi

EASi-HF® Preserved
Heart failure with LVEF ≥40%

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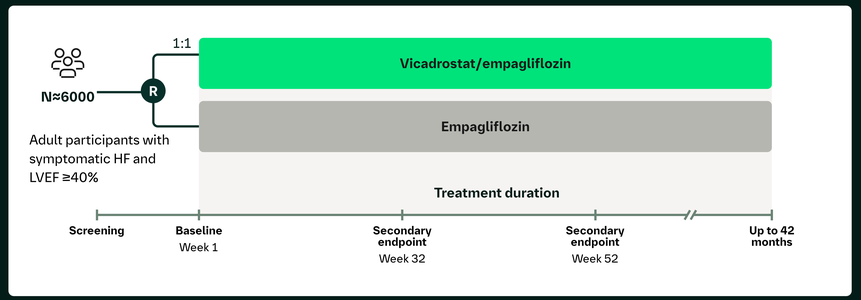
Phase III

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 HHFs (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).

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Cardiovascular-Renal-Metabolic pipeline

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Vicadrostat/empagliflozin | SGLT2i/ASi

EASi-HF® Reduced Heart failure with LVEF <40%

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Phase III

ClinicalTrials.gov ID NCT06935370 | **Study start** May 2025 | **Study end** February 2029 (estimated)

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%.[1]

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.[2–15]

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

Intervention

Vicadrostat/empagliflozin compared with empagliflozin.[1]

Patient population

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

Key inclusion criteria[1]

- ≥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[1]

- 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.

Overview | Study design

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. Díez 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.

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HF with LVEF ≥40% →

T2D, hypertension, and established CVD →

CKD (EASi-SYNC™) →

CKD (EASi-KIDNEY®) →

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Vicadrostat/empagliflozin | SGLT2i/ASi

EASi-HF® Reduced
Heart failure with LVEF <40%

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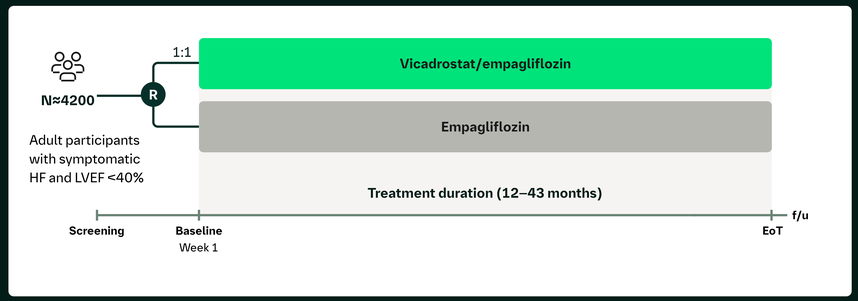
Phase III

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 HHFs (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).

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Vicadrostat/empagliflozin | SGLT2i/ASi

Phase III

EASi-PROTKT™

Type 2 diabetes, hypertension, and established cardiovascular disease

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 vicadrostat/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.[1]

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.[3–16]

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

Intervention

Vicadrostat/empagliflozin compared with empagliflozin.[1]

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).[1,2]

Key inclusion criteria[1]

- ≥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[1]

- 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.

Overview | Study design

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.

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HF with LVEF ≥40%

Heart failure with LVEF <40%

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Cardio

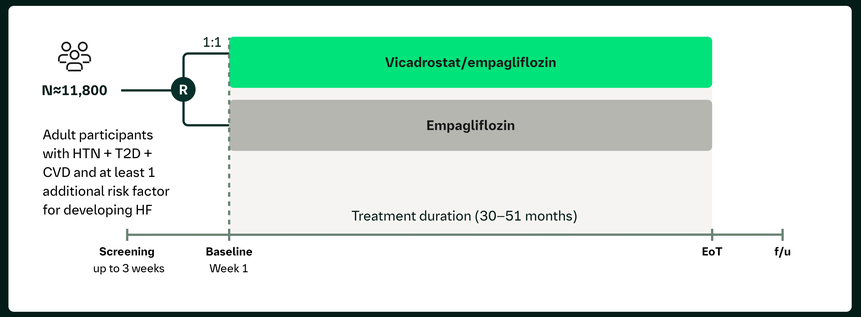
Vicadrostat/empagliflozin | SGLT2i/ASi

Phase III

EASi-PROTKT™
Type 2 diabetes, hypertension, and established cardiovascular disease

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).

