LAPaL
THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE

Developed by

medicines patent pool

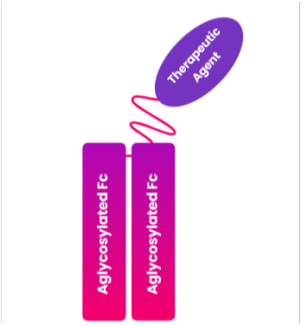
UNIVERSITY OF LIVERPOOL

CELT

Supported by

Unitaid
SAVE LIVES FASTER

leap



LAPSCOVERY (Long Acting Protein / Peptide Discovery Platform Technology)

Developer(s)

Hanmi Pharmaceutical

Originator

https://hanmipharm.com/

South Korea

Hanmi Pharmaceutical Ltd., founded in 1973 in South Korea, is a leading R&D-driven company specializing in innovative drug development. It pioneers platform technologies like LAPSCOVERY for long-acting biologics and ORASCOVERY for oral chemotherapeutics. Hanmi collaborates with global firms, including Sanofi, Eli Lilly, and Genentech, advancing oncology, diabetes, and rare disease treatments.

Sponsor(s)

No sponsor indicated

Partnerships

Merck Sharp & Dohme

https://www.msd.com/

Technology information

Type of technology

aglycosylated Fc based particles

Administration route

Intravenous, Subcutaneous, Intramuscular

Development state and regulatory approval

Active Pharmaceutical Ingredient (API)

efocipegtrutide (GLP-1 triple agonist)

Development Stage

Phase II

Regulatory Approval

Efocipegtrutide Fast Track designation and orphan drug status for the treatment of nonalcoholic steatohepatitis (MASH).

Description

LAPSCOVERY is a long-acting platform technology designed to extend the half-life of biologics administered systemically. The API (therapeutic proteins) is fused with aglycosylated Fc fragments, which enhances the pharmacokinetics of the API. The monomeric Fc fragments help to reduce receptor-mediated clearance, thereby delaying renal filtration and prolonging the therapeutic effect.

Technology highlight

1. The flexible linker minimizes loss of intrinsic activity 2. Highest bioavailability reduces dose level 3. Low Immunogenicity 4. Minimal Loss of activity 5. Increased cellular solubility 6. No loss of neonatal Fc receptor (FcRn) binding

Technology main components

1. Two Aglycolated Fc Fragments 2. Carrier (e.g., Ethylene vinyl acetate) 3. Non-peptide biocompatible polymer (Linker) 4. Excipients—lactose , dextrose , sucrose , sorbitol, mannitol , xylitol , erythritol , maltitol , starch , acacia rubber, alginate , gelatin , calcium phosphate , calcium silicate , cellulose , methyl cellulose , microcrystalline cellulose , polyvinylpyrrolidone, water , methyl hydroxybenzoate , propyl hydroxybenzoate , talc , magnesium stearate , mineral oil , etc. 5. Fillers, anti-coagulant , lubricants, humectants, flavoring agents, preservatives, etc.

Information on the raw materials sourcing, availability and anticipated price

Not provided

Delivery device(s)

Single-dose prefilled syringe

APIs compatibility profile

API desired features

Small molecules

LAPSCOVERY specially focuses on protein-based small molecules designed to target epidermal growth factor receptors (EGFR), including HER2 and HER4, with compounds such as poziotinib,Tuspetinib.

Proteins

LAPSCOVERY targets a diverse range of proteins, including insulin homologues, human growth hormone, GLP-1 agonists, glucagon, granulocyte colony-stimulating factor, interleukins, and bispecific antibodies.

Additional solubility data

Not provided

Additional stability data

Not provided

API loading: Maximum drug quantity to be loaded

50-75 wt%

API co-administration

2 different APIs : Not provided

LogP

Not provided

Not provided

Scale-up and manufacturing prospects

Scale-up prospects

Hanmi has a bio plant in Pyeongtaek for the LAPSCOVERY-based biologics occupying a 4,600 m^2 area.

Tentative equipment list for manufacturing

Not provided

Manufacturing

Not provided

Specific analytical instrument required for characterization of formulation

Not provided

Clinical trials

HM-FLUT-301

Identifier

NCT02941679

Link

https://clinicaltrials.gov/study/NCT02941679

Phase

Phase III

Status

Unknown status

Sponsor

Hanmi Pharmaceutical Company Limited

More details

A phase 3 study to evaluate efficacy and safety of HCP1202

Purpose

Clinical Efficacy and Safety Evaluation of HCP1202 in COPD Patients

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2016-10-01

Anticipated Date of Last Follow-up

2016-10-19

Estimated Primary Completion Date

2018-02-01

Estimated Completion Date

2018-04-01

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

No

Comments about the studied populations

Inclusion Criteria: * Male or Female adults aged ≥ 40 years. * Patients diagnosed with COPD. * Patients with FEV1/FVC \< 0.7 at screening. * Patients with a post-bronchodilator FEV1 \< 60% of the predicted normal OR Patients with a post-bronchodilator FEV1 \< 80% of the predicted normal if COPD exacerbation is moderate or worse developed at least twice within the past year or hospitalization occurred at least once within the past year due to COPD exacerbation. * Patients with COPD Assessment Test ≥ 10. * Patients with a history (current or ex-smokers) of smoking 10 pack-years or more (e.g. 10 pack years = 1 pack/day x 10 years, or ½ pack/day x 20 years). * Patients who understand the process of clinical trial and signed written informed consent. Exclusion Criteria: * Patients with a cur

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

252

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Double-blind masking

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

AMPLITUDE-M

Identifier

NCT03353350

Link

https://clinicaltrials.gov/study/NCT03353350

Phase

Phase III

Status

Completed

Sponsor

Hanmi Pharmaceutical Company Limited

More details

Primary Objective: To demonstrate the superiority of once weekly injection of efpeglenatide in comparison to placebo in glycated hemoglobin (HbA1c) change in participants with T2DM (Type 2 Diabetes Mellitus) inadequately controlled with diet and exercise. Secondary Objectives: * To demonstrate the superiority of once-weekly injection of efpeglenatide in comparison to placebo on glycemic control * To demonstrate the superiority of once-weekly injection of efpeglenatide in comparison to placebo on body weight * To evaluate the safety of once-weekly injection of efpeglenatide

Purpose

Efficacy and Safety of Efpeglenatide Versus Placebo in Patients With Type 2 Diabetes Mellitus Inadequately Controlled With Diet and Exercise

