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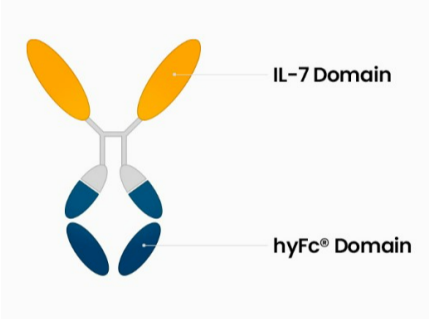


Long-acting hyFc Fusion Technology

Based on public information

Developer(s)

Genexine

Originator

http://www.genexine.com/

South Korea

Genexine is a leading South Korean biopharmaceutical company founded in 1999, focusing on developing and commercializing novel therapies using their two proprietary technologies for unmet medical needs. Their core R&D interest lies in immunotherapies for cancer and next-generation long-acting biologics. Their R&D efforts have yielded positive results.

Sponsor(s)

No sponsor indicated

Partnerships

KGbio
https://www.kg-biologics.com

Handok Pharmaceuticals, Inc.
https://www.handok.co.kr

I-MAB Biopharma
https://www.i-mabbiopharma.com/

Merck
https://www.merckgroup.com/en

NeoimmuneTech
https://neoimmunetech.com/

Hoffmann La Roche
https://www.roche.com

GenNBio, Inc.
http://gennbio.com/

Turret Capital, Inc.
https://www.turretfunds.com/

Ilkogen, Inc.
https://www.ilkogen.com.tr/

CSPC Pharmaceutical Group ltd
https://www.cspc.com.hk/en/global/home.php

Fosun Pharma

https://www.fosunpharma.com/en/

Coimmune

https://www.linkedin.com/company/coimmune/

PharmaJet

https://pharmajet.com/

Rezolute, Inc.

https://www.rezolutebio.com/

Kingen Biotech

www.kingenbiotech.com

ToolGen, Inc.

http://www.toolgen.com/eng

EPD Biotherapeutics

http://www.epdbio.com/home/en

Technology information

Type of technology

Antibody Fragment proteins

Administration route

Intramuscular, Subcutaneous, Intravenous

Development state and regulatory approval

Active Pharmaceutical Ingredient (API)

erythropoietin (EPO)

Development Stage

Marketed

Regulatory Approval

Efesa is approved in Indonesia by the Indonesian Food and Drug Adminstration (BPOM)

Description

The novel noncytolytic hybrid Fc (hyFc) is a nonimmunogenic long-acting Fc fusion technology that uses national proteins to maximize drug stability. hyFc acts as a carrier of agonistic protein drugs using naturally existing IgD and IgG4 Fcs without any mutation in the hyFc region. IgD in the hyFC has high hinge flexibility, minimizing protein-to-protein interaction to increase drug efficacy, and lowering cytotoxicity problems through ADCC and CDC. By binding with neonatal Fc receptor (FcRn), IgG4 is recycled (regeneration) in vivo, enabling it to have long-acting pharmacokinetics.

Technology highlight

• Unmodified Natural Proteins as Carriers • Enhanced Efficacy with Reduced Cytotoxicity • Highly stable and versatile • Broad therapeutic potential • Potentially can be used in combination therapy

Technology main components

• Core Components: (i) Fc Fusion Protein: This protein is a hybrid of the Fc (fragment crystallizable) region of IgD and IgG4. (ii) IL-7 N-Terminals: These are two separate N-terminals (beginning sections) of the interleukin-7 protein bonded to the API and Fc fusion protein. • Additional Components: (I) Oligopeptide: This is a short chain of amino acids (II) Pharmaceutically accepted adjuvants -buffering agents, dispersing agents (for example: Sodium acetate, sodium chloride, potassium chloride, calcium chloride, Sodium lactate, etc)

Information on the raw materials sourcing, availability and anticipated price

Efesa (Long-acting erythropoietin) has been commercially marketed in Indonesia.

Delivery device(s)

No delivery device

APIs compatibility profile

API desired features

Proteins

Human growth hormone, bone morphogenetic protein-1 (BMP-1), growth hormone-releasing hormone, growth hormone-releasing peptide, interferons and interferon receptors (e.g., interferon-C, -3, and water-soluble type I interferon receptor, etc.), granulocyte colony-stimulating factor (G-CSF), granulocyte-macrophage colony-stimulating factor (GM-CSF), glucagon-like peptides (e.g., GLP-1), G-protein-coupled receptor, interleukins and interleukin receptors, enzymes, interleukin and cytokine binding proteins, macrophage activating factor, monoclonal/polyclonal antibodies are targeted.