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Browse this asset in other indications

HF with LVEF ≥40%

Heart failure with LVEF <40%

CKD (EASi-SYNC™)

CKD (EASi-KIDNEY®)

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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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Cardiovascular-Renal-Metabolic pipeline

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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.[1]

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.[2–15]

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

Intervention

Staggered initiation of empagliflozin followed by vicadrostat/empagliflozin compared with simultaneous initiation of vicadrostat/empagliflozin.[1]

Patient population

CKD at risk of progression.[1]

Key inclusion criteria[1]

- ≥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^2, 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[1]

- 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

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.

Overview | Study design

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. Díez 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.

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HF with LVEF <40% →

T2D, hypertension, and established CVD →

CKD (EASi-KIDNEY®) →

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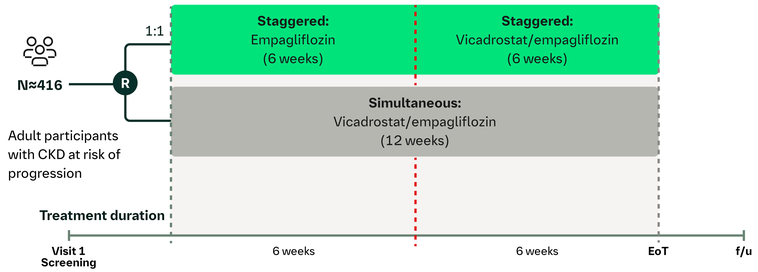
Vicadrostat/empagliflozin | SGLT2i/ASi

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 m²) from baseline to Week 14 and Week 16

Key secondary endpoints

- Absolute change in eGFR (mL/min/1.73 m²) 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).

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Vicadrostat/empagliflozin | SGLT2i/ASi

EASi-KIDNEY®
Chronic kidney disease

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Phase III

ClinicalTrials.gov ID NCT06531824 | **Study start** August 2024 | **Study end** August 2028 (estimated)

Overview

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

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.[2–15]

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

Intervention

Vicadrostat/empagliflozin compared with empagliflozin.[1,5]

Patient population

CKD at risk of progression with or without T2D.[1]

Key inclusion criteria[1]

- 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 m² or
  - CKD-EPI eGFR ≥45 to <90 mL/min/1.73 m² 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[1]

- 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.

Overview | Study design

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; 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.

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T2D, hypertension, and established CVD →

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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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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.[1]

Asset description

Apecotrep is an oral TRPC6 inhibitor differentiated from current SoC by a non-immunosuppressive, podocyte-targeted MoA.[2–4]

Intervention

Apecotrep given as an oral tablet once a day + SoC compared with placebo + SoC.[1]

Patient population

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

Key inclusion criteria[1]

- Male or female patients aged ≥12 years
- Biopsy-proven pFSGS or documented TRPC6 gene mutation causing FSGS
- Mean UPCR ≥1500 mg/g based on first morning void urine sample during screening
- Weight ≥40 kg and BMI ≤40 kg/m² at screening visit
- eGFR ≥25 mL/min/1.73 m² at screening visit

Key exclusion criteria[1]

- 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.

Overview | Study design

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.

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PODOMOUNT-Basket

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Apecotrep | TRPC6 inhibitor

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

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Phase II

ClinicalTrials.gov ID NCT07355296 | **Study start** February 2026[1] | **Study end** January 2028 (estimated)[1]

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.[1]

Asset description

Apecotrep is an oral TRPC6 inhibitor differentiated from current SoC by a non-immunosuppressive, podocyte-targeted MoA.[2–4]

Intervention

Apecotrep given as an oral table once a day compared with placebo + SoC.[1]

Patient population

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

Key inclusion criteria[1]

- Male and female patients aged ≥18 years (≥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 ≤160 mmHg (adult participant ≥18 years) or SBP ≤140 mmHg (participants <18 years) at screening
- BMI ≤40 kg/m^2 at screening visit
- eGFR ≥25 mL/min/1.73 m^2 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 ≥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 ≥12 weeks prior to screening with no plan to change the dose
- Patients treated with oral glucocorticoids have to be at a dose ≤10 mg/d for ≥4 weeks prior to screening with no plan to change the dose

Key exclusion criteria[1]

- 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× 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.