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2017-12-05

Anticipated Date of Last Follow-up

2022-01-11

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2020-01-29

Actual Completion Date

2020-09-07

Studied populations

Age Cohort

- Adults

Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

No

Comments about the studied populations

Inclusion criteria: * Participants must be at least 18 years of age at the time of signing the informed consent. * Participants with T2DM, and treated with diet and exercise. * Hemoglobin A1c between 7.0% and 10.0% (inclusive) measured by the central laboratory at Screening. Exclusion criteria: * Clinically relevant history of gastrointestinal disease associated with prolonged nausea and vomiting, including (but not limited to) gastroparesis, unstable and not controlled gastroesophageal reflux disease within 6 months prior to Screening or history of surgery affecting gastric emptying. * History of pancreatitis (unless pancreatitis was related to gallstone and cholecystectomy has been performed) and pancreatitis during previous treatment with incretin therapies, chronic pancreatitis, and

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

406

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

HM-LIL2-101

Identifier

NCT06724016

Link

https://clinicaltrials.gov/study/NCT06724016

Phase

Phase I

Status

Recruiting

Sponsor

Hanmi Pharmaceutical Company Limited

More details

This is a First-in-Human, Phase 1, Dose-Escalation and Dose-Expansion study of HM16390, as a single agent to assess safety, tolerability, MTD, RP2D, PK, and efficacy in patients with advanced or metastatic solid tumors. Dose-Escalation Part is planned to establish the MTD or RDs for the randomized Dose-Ranging Part. Based on the results of the Dose-Escalation Part, additional eligible subjects will be randomized 1:1 into at each dose level. After a comprehensive review of available data from both Dose-Escalation Part and Dose-Ranging Part, the potential RP2D to be tested in the Dose-Expansion Part is determined. Dose-Expansion Part is designed to assess the potential efficacy of HM16390 as a single agent when administered at the potential RP2D to subjects in indication-specific expansion

Purpose

Dose Escalation and Expansion Study of HM16390 in Advanced or Metastatic Solid Tumors

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2024-12-11

Actual Start Date

Not provided

Anticipated Date of Last Follow-up

2024-12-11

Estimated Primary Completion Date

2030-03-01

Estimated Completion Date

2030-03-01

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

No

Comments about the studied populations

Key Inclusion Criteria: * Have a histologically and/or cytologically confirmed advanced or metastatic solid tumor and have failed or are intolerant to standard therapy with clinical benefit. * Patients in the Dose-Escalation Part must have evaluable or measurable disease at baseline and the patients for Dose-Ranging and Dose-Expansion Part must have at least one measurable lesion at baseline by computed tomography (CT) or magnetic resonance imaging (MRI) per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1. * Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. * Age of 18 years or older (or country's legal age of majority if the legal age was \>18 years) * Adequate renal function. * Adequate hematologic function. * Adequate liver function. Key Exclusion Crit

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

215

Allocation

Not provided

Intervention model

Single group assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

HM-FLUT-301

Identifier

NCT02941679

Link

https://clinicaltrials.gov/study/NCT02941679

Phase

Phase III

Status

Unknown status

Sponsor

Hanmi Pharmaceutical Company Limited

More details

A phase 3 study to evaluate efficacy and safety of HCP1202

Purpose

Clinical Efficacy and Safety Evaluation of HCP1202 in COPD Patients

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2016-10-01

Anticipated Date of Last Follow-up

2016-10-19

Estimated Primary Completion Date

2018-02-01

Estimated Completion Date

2018-04-01

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

No

Comments about the studied populations

Inclusion Criteria: * Male or Female adults aged ≥ 40 years. * Patients diagnosed with COPD. * Patients with FEV1/FVC \< 0.7 at screening. * Patients with a post-bronchodilator FEV1 \< 60% of the predicted normal OR Patients with a post-bronchodilator FEV1 \< 80% of the predicted normal if COPD exacerbation is moderate or worse developed at least twice within the past year or hospitalization occurred at least once within the past year due to COPD exacerbation. * Patients with COPD Assessment Test ≥ 10. * Patients with a history (current or ex-smokers) of smoking 10 pack-years or more (e.g. 10 pack years = 1 pack/day x 10 years, or ½ pack/day x 20 years). * Patients who understand the process of clinical trial and signed written informed consent. Exclusion Criteria: * Patients with a cur

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

252

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Double-blind masking

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

HM-TRIA-101

Identifier

NCT03374241

Link

https://clinicaltrials.gov/study/NCT03374241

Phase

Phase I

Status

Completed

Sponsor

Hanmi Pharmaceutical Company Limited

More details

Single ascending dose of HM15211 in healthy obese subjects.

Purpose

A First-in-human Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of HM15211(Efocipegtrutide)

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2018-04-04

Anticipated Date of Last Follow-up

2025-01-23

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2018-09-14

Actual Completion Date

2018-09-14

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: * Female subjects must be non-pregnant and non-lactating Exclusion Criteria: * Participation in an investigational study within 30 days prior to dosing

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

41

Allocation

Randomized

Intervention model

Sequential assignment

Intervention model description

Not provided

Masking

Triple-blind masking

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

HM-TRIA-102

Identifier

NCT03744182

Link

https://clinicaltrials.gov/study/NCT03744182

Phase

Phase I

Status

Completed

Sponsor

Hanmi Pharmaceutical Company Limited

More details

This study is a phase 1 study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of multiple doses of HM15211 in obese subjects with NAFLD

Purpose

A Study of Multiple Doses of HM15211(Efocipegtrutide) in Obese Subjects With NAFLD

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2018-11-01

Anticipated Date of Last Follow-up

2025-01-23

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2020-03-18

Actual Completion Date

2020-03-18

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: * Body mass index ≥ 30 kg/m2 * Waist circumference ≤ 57 inches * Fasting Plasma Glucose \< 7 mmol/L (126 mg/dL) * HbA1c \< 6.5% * Controlled Attenuation Parameter ≥ 300 dB/m by FibroScan * Liver fat by MRI-PDFF ≥ 10%. Exclusion Criteria: * A history of or active chronic liver disease due to alcohol, auto-immune, HIV, HBV or active HCV-infection or NASH disease * Any history of clinically significant chronic liver disease including esophageal varices, ascites, encephalopathy or any hospitalization for treatment of chronic liver disease; or Model for End Stage Liver Disease (MELD) ≥ 10 * Previous surgical treatment for obesity * Uncontrolled hypertension * Any weight control treatment * History or current diagnosis of acute or chronic pancreatitis or factors for pancre