Additional solubility data

Not provided

Additional stability data

Not provided

API loading: Maximum drug quantity to be loaded

75-90 wt%

API co-administration

2 different APIs : Therapeutic proteins can be combined however further information is not disclosed by the company

LogP

Not provided

Scale-up and manufacturing prospects

Scale-up prospects

Efesa (Efepoetin alfa), the inaugural hyFC product, has gained regulatory approval and is commercially accessible in Indonesia. Amid that, Genexine gained a 20,000 square-foot manufacturing facility located in Durham, North Carolina, United States.

Tentative equipment list for manufacturing

Not provided

Manufacturing

Manufacturing of Efesa (Efineptakin alfa) in a cleanroom involves: • Construction of a Plasmid Encoding IL 1 Ra-hyFc Fusion Protein • Establishment of Cell Lines Expressing the Present Fusion Protein • Confirmation of Protein Expression by Western • Blotting • Purification and Concentration of Protein • Characterization of hL1 RA-hFC Fusion Protein • Determination and Comparison of Binding Affinity • Detection of IL-8 Using ELISA

Specific analytical instrument required for characterization of formulation

• Field emission scanning electron microscope • Transmission electron microscopy • Photon correlation spectroscopy • Enzyme-linked immunosorbent assay (ELISA) • Circular dichroism (CD) spectroscopy • SDS-PAGE and Immunoblotting

Clinical trials

GX-I7-HV-001

Identifier

NCT02860715

Link

https://clinicaltrials.gov/study/NCT02860715

Phase

Phase I

Status

Completed

Sponsor

Genexine, Inc.

More details

This is a Phase 1, randomized, double-blind, placebo-controlled, single ascending dose study designed to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of GX-I7 in healthy volunteers.

Purpose

Clinical Trial of GX-I7 in Healthy Volunteers

Interventions

Intervention 1

GX-I7

Intervention 2

Placebo

Countries

Korea, Republic of

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2016-07-11

Anticipated Date of Last Follow-up

2018-10-21

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2017-01-20

Actual Completion Date

2018-06-02

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: 1. Subject is willing and able to give informed consent after listening character of the clinical trial 2. Must be 19-45 years of age, inclusive 3. Weight 50-100kg, BMI 18-30kg/m2 4. Subject who is adequately able to attend the study based on medical history and physical exam, no clinically significant abnormality from vital sign and clinical laboratory values 5. No clinical abnormality from ECG test 6. Non-smoker (no smoking or no use of any product containing nicotine least for one month and negative from urine test) Exclusion Criteria: 1. Suspected or confirmed malignancy, or has malignancy history 2. Any clinically significant acute or chronic medical condition requiring care of a physician, in liver, biliary tract, renal, nervous system (CNS or peripheral).

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

30

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Not provided

Frequency of administration

Other(s) : "Single dose "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Subcutaneous
Intramuscular

Use case

Treatment

Key results

Not provided

GX-G6_HV1

Identifier

NCT03651466

Link

https://clinicaltrials.gov/study/NCT03651466

Phase

Phase I

Status

Completed

Sponsor

Genexine, Inc.

More details

This study is a single-center, double-blind, placebo-controlled, phase I study with healthy male subjects receiving ascending single s.c. doses of GX-G6

Purpose

Safety and Tolerability of GX-G6 in Healthy Male Subjects

Interventions

Intervention 1

Gx-G6

Intervention 2

Placebo

Countries

Germany

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2017-08-31

Anticipated Date of Last Follow-up

2018-08-27

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2018-06-06

Actual Completion Date

2018-06-28

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. male subjects aged between 18-50 years (both inclusive) 2. healthy subjects as determined by medical history, physical examination including vital signs, ECG and clinical laboratory testing 3. subjects who are able and willing to give written informed consent 4. male subjects must be using 2 acceptable methods for contraception (one of these methods should be a barrier method e.g. spermicide and condom) from start of dosing and refrain from fathering a child in the 3 months following dosing. Exclusion Criteria: History of: 1. clinically relevant allergy (except for untreated, asymptomatic, seasonal allergies at time of dosing), especially allergy to macrolide antibiotics; 2. any clinically significant pancreatic, hepatic, renal, gastrointestinal, cardiovascular.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

48

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Double-blind masking

Masking description

Not provided

Frequency of administration

Other(s) : "Single dose "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Subcutaneous

Use case

Treatment

Key results

Not provided

GX-I7M-HPV-002

Identifier

NCT03144934

Link

https://clinicaltrials.gov/study/NCT03144934

Phase

Phase I

Status

Completed

Sponsor

Genexine, Inc.