Overview | Study design

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.

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Renal

Apecotrep | TRPC6 inhibitor

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

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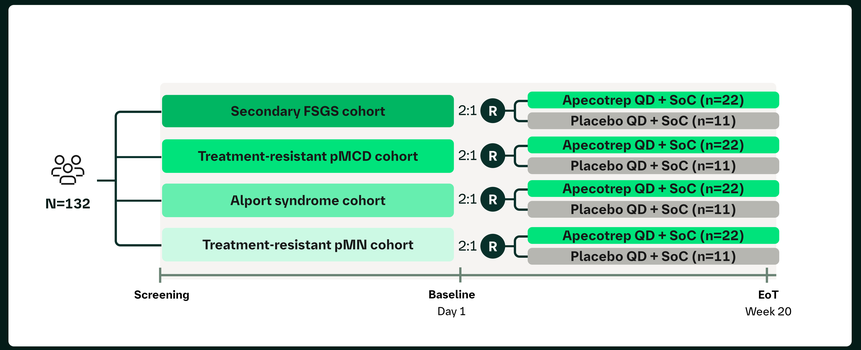
Phase II

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 eGFRcys from baseline to Week 20

Abbreviations:
eGFR, estimated glomerular filtration rate; eGFRcys, 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).

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PODOMOUNT-pFSGS

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Vicadrostat/empagliflozin | SGLT2i/ASi

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Chronic kidney disease

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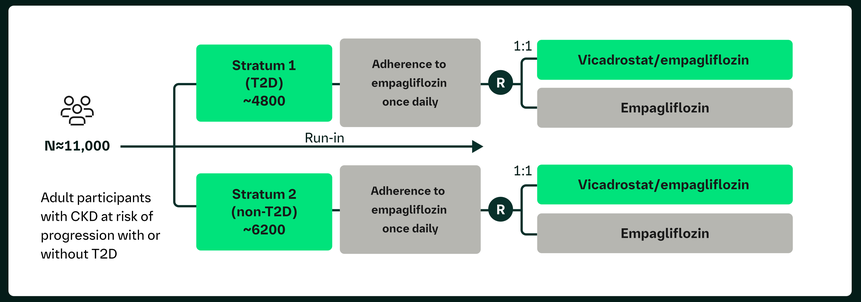
Phase III

ClinicalTrials.gov ID NCT06531824

Study start August 2024

Study end August 2028 (estimated)

Study design



Primary composite outcome

- Kidney disease progression, defined as kidney failure or sustained decline of ≥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).

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HF with LVEF <40% →

T2D, hypertension, and established CVD →

CKD (EASi-SYNC™) →

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

Phase III

SYNCHRONIZE™-1
Overweight or obesity without type 2 diabetes

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.[1,2]

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.[3–5]

Intervention

Survodutide subcutaneous injection (6.0 mg or 3.6 mg) once per week compared with placebo.[1,2]

Patient population

Adults with overweight or obesity without T2D.[1,2]

Key inclusion criteria[1,2]

- Adults aged ≥18 years
- BMI ≥30 kg/m², OR BMI ≥27 kg/m² and ≥1 obesity-related comorbidities (e.g. hypertension, dyslipidemia, or obstructive sleep apnea)
- History of ≥1 self-reported unsuccessful dietary effort to lose weight

Key exclusion criteria[1,2]

- Body weight change of >5% within 3 months before screening
- Treatment with any medication for obesity within 3 months before screening
- HbA1c ≥6.5% (≥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 × 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.