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

66

Allocation

Randomized

Intervention model

Sequential assignment

Intervention model description

Not provided

Masking

Double-blind masking

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

HM-TRIA-201

Identifier

NCT04505436

Link

https://clinicaltrials.gov/study/NCT04505436

Phase

Phase II

Status

Recruiting

Sponsor

Hanmi Pharmaceutical Company Limited

More details

This study is a phase 2 study to Evaluate Efficacy, Safety and Tolerability of HM15211 Treatment for 12 Months in Subjects with Biopsy Confirmed NASH

Purpose

Study to Evaluate Efficacy, Safety and Tolerability of HM15211(efocipegtrutide) in Subjects

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2020-07-31

Anticipated Date of Last Follow-up

2025-01-20

Estimated Primary Completion Date

2025-05-11

Estimated Completion Date

2025-11-10

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

No

Comments about the studied populations

Inclusion Criteria: * United States Sites: Adults ≥ 18 to ≤ 70 years. * Korean Sites: Adults ≥ 19 to ≤ 70 years. * BMI ≥ 18 kg/m2, with stable body weight (defined as change \< 5%) by history for 3 months prior to screening or since baseline liver biopsy, whichever is earlier. * Subjects have a diagnosis of noncirrhotic NASH with liver fibrosis (Fibrosis stage F1-F3) confirmed by liver biopsy within 6 months of Day -7. * MRI-PDFF performed at screening with ≥ 8% steatosis. Exclusion Criteria: * Subjects with a history of active or chronic liver disease, including alcoholic liver disease, viral hepatitis, primary biliary cirrhosis, primary sclerosing cholangitis, autoimmune hepatitis, Wilson's disease, hemochromatosis, alpha-1 antitrypsin deficiency, human immunodeficiency virus (HIV). *

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

240

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

6024-014

Identifier

NCT06052566

Link

https://clinicaltrials.gov/study/NCT06052566

Phase

Phase I

Status

Completed

Sponsor

Merck Sharp & Dohme LLC

More details

The purpose of this study is to evaluate the pharmacokinetics of efinopegdutide in participants with hepatic impairment compared to healthy participants, and to examine the safety and tolerability of efinopegdutide.

Purpose

A Study of Efinopegdutide in Participants With Hepatic Impairment (MK-6024-014)

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2023-11-21

Anticipated Date of Last Follow-up

2024-12-13

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2024-12-05

Actual Completion Date

2024-12-05

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

The main inclusion and exclusion criteria include but are not limited to the following: Inclusion Criteria: * A participant assigned female at birth is eligible to participate if not pregnant or breastfeeding, is not a participant of childbearing potential (POCBP), or is a POCBP and agrees to follow contraceptive guidance during the study intervention period and for at least 35 days after the last dose of study intervention. * For participants with moderate or severe hepatic impairment: Have a diagnosis of chronic (\>6 months), stable, hepatic impairment with features of cirrhosis due to any etiology (stability of hepatic disease should correspond to no acute episodes of illness within the previous 2 months due to deterioration in hepatic function). Exclusion Criteria: * History of can

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

22

Allocation

Not provided

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

6024-016

Identifier

NCT06482112

Link

https://clinicaltrials.gov/study/NCT06482112

Phase

Phase II

Status

Not provided

Sponsor

Merck Sharp & Dohme LLC

More details

This study will evaluate the effect of efinopegdutide administration once every 2 weeks (Q2W) versus once weekly (Q1W) on mean relative reduction from baseline in liver fat content (LFC) after 28 weeks, as well as the safety and tolerability of the different regimens of efinopegdutide.

Purpose

Alternate Dosing Study of MK-6024 in Adults With Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD) (MK-6024-016)

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2024-07-29

Anticipated Date of Last Follow-up

2024-11-20

Estimated Primary Completion Date

2025-06-23

Estimated Completion Date

2025-06-23

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

No

Comments about the studied populations

Inclusion Criteria: The main inclusion criteria include but are not limited to the following: * Has body mass index (BMI) ≥25 kg/m\^2 (≥23 kg/m\^2 for Asian participants) AND has stable weight, defined as ≤5% gain or loss of body weight for at least 3 months before screening * Has no history of type 2 diabetes mellitus (T2DM) OR has a history of T2DM with a glycated hemoglobin (A1C) ≤9% AND the T2DM is controlled by diet or stable doses of oral antihyperglycemic agents (AHAs) Exclusion Criteria: The main exclusion criteria include but are not limited to the following * Has a history or evidence of chronic liver disease other than Metabolic dysfunction-associated steatotic liver disease (MASLD) or Metabolic dysfunction-associated steatohepatitis (MASH) * Has evidence of decompensated l

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

129

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

AMPLITUDE-O

Identifier

NCT03496298

Link

https://clinicaltrials.gov/study/NCT03496298

Phase

Phase III

Status

Terminated

Sponsor

Sanofi

More details

Primary Objective: To demonstrate that efpeglenatide 4 and 6 mg was noninferior to placebo on 3-point major adverse cardiac events (MACE) in Type 2 diabetes mellitus (T2DM) participants at high cardiovascular (CV) risk. Secondary Objectives: To demonstrate that efpeglenatide 4 and 6 mg was superior to placebo in T2DM participants with high CV risk on the following parameters: * 3-point MACE. * Expanded CV outcome. * Composite outcome of new or worsening nephropathy. To assess the safety and tolerability of efpeglenatide 4 and 6 mg, both added to standard of care in T2DM participants at high CV risk.

Purpose

Effect of Efpeglenatide on Cardiovascular Outcomes

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2018-04-27

Anticipated Date of Last Follow-up

2021-09-16

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2020-12-10

Actual Completion Date

2020-12-10

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

No

Comments about the studied populations

Inclusion criteria: * T2DM with glycosylated hemoglobin (HbA1c) greater than (\>) 7 percentage. * Age 18 years or older who met at least one of the cardiovascular disease criteria or age 50 years (male), 55 years (female) or older with glomerular filtration rate greater than or equal to 25 and less than 60 milliliters per minute and at least had one cardiovascular risk factor. * Female participants agreed to follow contraceptive guidance. * Signed written informed consent. Exclusion criteria: * Clinically relevant history of gastrointestinal disease associated with prolonged nausea and vomiting. * History of chronic pancreatitis or acute idiopathic pancreatitis or diagnosis of any type of acute pancreatitis within 3 months prior to screening. * Personal or family history of medullary th