More details

This is a phase 1, randomized, double-blind, placebo-controlled, multiple ascending dose study to evaluate the safety and tolerability of GX-I7 in HPV-infected female volunteers

Purpose

Safety and Tolerability of GX-I7 in HPV-infected Female Volunteers

Interventions

Intervention 1

GX-I7

Intervention 2

Placebo

Countries

Korea, Republic of

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2017-02-16

Anticipated Date of Last Follow-up

2018-10-21

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2018-03-22

Actual Completion Date

2018-03-22

Studied populations

Age Cohort

- Adults

Genders

- Female

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

No

Comments about the studied populations

Inclusion Criteria: * Subject willing and able to give informed consent * Must be ≥19 and ≤45 years diagnosed with HPV infection in two tests within screening periods or have history of HPV infection within 6 months and diagnosed with HPV infection in one test within screening periods * No clinical abnormality from ECG test * Must agree to use appropriate contraceptive methods (ie, condoms, cervical cap in conjunction with spermicide, sterilization, and intra uterine device) during the study and for 3 months after the last dose of study drug. Exclusion Criteria: * Subject with HSIL or more severe HPV infection * History of a known or suspected hypersensitivity, shock, or past history to the investigational drug or to similar drugs * Malignant tumor within 5 years other than successfully.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

32

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Double-blind masking

Masking description

Not provided

Frequency of administration

Other(s) : "Q2W "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

Treatment

Key results

Not provided

GX-H9-003

Identifier

NCT03309891

Link

https://clinicaltrials.gov/study/NCT03309891

Phase

Phase II

Status

Completed

Sponsor

Genexine, Inc.

More details

This is a randomized, open-label, active controlled, Phase 2 study designed to assess the safety, tolerability, efficacy, pharmacokinetics, and pharmacodynamics of weekly and semi-monthly doses of GX-H9 in the treatment of Paediatric Growth Hormone Deficiency (PGHD) as compared to the standard of care daily rhGH treatment.

Purpose

Dose Finding Study of GX-H9 in Paeditaric Patients With Growth Hormone Deficiency

Interventions

Intervention 1

GX-H9

Intervention 2

Genotropin

Countries

Ukraine

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2016-01-18

Anticipated Date of Last Follow-up

2020-04-16

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2017-10-27

Actual Completion Date

2019-05-15

Studied populations

Age Cohort

- Children

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

No

Comments about the studied populations

Inclusion Criteria: 1. Pre-pubertal children with either isolated GHD, or GH insufficiency as part of multiple pituitary hormone insufficiency, idiopathic or organic GH insufficiency (e.g., due to pituitary tumor, pituitary or brain surgery): * Boys: 3 years ≤ boy's age ≤ 11 years * Girls: 3 years ≤ girl's age ≤ 10 years 2. GHD confirmed by 2 different GH provocation tests with peak GH concentration below 10 ng/mL as described in consensus guidelines. Well documented historical GH provocation tests can be used for study eligibility providing that the tests are performed as defined in Appendix 2 (e.g. the same sampling time points). Data of each historical GH stimulation test will be reviewed by Medical Monitor and Sponsor in order to assess acceptance for the study.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

56

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

GX-I7-CA-010

Identifier

NCT05191784

Link

https://clinicaltrials.gov/study/NCT05191784

Phase

Phase II

Status

Not provided

Sponsor

Genexine, Inc.

More details

The purpose of this study is to evaluate the efficacy and safety of GX-I7 in combination with bevacizumab in subjects with recurrent glioblastoma.

Purpose

GX-I7 in Combination With Bevacizumab in Recurrent Glioblastoma (GBM) Patients

Interventions

Intervention 1

GX-I7

Intervention 2

Bevacizumab

Countries

Ukraine

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2022-01-26

Anticipated Date of Last Follow-up

2023-06-08

Estimated Primary Completion Date

2024-12-31

Estimated Completion Date

2024-12-31

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. Age ≥ 19 years 2. Histologically diagnosed glioblastoma patients who have been confirmed the progression of disease after attempting standard therapy (RT/CCRT and/or adjuvant chemotherapy (TMZ)) 3. Karnofsky Performance Status; KPS ≥ 60 or ECOG status 0-2 4. Life expectancy \> 12 weeks 5. Adequate hematologic and end organ function Exclusion Criteria: 1. Malignancies other than disease under study within 5 years prior to the first dose of study drug 2. Subjects who have received bevacizumab or other VEGF inhibitors prior to study participation 3. Body Mass Index (BMI) ≥ 30 kg/m2 4. Subjects confirmed intracranial hemorrhage with non-contrast CT or MRI 5. Clinically significant cardiovascular disease 6. History of arterial or venous thromboembolism 6 months prior t

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

20

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)

Injectable

Studied route(s) of administration

Not provided

Use case

Treatment

Key results

Not provided

GX-G3

Identifier

NCT01951027

Link

https://clinicaltrials.gov/study/NCT01951027

Phase

Phase I

Status

Completed

Sponsor

Genexine, Inc.

More details

pharmacokinetics/pharmacodynamics of GX-G3 after single subcutaneous administration in healthy male subjects.