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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 →

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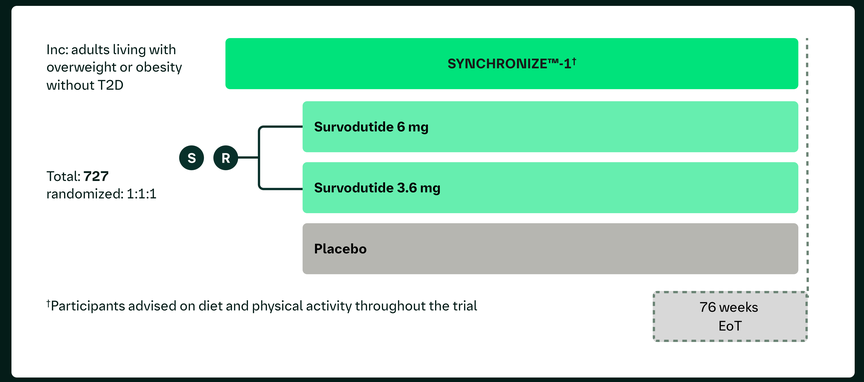
Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist

Phase III

SYNCHRONIZE™-1
Overweight or obesity without type 2 diabetes

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

Study design



Primary endpoints[1,2]

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

Secondary endpoints[1,2]

- ≥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
  - 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.

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Cardiovascular-Renal-Metabolic pipeline

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Date of Preparation: April 2026
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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 →

Boehringer Ingelheim

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

Phase III

SYNCHRONIZE™-2
Overweight or obesity with type 2 diabetes

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.[1,2]

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.[3–5]

Intervention

Survodutide subcutaneous injection (6.0 mg or 3.6 mg) once per week compared with placebo.[1,2]

Patient population

Adults with overweight or obesity and T2D.[1,2]

Key inclusion criteria[1,2]

- Adults aged ≥18 years
- BMI ≥27 kg/m^2
- Diagnosis of T2D; HbA1c ≥6.5% (≥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 ≥1 self-reported unsuccessful dietary effort to lose body weight

Key exclusion criteria[1,2]

- 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 × 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; 4. Sanyal AJ *et al. N Engl J Med* 2024;391:311–319; 5. Zimmermann T *et al. Mol Metab* 2022;66:101633.

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Cardiovascular-Renal-Metabolic pipeline

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Browse this asset in other indications

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 →

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Metabolic

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

Phase III

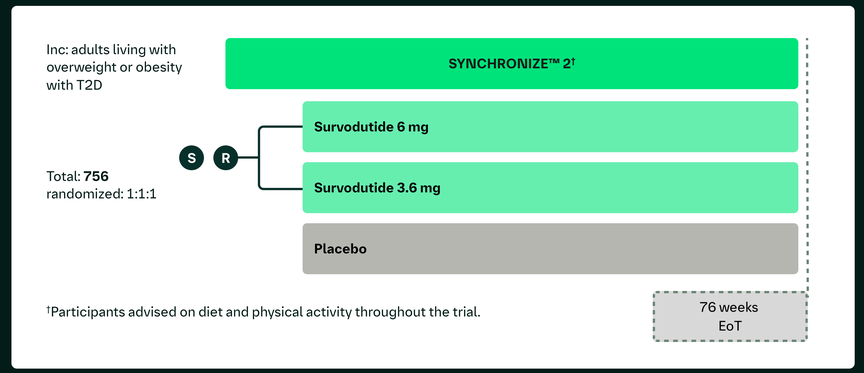
SYNCHRONIZE™-2
Overweight or obesity with type 2 diabetes

ClinicalTrials.gov ID
NCT06066528

Study start
November 2023

Study end
April 2026 (estimated)

Study design



Primary endpoints[1,2]

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

Secondary endpoints[1,2]

- ≥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.

← Back to Metabolic research

Browse this asset in other indications

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 →

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

Phase III

SYNCHRONIZE™-CVOT
Overweight or obesity with cardiovascular disease or chronic kidney disease

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.[1,2]

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.[3–5]

Intervention

Survodutide subcutaneous injection (6.0 mg or 3.6 mg) once per week compared with placebo.[1,2]

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.[1,2]

Key inclusion criteria[1,2]

- Adults aged ≥18 years
- BMI ≥27 kg/m^2 with established CVD and/or ≥2 weight-related complications or risk factors for CVD or BMI ≥30 kg/m^2 at screening with established CVD or CKD, and/or ≥2 weight-related complications or risk factors for CVD

Key exclusion criteria[1,2]

- 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 ≥2 × 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.

Overview | Study design

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.