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

4076

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

AMPLITUDE-M

Identifier

NCT03353350

Link

https://clinicaltrials.gov/study/NCT03353350

Phase

Phase III

Status

Completed

Sponsor

Hanmi Pharmaceutical Company Limited

More details

Primary Objective: To demonstrate the superiority of once weekly injection of efpeglenatide in comparison to placebo in glycated hemoglobin (HbA1c) change in participants with T2DM (Type 2 Diabetes Mellitus) inadequately controlled with diet and exercise. Secondary Objectives: * To demonstrate the superiority of once-weekly injection of efpeglenatide in comparison to placebo on glycemic control * To demonstrate the superiority of once-weekly injection of efpeglenatide in comparison to placebo on body weight * To evaluate the safety of once-weekly injection of efpeglenatide

Purpose

Efficacy and Safety of Efpeglenatide Versus Placebo in Patients With Type 2 Diabetes Mellitus Inadequately Controlled With Diet and Exercise

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2017-12-05

Anticipated Date of Last Follow-up

2022-01-11

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2020-01-29

Actual Completion Date

2020-09-07

Studied populations

Age Cohort

- Adults

Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

No

Comments about the studied populations

Inclusion criteria: * Participants must be at least 18 years of age at the time of signing the informed consent. * Participants with T2DM, and treated with diet and exercise. * Hemoglobin A1c between 7.0% and 10.0% (inclusive) measured by the central laboratory at Screening. Exclusion criteria: * Clinically relevant history of gastrointestinal disease associated with prolonged nausea and vomiting, including (but not limited to) gastroparesis, unstable and not controlled gastroesophageal reflux disease within 6 months prior to Screening or history of surgery affecting gastric emptying. * History of pancreatitis (unless pancreatitis was related to gallstone and cholecystectomy has been performed) and pancreatitis during previous treatment with incretin therapies, chronic pancreatitis, and

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

406

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

AMPLITUDE-D

Identifier

NCT03684642

Link

https://clinicaltrials.gov/study/NCT03684642

Phase

Phase III

Status

Terminated

Sponsor

Sanofi

More details

Primary Objective: To demonstrate the non-inferiority of once weekly injection of efpeglenatide in comparison to once weekly injection of dulaglutide on glycated hemoglobin (HbA1c) change in participants with Type 2 diabetes mellitus (T2DM) inadequately controlled with metformin. Secondary Objectives: * To demonstrate the superiority of once weekly injection of efpeglenatide with once weekly injection of dulaglutide on glycemic control. * To demonstrate the superiority of once weekly injection of efpeglenatide with once weekly injection of dulaglutide on body weight. * To evaluate the safety of once weekly injection of efpeglenatide and once weekly injection of dulaglutide.

Purpose

Efficacy and Safety of Efpeglenatide Versus Dulaglutide in Patients With Type 2

Diabetes Mellitus Inadequately Controlled With Metformin

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2018-09-26

Anticipated Date of Last Follow-up

2021-10-28

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2020-10-13

Actual Completion Date

2020-11-17

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

No

Comments about the studied populations

Inclusion criteria: * Participant must be greater than or equal to (\>=) 18 years of age at the time of signing the informed consent. * Participants with T2DM. * Diabetes diagnosed at least 1 year before screening. * Participants on stable dose of at least 1500 milligram per day (mg/day) of metformin, or tolerated maximum dose, or as per country regulation if less, for at least 3 months prior to screening. * HbA1c between 7.0 percent (%) and 10.0% (inclusive) measured by the central laboratory at screening. Exclusion criteria: * Retinopathy or maculopathy with one of the following treatments, either recent (within 3 months prior to screening) or planned: intravitreal injections or laser or vitrectomy surgery. * Clinically relevant history of gastrointestinal (GI) disease associated with

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

908

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

AMPLITUDE-S

Identifier

NCT03770728

Link

https://clinicaltrials.gov/study/NCT03770728

Phase

Phase III

Status

Terminated

Sponsor

Sanofi

More details

Primary Objective: To demonstrate the superiority of once weekly injection of efpeglenatide in comparison to placebo in glycated hemoglobin (HbA1c) change in participants with type 2 diabetes mellitus (T2DM) inadequately controlled with metformin alone or in combination with sulfonylurea (SU). Secondary Objectives: * To demonstrate the superiority of once weekly injection of efpeglenatide in comparison to placebo on glycemic control. * To demonstrate the superiority of once weekly injection of efpeglenatide in comparison to placebo on body weight. * To evaluate the safety of once weekly injection of efpeglenatide.

Purpose

Efficacy and Safety of Efpeglenatide Versus Placebo in Patients With Type 2 Diabetes Mellitus Inadequately Controlled With Metformin Alone or in Combination With

Sulfonylurea

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2019-08-01

Anticipated Date of Last Follow-up

2021-11-04

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2020-11-28

Actual Completion Date

2020-12-27

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

No

Comments about the studied populations

Inclusion criteria: * Participant must be greater than or equal to (\>=)18 years of age at the time of signing the informed consent. * Participants with T2DM. * Diabetes diagnosed at least 1 year before screening. * Participants on metformin alone or in combination with SU, for at least 3 months prior to screening. * Glycated hemoglobin between 7.0% and 10.0% (inclusive) measured by the central laboratory at screening. Exclusion criteria: * History of severe hypoglycemia requiring emergency room admission or hospitalization within 3 months prior to screening. * Retinopathy or maculopathy with one of the following treatments, either recent (within 3 months prior to screening) or planned: intravitreal injections or laser or vitrectomy surgery. * Clinically relevant history of gastrointest

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

312

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

AMPLITUDE-L

Identifier

NCT03713684

Link

https://clinicaltrials.gov/study/NCT03713684

Phase

Phase III

Status

Terminated

Sponsor

Sanofi

More details

Primary Objective: To demonstrate the superiority of once weekly injection of efpeglenatide in comparison to placebo in glycated hemoglobin (HbA1c) change in participants with type 2 diabetes mellitus (T2DM) inadequately controlled with basal insulin alone or in combination with oral antidiabetic drugs (OADs). Secondary Objectives: * To demonstrate the superiority of once weekly injection of efpeglenatide in comparison to placebo on glycemic control. * To demonstrate the superiority of once weekly injection of efpeglenatide in comparison to placebo on body weight. * To evaluate the safety of once weekly injection of efpeglenatide.