Purpose

Phase I Study GX-G3 in Healthy Subjects

Interventions

Intervention 1

GX-G3 12.5 µg/kg or Placebo

Intervention 2

GX-G3 25 µg/kg or Placebo

Intervention 3

GX-G3 50 µg/kg or Placebo

Intervention 4

GX-G3 100 µg/kg or Placebo

Countries

Korea, Republic of

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2013-09-01

Anticipated Date of Last Follow-up

2015-01-27

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2014-07-01

Actual Completion Date

2014-12-01

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: Subjects may be entered in the study only if they meet all of the following criteria: 1. Are capable of understanding and complying with the requirements of the study and have voluntarily signed the informed consent form (ICF); 2. Healthy male volunteers aged 20-45 years; 3. Have a body weight of 60-90 kg (inclusive), have a body mass index (BMI) equal to or greater than 19 and less than 27 kg/m2; 4. Are eligible for the study based on screening data (Subjects may participate if Investigator considered eligible after looking at other screening data); Exclusion Criteria: Subjects presenting with any of the following will not be entered in to the study: 1. Have a history of or current evidence of disease; 2. Have percent of white blood cell (WBC) or neutrophil \> UNL.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

53

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Double-blind masking

Masking description

Not provided

Frequency of administration

Other(s) : "Single dose "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Subcutaneous

Use case

Treatment

Key results

Not provided

GX-P1-001

Identifier

NCT04298749

Link

https://clinicaltrials.gov/study/NCT04298749

Phase

Phase I

Status

Completed

Sponsor

Genexine, Inc.

More details

This study is a single-center, double-blind, placebo-controlled, phase I study with healthy male volunteers receiving ascending single dose of GX-P1

Purpose

Safety and Tolerability of GX-P1 in Healthy Male Volunteers

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2020-08-11

Anticipated Date of Last Follow-up

2021-07-21

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2021-06-07

Actual Completion Date

2021-06-07

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. Capable of understanding and complying with the requirements of the study and have voluntarily signed the informed consent form (ICF) 2. Healthy male volunteers aged 19-45 years within screening periods 3. Body weight of 50-90 kg, and body mass index (BMI) of 18.0-30.0 kg/m2 4. Healthy subjects as determined by medical history, physical examination vital signs, ECG and clinical laboratory testing Exclusion Criteria: 1. Any clinical significant pancreatic, hepatic, renal, gastrointestinal, cardiovascular, respiratory, hematological, central nervous system disease or other significant diseases which might influence either the safety of the subject or the absorption, metabolism or excretion of the active agent under investigation.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

24

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

Treatment

Key results

Not provided

GX-G6-002

Identifier

NCT03962010

Link

https://clinicaltrials.gov/study/NCT03962010

Phase

Phase II

Status

Unknown status

Sponsor

Genexine, Inc.

More details

GX-G6-002 is a Phase 2, 12-week, randomized, parallel group, multi-centre, double blind, placebo-controlled and an open-label active comparator study.

Purpose

A Phase 2, 12-Week, Double-Blind, Efficacy and Safety of GX-G6 in Patients With Uncontrolled Type 2 Diabetes Mellitus

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2019-06-01

Actual Start Date

Not provided

Anticipated Date of Last Follow-up

2019-05-22

Estimated Primary Completion Date

2022-06-01

Estimated Completion Date

2022-07-01

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. Diagnosis of T2DM ≥ 6 months prior to screening 2. HbA1c level of 7-10% (inclusive) Exclusion Criteria: 1. Have known type 1 diabetes mellitus (T1DM) 2. History of severe hypoglycaemia defined as ≥ 2 episodes of severe hypoglycaemia within 6 months prior to screening 3. Have had ≥ 2 episodes of ketoacidosis or hyperosmolar state/coma requiring hospitalization in the 6 months prior to screening 4. Has fasting serum TG ≥ 500 mg/dL or 9 mmol/L at screening. 5. Patients receiving lipid-lowering therapy must have been on the same dose of therapy for the past three months

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

78

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)

Injectable

Studied route(s) of administration

Not provided

Use case

Treatment

Key results

Not provided

GX30_P1/2

Identifier

NCT03276988

Link

https://clinicaltrials.gov/study/NCT03276988

Phase

Phase I/II

Status

Completed

Sponsor

Genexine, Inc.

More details

This study is designed as a combination of phase 1 (Part A) and phase 2 (Part B). The purpose of Part A was to determine the safety, tolerability, and pharmacokinetics in patients with total thyroidectomy or near total thyroidectomy of GX-30 and it has been completed. The Part B is currently recruiting and will investigate the efficacy and safety of GX-30 compared with THYROGEN®.