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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 →

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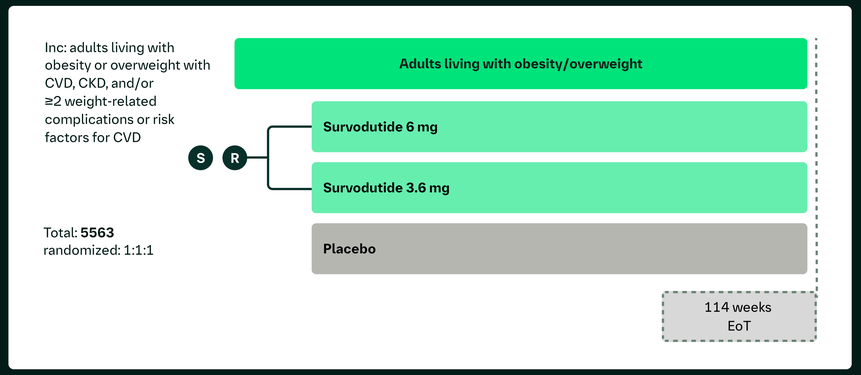
Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist

Phase III

SYNCHRONIZE™-CVOT
Overweight or obesity with cardiovascular disease or chronic kidney disease

ClinicalTrials.gov ID NCT06077864 | **Study start** November 2023 | **Study end** July 2026 (estimated)

Study design



Primary endpoints[1,2]

- 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†

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

Secondary endpoints[1,2]

- 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‡ (5P-MACE) (to demonstrate superiority)

‡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.

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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 →

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

Phase III

SYNCHRONIZE™-MASLD
Overweight or obesity and MASLD/MASH

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.[1]

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.[2–4]

Intervention

Survodutide subcutaneous injection once per week compared with placebo.[1]

Patient population

Adults living with obesity or overweight and confirmed or presumed MASLD/MASH.[1]

Key inclusion criteria[1]

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

Key exclusion criteria[1]

- 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.

Overview | Study design

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.

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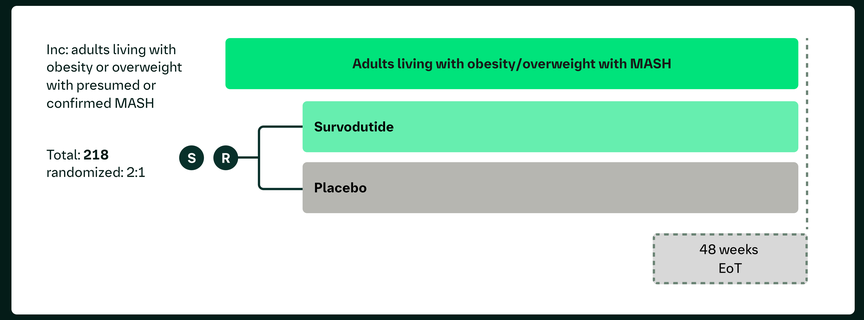
Survodutide (BI 456906) | Glucagon/GLP-1 receptor dual agonist

Phase III

SYNCHRONIZE™-MASLD
Overweight or obesity and MASLD/MASH

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

Study design



Primary endpoints

- Reduction in liver fat content of ≥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 ≥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).

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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

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).[1]

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.[2–4]

Intervention

Survodutide subcutaneous injection once per week compared with placebo.[1]

Patient population

Adults with non-cirrhotic MASH and moderate or advanced liver fibrosis (F2–F3).[1]

Key inclusion criteria[1]

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

†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[1]

- Any of the following liver laboratory test abnormalities at screening:
- Serum AST and/or ALT elevation ≥5× ULN
  - Platelet count <140,000/mm^3 (<140 GI/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.