Purpose

Efficacy and Safety of Efpeglenatide Versus Placebo in Patients With Type 2 Diabetes Mellitus Inadequately Controlled With Basal Insulin Alone or in Combination With Oral

Antidiabetic Drug(s)

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2018-11-09

Anticipated Date of Last Follow-up

2021-11-04

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2020-11-20

Actual Completion Date

2021-01-04

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

No

Comments about the studied populations

Inclusion criteria: * Participant must be greater than or equal to (\>=)18 years of age at the time of signing the informed consent. * Participants with T2DM. * Diabetes diagnosed at least 1 year before screening. * Participants on basal insulin regimen alone or in combination with OADs for at least 6 months prior to screening. * HbA1c between 7.0 percent (%) and 10.0% (inclusive) measured by the central laboratory at screening. Exclusion criteria: * History of severe hypoglycemia requiring emergency room admission or hospitalization within 3 months prior to screening. * Retinopathy or maculopathy with one of the following treatments, either recent (within 3 months prior to screening) or planned: intravitreal injections or laser or vitrectomy surgery. * Clinically relevant history of ga

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

370

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

HM-LIL2-101

Identifier

NCT06724016

Link

https://clinicaltrials.gov/study/NCT06724016

Phase

Phase I

Status

Recruiting

Sponsor

Hanmi Pharmaceutical Company Limited

More details

This is a First-in-Human, Phase 1, Dose-Escalation and Dose-Expansion study of HM16390, as a single agent to assess safety, tolerability, MTD, RP2D, PK, and efficacy in patients with advanced or metastatic solid tumors. Dose-Escalation Part is planned to establish the MTD or RDs for the randomized Dose-Ranging Part. Based on the results of the Dose-Escalation Part, additional eligible subjects will be randomized 1:1 into at each dose level. After a comprehensive review of available data from both Dose-Escalation Part and Dose-Ranging Part, the potential RP2D to be tested in the Dose-Expansion Part is determined. Dose-Expansion Part is designed to assess the potential efficacy of HM16390 as a single agent when administered at the potential RP2D to subjects in indication-specific expansion

Purpose

Dose Escalation and Expansion Study of HM16390 in Advanced or Metastatic Solid Tumors

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2024-12-11

Actual Start Date

Not provided

Anticipated Date of Last Follow-up

2024-12-11

Estimated Primary Completion Date

2030-03-01

Estimated Completion Date

2030-03-01

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

No

Comments about the studied populations

Key Inclusion Criteria: * Have a histologically and/or cytologically confirmed advanced or metastatic solid tumor and have failed or are intolerant to standard therapy with clinical benefit. * Patients in the Dose-Escalation Part must have evaluable or measurable disease at baseline and the patients for Dose-Ranging and Dose-Expansion Part must have at least one measurable lesion at baseline by computed tomography (CT) or magnetic resonance imaging (MRI) per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1. * Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. * Age of 18 years or older (or country's legal age of majority if the legal age was \>18 years) * Adequate renal function. * Adequate hematologic function. * Adequate liver function. Key Exclusion Crit

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

215

Allocation

Not provided

Intervention model

Single group assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

HM-TRIA-101

Identifier

NCT03374241

Link

https://clinicaltrials.gov/study/NCT03374241

Phase

Phase I

Status

Completed

Sponsor

Hanmi Pharmaceutical Company Limited

More details

Single ascending dose of HM15211 in healthy obese subjects.

Purpose

A First-in-human Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of HM15211(Efocipegtrutide)

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2018-04-04

Anticipated Date of Last Follow-up

2025-01-23

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2018-09-14

Actual Completion Date

2018-09-14

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: * Female subjects must be non-pregnant and non-lactating Exclusion Criteria: * Participation in an investigational study within 30 days prior to dosing

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

41

Allocation

Randomized

Intervention model

Sequential assignment

Intervention model description

Not provided

Masking

Triple-blind masking

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

HM-TRIA-102

Identifier

NCT03744182

Link

https://clinicaltrials.gov/study/NCT03744182

Phase

Phase I

Status

Completed

Sponsor

Hanmi Pharmaceutical Company Limited

More details

This study is a phase 1 study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of multiple doses of HM15211 in obese subjects with NAFLD

Purpose

A Study of Multiple Doses of HM15211(Efocipegtrutide) in Obese Subjects With NAFLD

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2018-11-01

Anticipated Date of Last Follow-up

2025-01-23

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2020-03-18

Actual Completion Date

2020-03-18

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: * Body mass index ≥ 30 kg/m2 * Waist circumference ≤ 57 inches * Fasting Plasma Glucose \< 7 mmol/L (126 mg/dL) * HbA1c \< 6.5% * Controlled Attenuation Parameter ≥ 300 dB/m by FibroScan * Liver fat by MRI-PDFF ≥ 10%. Exclusion Criteria: * A history of or active chronic liver disease due to alcohol, auto-immune, HIV, HBV or active HCV-infection or NASH disease * Any history of clinically significant chronic liver disease including esophageal varices, ascites, encephalopathy or any hospitalization for treatment of chronic liver disease; or Model for End Stage Liver Disease (MELD) ≥ 10 * Previous surgical treatment for obesity * Uncontrolled hypertension * Any weight control treatment * History or current diagnosis of acute or chronic pancreatitis or factors for pancre

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

66

Allocation

Randomized

Intervention model

Sequential assignment

Intervention model description

Not provided

Masking

Double-blind masking

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

HM-TRIA-201

Identifier

NCT04505436

Link

https://clinicaltrials.gov/study/NCT04505436

Phase

Phase II

Status

Recruiting

Sponsor

Hanmi Pharmaceutical Company Limited

More details

This study is a phase 2 study to Evaluate Efficacy, Safety and Tolerability of HM15211 Treatment for 12 Months in Subjects with Biopsy Confirmed NASH

Purpose

Study to Evaluate Efficacy, Safety and Tolerability of HM15211(efocipegtrutide) in Subjects

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2020-07-31

Anticipated Date of Last Follow-up

2025-01-20

Estimated Primary Completion Date

2025-05-11

Estimated Completion Date

2025-11-10

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

No

Comments about the studied populations

Inclusion Criteria: * United States Sites: Adults ≥ 18 to ≤ 70 years. * Korean Sites: Adults ≥ 19 to ≤ 70 years. * BMI ≥ 18 kg/m2, with stable body weight (defined as change \< 5%) by history for 3 months prior to screening or since baseline liver biopsy, whichever is earlier. * Subjects have a diagnosis of noncirrhotic NASH with liver fibrosis (Fibrosis stage F1-F3) confirmed by liver biopsy within 6 months of Day -7. * MRI-PDFF performed at screening with ≥ 8% steatosis. Exclusion Criteria: * Subjects with a history of active or chronic liver disease, including alcoholic liver disease, viral hepatitis, primary biliary cirrhosis, primary sclerosing cholangitis, autoimmune hepatitis, Wilson's disease, hemochromatosis, alpha-1 antitrypsin deficiency, human immunodeficiency virus (HIV). *

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

240

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

HM-GHA-101

Identifier

NCT01093742

Link

https://clinicaltrials.gov/study/NCT01093742

Phase

Phase I

Status

Completed

Sponsor

Hanmi Pharmaceutical Company Limited

More details

* Study Design * Randomized, Double-blind, Placebo-controlled, escalating single-dose design. * Four ascending dose cohorts. * In each cohort, subjects will be randomized to receive a single dose of HM10560A or placebo (negative control). * Objectives * The primary objective of the study is to assess the safety and tolerability of single escalating subcutaneous doses of HM10560A in healthy male subjects.