Purpose

Tolerability, Safety and Pharmacokinetics Study of GX-30 in Total Thyroidectomy or Near Total Thyroidectomy Patients

Interventions

Intervention 1

Thyrotropin alpha (THYROGEN)

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2017-09-07

Anticipated Date of Last Follow-up

2020-09-07

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2020-01-20

Actual Completion Date

2020-01-20

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: * Subjects who voluntarily consented, after listing enough explanation for this study and investigational product. * Minimum 19 years old. * Minimum 50kg of body weight. * Patients who had undergone total thyroidectomy or near total thyroidectomy due to differentiated thyroid carcinoma. * Patient undergoing thyroid hormone administration. Exclusion Criteria: * Thyroid cancer excluding differentiated thyroid carcinoma. * Thyroidectomy excluding total thyroidectomy and near total thyroidectomy. * Patients with heart, renal, or liver failure. * Patients with ischemic stroke or the history of ischemic stroke. * Smoker or Ex-smoker with less than 3 months of stopping * Patients with migraine or the history of migraine. * Patients that the researchers do not think fit into.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

8

Allocation

Randomized

Intervention model

Cross-over assignment

Intervention model description

Not provided

Masking

Double-blind masking

Masking description

Not provided

Frequency of administration

Other(s) : "Two doses "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

Treatment

Key results

Not provided

GX-H9-002

Identifier

NCT02946606

Link

https://clinicaltrials.gov/study/NCT02946606

Phase

Phase II

Status

Completed

Sponsor

Genexine, Inc.

More details

This is a randomized, active-controlled, open-label, sequential dose group, Phase 1b/2 study designed to assess the safety, tolerability, efficacy, pharmacokinetics, and pharmacodynamics of weekly and every other week doses of GX-H9 in the treatment of AGHD.

Purpose

A Clinical Study in AGHD to Assess Safety, Tolerability and Efficacy of GX-H9

Interventions

Intervention 1

GX-H9

Intervention 2

Genotropin

Countries

Korea, Republic of

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2015-01-01

Anticipated Date of Last Follow-up

2017-09-04

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2016-12-30

Actual Completion Date

2016-12-30

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 Each subject must meet all of the following criteria to be enrolled in this study: 1. Is a male or female aged ≥20 and 65 years with AGHD, either adult onset GHD due to hypothalamic pituitary disease or childhood onset GHD that is either idiopathic or due to hypothalamic pituitary disease or due to genetic causes. 2. Has documented confirmation (medical history) of GH deficiency during adulthood by 1 or more growth hormone (GH) stimulation tests, as follows: 3. Has been treated with stable hormonal replacement therapies for deficiencies of other hypothalamo pituitary axes and must have been on an optimized and stable treatment regimen for at least 3.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

45

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)

Injectable

Studied route(s) of administration

Intramuscular

Use case

Treatment

Key results

Not provided

GX-E2_P2

Identifier

NCT02044653

Link

https://clinicaltrials.gov/study/NCT02044653

Phase

Phase II

Status

Completed

Sponsor

Genexine, Inc.

More details

The primary objective of study is * Part A : To explore the optimal fixed starting dose and dosing interval of GX-E2 * Part B : To evaluate the proof of concept (POC) of GX-E2

Purpose

Study to Evaluate the Efficacy and Safety of GX-E2 in the Anemic Patients Diagnosed With Chronic Kidney Disease (CKD)

Interventions

Intervention 1

GX-E2

Intervention 2

GX-E2

Intervention 3

GX-E2

Intervention 4

NESP

Intervention 5

MIRCERA

Countries

Korea, Republic of

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2014-04-15

Anticipated Date of Last Follow-up

2017-10-13

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2017-04-20

Actual Completion Date

2017-04-20

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: * Written informed consent * ≥18 yr of age * Chronic Kidney diseases with hemodialysis, peritoneal dialysis with Kt/V ≥ 1.2 (hemodialysis) or Kt/V ≥ 1.7 (peritoneal dialysis) within a year * Adequate transferrin saturation (≥20%), serum ferritin (≥100ug/L) * Should have received Vitamine B12 ≥ 3 months before the first dose of study agent * Should have received Folate ≥3 months before the first dose of study agent * No erythropoietin (EPO) therapy within 2 months before the planned first dose of GX-E2 and Hb\<10g/dL or No EPO therapy within a month (peritoneal dialysis) or 2 weeks (hemodialysis) before the planned first dose of GX-E2 and Hb\<10g/dL.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

257

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Single blind masking

Masking description

Not provided

Frequency of administration

Other(s) : "Q2W "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Subcutaneous
Intravenous

Use case

Treatment

Key results

Not provided

GX-E4-HV-003

Identifier

NCT06490939

Link

https://clinicaltrials.gov/study/NCT06490939

Phase

Phase I

Status

Not yet recruiting

Sponsor

Genexine, Inc.