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Cardiovascular-Renal-Metabolic pipeline

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Browse this asset in other indications

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 →

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Metabolic

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

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Non-cirrhotic MASH and moderate or advanced liver fibrosis

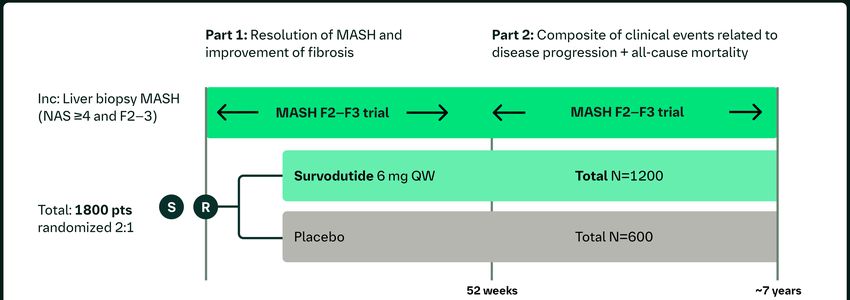
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Phase III

ClinicalTrials.gov ID NCT06632444 | **Study start** October 2024 | **Study end** December 2031 (estimated)

Study design



Primary endpoints

Part 1 (Week 52):
- Resolution of MASH without worsening of liver fibrosis on the MASH CRN fibrosis score
- ≥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 ≥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)
- No progression of fibrosis (assessed by histology)

Part 2:
- 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).

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Browse this asset in other indications

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 →

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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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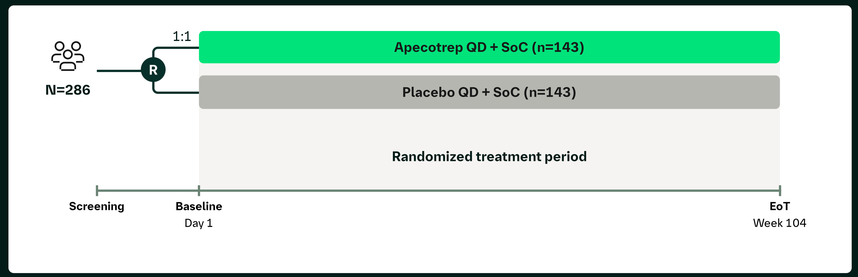
Phase III

ClinicalTrials.gov ID NCT07220083

Study start February 2026

Study end December 2029 (estimated)

Study design



Primary endpoint

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

Secondary endpoints

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

Abbreviations:
eGFRcys, 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).

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PODOMOUNT-Basket →

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

LIVERAGE™-CIRRHOSIS
Compensated MASH cirrhosis

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Phase III

ClinicalTrials.gov ID NCT06632457 | **Study start** December 2024 | **Study end** June 2029 (estimated)

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).[1]

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.[2–4]

Intervention

Survodutide subcutaneous injection once per week compared with placebo.[1]

Patient population

Adults with compensated MASH cirrhosis and BMI ≥27 kg/m² (≥25 kg/m² in Asian participants).[1]

Key inclusion criteria[1]

- Adults aged ≥18 years with compensated MASH cirrhosis†
- BMI ≥27 kg/m² (or 25 kg/m² for Asian participants)

†Confirmed by historical biopsy (≤5 years) or non-invasive tests and metabolic comorbidities.

Key exclusion criteria[1]

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

‡Including portal hypertension–related upper gastrointestinal bleeding, ascites, or hepatic encephalopathy ≥ 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.

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Cardiovascular-Renal-Metabolic pipeline

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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 →

Non-cirrhotic MASH and moderate or advanced liver fibrosis →

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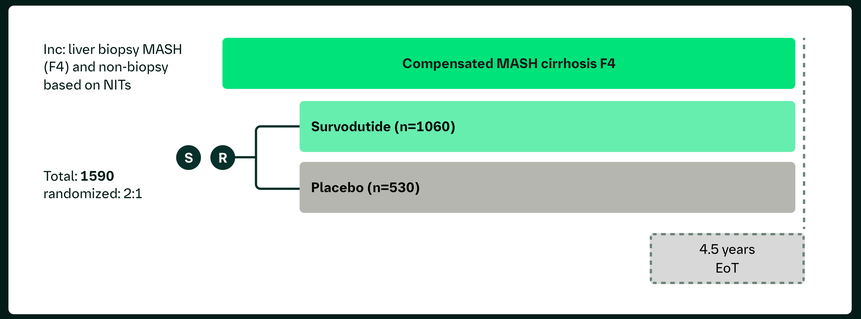
Phase III

ClinicalTrials.gov ID
NCT06632457

Study start
December 2024

Study end
June 2029 (estimated)

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 ≥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.

Overview | Study design

Reference:
ClinicalTrials.gov. NCT06632457 (accessed February 2026).

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