Purpose

A Study of HM10560A in Healthy Male Subject

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2010-03-01

Anticipated Date of Last Follow-up

2014-02-06

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2010-08-01

Actual Completion Date

2010-08-01

Studied populations

Age Cohort

- Adults

Genders

- Male

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: 1. Healthy male volunteers, age range 20 to 54 years are informed of the investigational nature of this study and voluntarily agrees to participate in this study 2. Body mass index of ≥19 and ≤26 Subject 3. Medically healthy with no clinically significant screening results through Physical examination, 12 lead ECG, Laboratory test 4. Able to participate in all procedure 5. SBP 90-140 mmHg, DBP 60-90 mmHg, Pulse rate 50-90 times/min 6. AST, ALT \<1.5 X UNL, CPK \< 2 X UNL 7. Able to abstain from alcohol and smoke during study period 8. Consented to contraception until 2 month after end of the study Exclusion Criteria: 1. Acute infection history within 14 days 2. Prior exposure or hypersensitivity to recombinant human growth hormone 3. Positive findings on HBsAg, Anti-

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

32

Allocation

Randomized

Intervention model

Single group assignment

Intervention model description

Not provided

Masking

Triple-blind masking

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

HM-GLP2-101

Identifier

NCT04076293

Link

https://clinicaltrials.gov/study/NCT04076293

Phase

Phase I

Status

Completed

Sponsor

Hanmi Pharmaceutical Company Limited

More details

A First-in-Human, Double-blind, Randomized, Placebo-controlled, Single Ascending Dose Study to Assess Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of HM15912 in Healthy Korean Subjects

Purpose

Single Ascending Dose Study to Assess Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of HM15912(Sonefpeglutide) in Healthy Korean Subjects

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2019-10-08

Anticipated Date of Last Follow-up

2025-01-23

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2020-11-10

Actual Completion Date

2021-05-03

Studied populations

Age Cohort

- Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: * Subject voluntarily agrees to participate in this study and signs an IRB-approved informed consent prior to performing any of the Screening visit procedures. * Korean males and females ≥ 19 and ≤ 60 years of age at the Screening visit Exclusion Criteria: * Subject with a history or presence of clinically significant active diseases. * Subject who has participated in other clinical studies (including bioequivalence tests) within 6 months before the Screening visit and has received IPs

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

40

Allocation

Randomized

Intervention model

Sequential assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

HM-GLP2-201

Identifier

NCT04775706

Link

https://clinicaltrials.gov/study/NCT04775706

Phase

Phase II

Status

Recruiting

Sponsor

Hanmi Pharmaceutical Company Limited

More details

This is a randomized, double-blind, placebo-controlled, proof-of-concept (PoC), Phase 2 study to assess the safety, PK, and PD of SC administration of HM15912(sonefpeglutide) in adult subjects with SBS-associated intestinal failure (SBS-IF).

Purpose

Phase 2 Study to Assess the Safety, PK, and PD in SBS-IF Subjects

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2022-03-03

Anticipated Date of Last Follow-up

2025-02-06

Estimated Primary Completion Date

2027-12-01

Estimated Completion Date

2028-05-01

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

No

Comments about the studied populations

Inclusion Criteria: 1. Men or women, aged 18 years of age or older with SBS resulting in intestinal failure at the time of signing the informed consent form (ICF) (or country's legal age of majority if the legal age is \<18 years) 2. Capable of giving signed informed consent which includes compliance with the requirements and restrictions listed in the ICF and in this protocol 3. Diagnosis of SBS with the latest intestinal resection being at least 6 months prior to Screening and considered stable regarding the PN/IV need. No restorative surgery planned in the study period. Exclusion Criteria: 1. Any history of colon cancer. 2. History of any other cancers (except margin-free resected cutaneous basal or squamous cell carcinoma or adequately treated in situ cervical cancer) unless disease

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

18

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Double-blind masking

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

HM-GCG-101

Identifier

NCT04032782

Link

https://clinicaltrials.gov/study/NCT04032782

Phase

Phase I

Status

Completed

Sponsor

Hanmi Pharmaceutical Company Limited

More details

This is a double-blind, randomized, placebo controlled, single ascending dose (SAD) study to investigate the safety, tolerability, PK and PD of the SC administration of HM15136 in healthy subjects. The study will be conducted in approximately 5 sequential dosing cohorts, enrolling 8 subjects per cohort. Subjects will be randomized to HM15136 or placebo in a ratio of 6:2 (6 active, 2 placebo).

Purpose

A First-in-Human, Study to Assess Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of HM15136(Efpegerglucagon) in Healthy Subjects

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2018-10-02

Anticipated Date of Last Follow-up

2025-02-03

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2019-08-29

Actual Completion Date

2019-08-29

Studied populations

Age Cohort

- Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: * Body mass index ≥ 18.5 and ≤ 27 kg/m2 and with a weight ≥ 50 kg Exclusion Criteria: * with personal or family history of hypercoagulability or thromboembolic disease * has had treatment with any incretin therapy * has FPG \< 70 or \> 110 mg/dL

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

40

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Double-blind masking

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

Excipients

Proprietary excipients used

No proprietary excipient used

Novel excipients or existing excipients at a concentration above Inactive Ingredients Database (IID) for the specified route of administration

No novel excipient or existing excipient used

Residual solvents used

No residual solvent used

Additional features

Other features of the technology

- Drug-eluting
- At least 1 year shelf life

Release properties

Upon reaching the target site, the aglycosylated Fc-bound API is released via the detachment of the flexible PEG linker. Once freed, the API binds to its target receptor, eliciting its therapeutic effect through agonistic or antagonistic activity. This monomeric complex partially reduces receptor-mediated clearance and renal filtration. Due to this mechanism, the activity of the API is prolonged.