More details

An open-label, parallel-group, single-center, Phase I study to compare the pharmacokinetic/pharmacodynamic characteristics, safety, and tolerability of a single intravenous administration of Efepoetin Alfa in healthy subjects

Purpose

Clinical Trial of Efepoetin Alfa in Healthy Subjects

Interventions

Intervention 1

Efepoetin Alfa

Countries

Korea, Republic of

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2024-08-01

Actual Start Date

Not provided

Anticipated Date of Last Follow-up

2024-07-08

Estimated Primary Completion Date

2025-01-31

Estimated Completion Date

2025-08-31

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Key Inclusion Criteria: 1. Adult males and females between the ages of 19-45 2. Asian or Caucasian 3. Body weight \>50 kg and \<90 kg, BMI 18 \~30 (BMI(kg/m2) = Weight(kg) / {Height(m)}2) 4. Normal hemoglobin range. 5. Normal Serum ferritin and transferrin saturation range. 6. Normal serum folate range 7. Normal vitamin B12 range 8. White blood cell \>=3.0 X 10\^3 /mm3 9. Platelet \>= 150 X 10\^3/mm\^3 and \<450 X 10\^3/mm\^3 10. Nonsmoker or smoker who smokes below 10 cigarettes a day. Key Exclusion Criteria: 1. An allergy history, including drug allergies(example: aspirin, antibiotics, etc.) or clinically significant allergy. 2. Liver(including viral hepatitis), renal, respiratory, endocrine, neurological, immunological, blood, psychological, or circulatory system abnormalities, or a

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

40

Allocation

Not provided

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Other(s) : "Single dose "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intravenous

Use case

Treatment

Key results

Not provided

GX-I7-COV-009

Identifier

NCT04730427

Link

https://clinicaltrials.gov/study/NCT04730427

Phase

Phase I

Status

Terminated

Sponsor

Genexine, Inc.

More details

This study is a phase 1b clinical trial to investigate the safety and preliminary effects of a single dose of a test drug or placebo to the subjects who has diagnosed as COVID-19 infection.

Purpose

Safety and Preliminary Efficacy Study of GX-I7 in Patients With COVID-19

Interventions

Intervention 1

GX-I7

Intervention 2

GX-I7 vehicle

Countries

Korea, Republic of

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2021-03-24

Anticipated Date of Last Follow-up

2022-11-25

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2022-05-08

Actual Completion Date

2022-07-07

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

Key Inclusion Criteria: 1. Subjects who have been confirmed to be COVID-19 corresponding to mild cases of severity categorization classified by FDA through polymerase chain reaction (PCR) test or virus gene test (sequencing) and who can be available to be administered within seven days from the date of manifestation. 2. Subjects who are or will be inpatient. Key Exclusion Criteria: 1. Patients with symptoms of moderate or higher in the severity classification presented by FDA have evidence of lower respiratory tract infection in their imaging findings or need supplemental oxygen therapy or mechanical respiration (ie, non-invasive ventilation, invasive mechanical ventilation, extracorporeal membrane oxygenation, etc) 2. Subjects with infectious diseases such as bacteremia or severe pneum

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

10

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Single blind masking

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Not provided

Use case

Treatment

Key results

Not provided

GX-I7-CA-007

Identifier

NCT04065087

Link

https://clinicaltrials.gov/study/NCT04065087

Phase

Phase I/II

Status

Withdrawn

Sponsor

Genexine, Inc.

More details

This is a phase 1/2, randomized, placebo-controlled study to evaluate safety, tolerability, anti-tumor activity and impact on absolute lymphocyte count of GX-I7 plus adjuvant temozolomide combination regimen in patients with newly diagnosed with glioblastoma who completed standard concurrent chemo-radiation therapy (CCRT)

Purpose

Efficacy and Safety Study of GX-I7 Plus Adjuvant Temozolomide Combination in Patients With Newly Diagnosed Glioblastoma

Interventions

Intervention 1

GX-I7

Intervention 2

Placebo

Intervention 3

Temozolomide

Countries

Korea, Republic of

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2019-08-22

Actual Start Date

Not provided

Anticipated Date of Last Follow-up

2022-03-02

Estimated Primary Completion Date

2022-05-27

Estimated Completion Date

2022-08-27

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. Signed Informed Consent Form (ICF) 2. Age ≥ 19 years 3. Gross total resection equal to or greater than 80% based on post-op MRI, compared to pre-op MRI (Patients requiring biopsy only is not eligible) 4. Patients newly diagnosed with glioblastoma either by imaging or pathology testing, requiring concurrent chemo-radiotherapy (CCRT) and adjuvant temozolomide chemotherapy with curative intent 5. Karnofsky score ≥ 60 6. Life expectancy \> 12 weeks Exclusion Criteria: 1. Gliomatosis cerebri 2. Isocitrate dehydrogenase 1 \& 2 mutation 3. Pregnant or breast feeding women

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

Not provided

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)

Injectable

Studied route(s) of administration

Not provided

Use case

Treatment

Key results

Not provided

GX-I7-CA-005

Identifier

NCT03733587

Link

https://clinicaltrials.gov/study/NCT03733587

Phase

Phase I

Status

Completed

Sponsor

Genexine, Inc.