Injectability

The prefilled injection of efpeglenatide (LAPScovery formulation) typically uses a 29-gauge needle for subcutaneous administration.

Safety

In the phase 3 clinical trial evaluating once-weekly efpeglenatide, the most frequently reported adverse events were mild to moderate gastrointestinal symptoms, including diarrhea, vomiting, and constipation. Treatment-emergent adverse events (TEAEs) occurred in 78.4–83.8% of patients in the treatment group, with two cases of diabetic retinopathy being reported. Serious TEAEs were observed in 9–11% of the patient population.

Stability

LASPSCOVERY formulation in its prefilled pen or vial is stable for up to 24 months when stored under the recommended refrigeration condition

Storage conditions and cold-chain related features

Store in a refrigerator at 2°C to 8°C (36°F to 46°F). Do not freeze. It can be stored at room temperature (up to 30°C/86°F) for a maximum of 14 days.

Potential application(s)

Therapeutic area(s)

Diabetes

Other(s) : "Obesity/ metabolic disorders and rare diseases"

Oncology

Use case(s)

Not provided

Use of technology

Ease of administration

- Administered by a community health worker
- Administered by a nurse
- Administered by a specialty health worker

Frequency of administration

Weekly, Monthly

User acceptance

Not provided

Targeted user groups

Age Cohort

- Adults
- Older Adults

Genders

- All

Pregnant individuals

Unspecified

Lactating individuals

Unspecified

Healthy individuals

Unspecified

Comment

Not provided

Potential associated API(s)

efpegerglucagon (glucagon analog)

Class(es)

Glucagon Analog

Development stage

Phase II

Clinical trial number(s)

NCT04732416

Foreseen/approved indication(s)

Congenital Hyperinsulinism (CHI)

Foreseen user group

2 years and older

Foreseen duration between application(s)

Once weekly

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

Efpegerglucagon received orphan drug designation from the FDA, EMA, and MFDS for the treatment of CHI

efpeglenatide (exendin-4 analog)

Class(es)

Exendin-4 Analog

Development stage

Phase III

Clinical trial number(s)

NCT03353350

Foreseen/approved indication(s)

Type 2 Diabetes

Foreseen user group

< 18 years and older

Foreseen duration between application(s)

Once weekly

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

Not provided

efocipegtrutide (GLP-1 triple agonist)

Class(es)

GLP-1 triple agonist

Development stage

Phase II

Clinical trial number(s)

NCT04505436

Foreseen/approved indication(s)

nonalcoholic steatohepatitis (MASH)

Foreseen user group

Adults ≥ 18 to ≤ 70 years

Foreseen duration between application(s)

Once weekly

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

Efocipegtrutide Fast Track designation and orphan drug status for the treatment of nonalcoholic steatohepatitis (MASH).

HM16390 (IL-2 analog)

Class(es)

Interleukin Analogues

Development stage

Phase I

Clinical trial number(s)

NCT06724016

Foreseen/approved indication(s)

Advanced or Metastatic Solid Tumors

Foreseen user group

Not provided

Foreseen duration between application(s)

Not provided

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

Not provided

efpegsomatropin (human growth hormone (hGh) analog)

Class(es)

Somatotropin receptor agonists

Development stage

Phase II

Clinical trial number(s)

Not provided

Foreseen/approved indication(s)

Somatotropin deficiency

Foreseen user group

Not provided

Foreseen duration between application(s)

Not provided

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

Not provided

sonefpeglutide (Glucagon-like peptide-2 (GLP-2) analogue)

Class(es)

GLP-2 analog

Development stage

Phase II

Clinical trial number(s)

NCT04775706

Foreseen/approved indication(s)

Short Bowel Syndrome-associated Intestinal Failure

Foreseen user group

Not provided

Foreseen duration between application(s)

Once monthly

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

Not provided

Patent info

Description

Composition for treating diabetes comprising long-acting insulin conjugate and long-acting insulinotropic peptide conjugate

Brief description

Not provided

Representative patent

Not provided

Category

Not provided

Patent holder

Hanmi Science Co Ltd

Exclusivity

Not provided

Expiration date

June 1, 2032

Status

Ceased

Description

Long-acting glucagon conjugate and pharmaceutical composition comprising the same for the prevention and treatment of obesity

Brief description

Disclosed is a novel long-acting glucagon conjugate in which glucagon or its derivative is covalently linked to a polymer carrier via a non-peptide linker, and a pharmaceutical composition comprising the same as an effective ingredient useful for the prevention and treatment of obesity. Since the long-acting glucagon conjugate of the present invention shows improved in vivo durability and stability, when used in combination with an anti-obesity drug, it is possible to induce synergistic effects on the loss of body weight and decrease in food intake without causing any side-effects such as fluctuation in blood glucose level. Accordingly, the long-acting peptide conjugate of the present invention is very effective for the prevention and treatment of obesity.

Representative patent

US9072794B2

Category

Not provided

Patent holder

Hanmi Science Co Ltd

Exclusivity

Not provided

Expiration date

September 28, 2031

Status

Active

Supporting material

Publications

** Choi, J., Lee, J., Park, E., Kwon, H., Kim, D., Bae, S., Choi, I. Y., & Kim, H. H. (2023). HM15912, a Novel Long-Acting Glucagon-Like Peptide-2 Analog, Improves Intestinal Growth and Absorption Capacity in a Male Rat Model of Short Bowel Syndrome. The Journal of pharmacology and experimental therapeutics, 384(2), 277–286. https://doi.org/10.1124/jpet.122.001381 **

Extensive bowel resection caused by various diseases that affect the intestines, such as Crohn's disease, volvulus, and cancer, leads to short bowel syndrome (SBS). Teduglutide is the only approved glucagon-like peptide-2 (GLP-2) drug for SBS; however, it requires daily administration. A novel GLP-2 analog with a prolonged duration of action to reduce dosing frequency and promote a greater efficacy may provide patients with a better quality of life. In the present study, the sustained exposure of HM15912 was characterized in normal male rats. The efficacy of HM15912 on intestinal growth and absorption capacity was also evaluated in normal male mice, rats, and SBS rats. HM15912 exhibited a remarkably extended half-life (42.3 hours) compared with teduglutide (0.6 hours) in rats. Despite somewhat lower in vitro potency on GLP-2 receptor than human GLP-2 or teduglutide, this longer-lasting mode of action promotes HM15912 to be more effective in terms of small intestinal growth than existing GLP-2 analogs even with a less frequent dosing interval of as little as once a week in rodents, including SBS rats. Furthermore, the small intestinal weight was approximately doubled, and the D-xylose absorption was significantly increased after pre-treatment of existing GLP-2 analogs on the market or under clinical development followed by HM15912 in rodents. These results indicate that HM15912 possesses a significant small bowel trophic effect driven by continuously increased exposure, supporting that HM15912 may be a novel treatment option with greater

efficacy and the longest dosing interval among existing GLP-2 analogs for SBS with intestinal failure. SIGNIFICANCE STATEMENT: HM15912, a novel long-acting glucagon-like peptide-2 (GLP-2) analog, has a significant small bowel hypertrophic effect in rodents with a reduced frequency of administration compared to the existing GLP-2 analogs on the market or currently under clinical development. This study supports the possibility that HM15912 could be administered much less frequently than other long-acting GLP-2 analogs for patients with short bowel syndrome.

Additional documents

- Monograph of Efpeglenatide
- American diabetes association (ADA) 81st Scientific sessions, 2021 Poster Presentation

Useful links

There are no additional links

Access principles

Collaborate for development

Consider on a case by case basis, collaborating on developing long acting products with potential significant public health impact, especially for low- and middle-income countries (LMICs), utilising the referred to long-acting technology

Not provided

Share technical information for match-making assessment

Provide necessary technical information to a potential partner, under confidentiality agreement, to enable preliminary assessment of whether specific medicines of public health importance in LMICs might be compatible with the referred to long-acting technology to achieve a public health benefit

Not provided

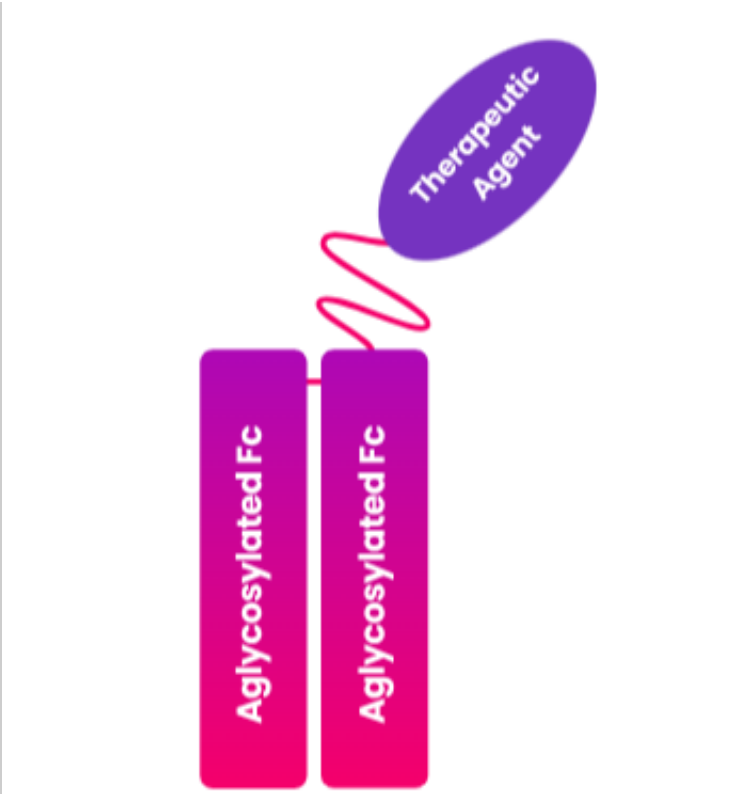
Work with MPP to expand access in LMICs

In the event that a product using the referred to long-acting technology is successfully developed, the technology IP holder(s) will work with the Medicines Patent Pool towards putting in place the most appropriate strategy for timely and affordable access in low and middle-income countries, including through licensing

Not provided

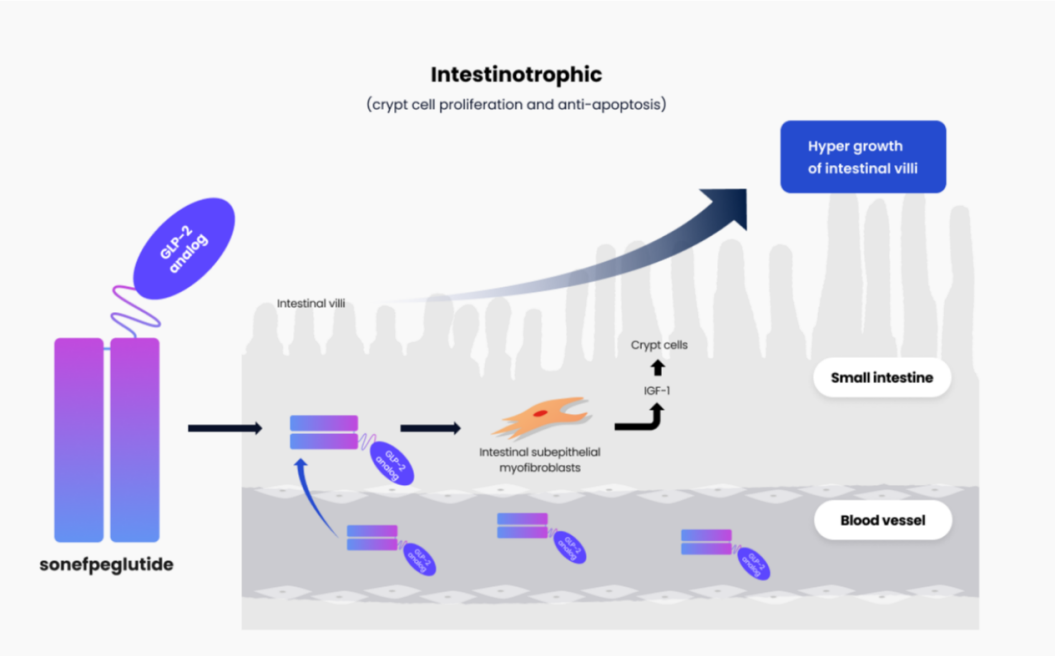
Comment & Information

Illustrations



API binded with the Aglycosylated Fc fragment via a Flexible PEG linker

Hanmi Pharm. (n.d.). LAPScovery™: Long-Acting Pharmaceutical Solutions. Retrieved February 18, 2025, from https://hanmipharm.com



Mechanism of Action of Sonefpeglutide in the intestinal villi

Hanmi Pharmaceutical. (n.d.). HM15912: Weekly GLP-1/glucagon dual agonist. Retrieved [Date], from https://hanmipharm.com/science/pipeline/focused/hm15912.hm