More details

This is a Phase 1b study to explore the safety and efficacy of GX-I7 in combination with CPA in patients with metastatic or recurrent solid tumors.

Purpose

GX-I7 With Cyclophosphamide in Patients With Metastatic or Recurrent Solid Tumors

Interventions

Intervention 1

GX-I7

Intervention 2

Cyclophosphamide

Intervention 3

Cyclophosphamide

Countries

Korea, Republic of

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2018-10-17

Anticipated Date of Last Follow-up

2020-05-12

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2020-04-02

Actual Completion Date

2020-05-13

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: * Histological confirmation of solid tumor, for which no standard therapy exists or is available any longer. * Aged ≥19 years(Korean age). * Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. * Life expectancy ≥12 weeks. * Adequate hematological and end organ function defined by the following * laboratory results obtained within 14 days prior to Cycle 1 Day 1 (C1D1) * Female subjects of childbearing potential (including a female who has undergone tubal ligation) requires a negative serum pregnancy test performed within 14 days prior to C1D1. * Have an evaluable lesion(s) by Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 * Subjects to be enrolled in the Phase 2a stage must be able to provide pre-treatment tissue biopsy or archival tissue

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

Allocation

Not provided

Intervention model

Sequential assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Not provided

Use case

Treatment

Key results

Not provided

GBM

Identifier

NCT03619239

Link

https://clinicaltrials.gov/study/NCT03619239

Phase

Phase I

Status

Completed

Sponsor

Genexine, Inc.

More details

Patients will be enrolled in two stages: * Dose-escalation stage: Approximately 12-24 patients will be enrolled.

Purpose

Dose-escalation Study to Evaluate the Safety and Tolerability of GX-I7 in Patients With Glioblastoma

Interventions

Intervention 1

GX-I7

Countries

Korea, Republic of

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2018-06-20

Anticipated Date of Last Follow-up

2020-11-08

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2020-09-25

Actual Completion Date

2020-09-25

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. Ability to understand and willingness to sign a written informed consent document (ICF). 2. Age ≥ 19 years 3. Able to comply with the study protocol, in the investigator's judgment 4. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. Exclusion Criteria 1. Unable to comply with study and follow-up procedures 2. Is pregnant or breastfeeding 3. Have clinically significant cardiac disease (New York Heart Association, Class II or greater) including myocardial infarction, unstable arrhythmias, and/or unstable angina in the past 3 months 4. Have clinically significant liver disease, including alcoholic, or other hepatitis, cirrhosis, and inherited liver disease or current alcohol abuse.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

15

Allocation

Not provided

Intervention model

Sequential assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Not provided

Use case

Treatment

Key results

Not provided

GX-I7-CA-003

Identifier

NCT03478995

Link

https://clinicaltrials.gov/study/NCT03478995

Phase

Phase I

Status

Completed

Sponsor

Genexine, Inc.

More details

Patients will be enrolled in two stages: * Dose-escalation stage: Approximately 15-30 patients will be enrolled. * Dose-expansion stage: 6-12 patients will be enrolled. Dose-escalation slots will be filled first, then dose-expansion slots.

Purpose

Study to Evaluate Safety and Tolerability of GX-I7 in Patients With Locally Advanced or Metastatic Solid Tumors

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2018-03-05

Anticipated Date of Last Follow-up

2020-05-07

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2020-03-16

Actual Completion Date

2020-03-16

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: * Signed Informed Consent Form (ICF) * Age ≥ 19 years * Able to comply with the study protocol, in the investigator's judgment * Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 * Life expectancy ≥ 12 weeks * Adequate hematologic and end organ function, defined by the following laboratory results obtained within 14 days prior to the first study treatment (Cycle 1, Day 1) * Serum pregnancy test for women of childbearing potential (including women who have had a tubal ligation) must be performed and documented as negative within 14 days prior to Cycle 1, Day 1 * For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures, and agreement to refrain from donating sperm

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

35

Allocation

Not provided

Intervention model

Sequential assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Other(s) : "Single dose "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Not provided

Use case

Treatment

Key results

Not provided

GX-E2-P1

Identifier

NCT02291991

Link

https://clinicaltrials.gov/study/NCT02291991

Phase

Phase I

Status

Completed

Sponsor

Genexine, Inc.

More details

This is a randomized, placebo controlled, single dose study to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of GX-E2 in healthy male subjects.

Purpose

Study to Evaluate Safety, Tolerability, and Pharmacokinetics/Pharmacodynamics of GX-E2 in Healthy Subjects

Interventions

Intervention 1

GX-E2

Intervention 2

GX-E2

Countries

Korea, Republic of

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2014-11-01

Anticipated Date of Last Follow-up

2015-01-27

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2015-01-01

Actual Completion Date

2015-01-01

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: * Written informed consent * Male subjects 20 to 55 years old * Adequate body weigth and BMI(19 ≤ BMI ≤ 27, 60.0kg ≤ body weigth ≤ 90.0kg) * The subject doesn't have a clinically significant abnormal laboratory value and/or clinically significant unstable medical or disease history. * Are eligible for the study hemoglobin data(12.0g/dL ≤ Hb ≤ 16.5g/dL) (Data is checked per 2 weeks within 28 days) * Adequate transferrin saturation, serum ferritin within 28 days * Adequate folate within 28 days * Adequate vitamin B12 within 28 days * Adequate WBC count (≥ 3.0 X 1000 μL) * Adequate PLT count(≥ 140 X 1000 μL) * nonsmoker or smoker smoked under 10 cigarettes a day Exclusion Criteria: * The subject has a clinically significant abnormal allergy including medical allergy.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

10

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Not provided

Frequency of administration

Other(s) : "Single dose "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Subcutaneous

Use case

Treatment

Key results

Not provided

GXI7KGBio-001

Identifier

NCT04810637

Link

https://clinicaltrials.gov/study/NCT04810637

Phase

Phase II

Status

Unknown status

Sponsor

PT Kalbe Genexine Biologics

More details

This is a Phase 2 prospective, randomized, placebo-controlled, double-blinded, parallel group, single administration, multi-center study to assess the safety and efficacy of efineptakin alfa single treatment compared to placebo in elderly participants (adults ≥50years) with asymptomatic or mild COVID-19

Purpose

A Study to Evaluate the Safety and Efficacy of GX-I7 in Elderly Patients With Asymptomatic or Mild Symptoms of COVID-19

Interventions

Intervention 1

GX-I7

Countries

Indonesia

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2020-11-01

Anticipated Date of Last Follow-up

2021-03-22

Estimated Primary Completion Date

2021-06-01

Estimated Completion Date

2021-09-01

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

No

Comments about the studied populations

Inclusion Criteria: 1. Adults aged 50 years and above at the time of consent 2. Subjects who have been confirmed to be COVID-19 corresponding to asymptomatic case or mild cases of severity categorization classified by FDA through authorized molecular saliva-based test or polymerase chain reaction (PCR) test and who can be available to be administered within 7 days from the onset of any symptoms. 3. Patients who provide a voluntarily consent to participate in the study and sign the consent form in his/her own handwriting. 4. Female patients of childbearing potential (including female received a tubal ligation) should be prove negative pregnancy through pregnancy test before 24 hours of the IP administration, and must be willing to maintain abstinence (restraint sexual relationships).

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

210

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Triple-blind masking

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Not provided

Use case

Treatment

Key results

Not provided

GX-I7-CA-006

Identifier

NCT03752723

Link

https://clinicaltrials.gov/study/NCT03752723

Phase

Phase I/II

Status

Completed

Sponsor

Genexine, Inc.

More details

To evaluate the safety and tolerability of escalating doses GX-I7 in combination with standard dose pembrolizumab, and to evaluate objective response rate (ORR) in subjects with refractory or relapsed TNBC

Purpose

Study of GX-I7 in Combination With Pembrolizumab in Refractory or Relapsed (R/R) TNBC Subjects(GX-I7-CA-006/KEYNOTE-899)

Interventions

Intervention 1

GX-I7

Intervention 2

Pembrolizumab(KEYTRUDA®)

Intervention 3

Cyclophosphamide

Countries

Korea, Republic of

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2019-03-27

Anticipated Date of Last Follow-up

2024-03-01

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2023-05-11

Actual Completion Date

2023-05-11

Studied populations

Age Cohort

Adults

- Older Adults

Genders

- Female

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

No

Comments about the studied populations

Key Inclusion Criteria: 1. Triple negative must be defined as guidelines of American Society of Clinical Oncology(ASCO)/ College of American Pathologist(CAP): Estrogen Receptor (ER) \< 1% positive tumor nuclei, Progesterone Receptor (PR) \< 1% positive tumor nuclei, and negative for HER2 by IHC 1+, 0 or negativity status confirmed by in situ hybridization (ISH). 2. Subject must have received anthracycline and taxane based chemotherapy for TNBC 3. Has measurable disease as defined by RECIST 1.1 as assessed by the the local site Investigator/radiology. 4. Female subjects, age ≥ 19 years at the time of consent. Key Exclusion Criteria: 1. Known severe hypersensitivity (≥ Grade 3) to pembrolizumab, pembrolizumab formulation excipients or GX-I7 formulation excipients or cyclophosphamide.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

Allocation

Not provided

Intervention model

Sequential assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Not provided

Use case

Treatment

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

- Single-use
- Other(s)

  Drug release from the protein fragments at intercellular level

Release properties

The fusion protein GX-H9, comprising the erythropoietin analog -Efepoietin Alfa and the Fc domain of human IgG4, exhibits a prolonged serum half-life due to FcRn-mediated endocytosis and recycling. The gradual release of Efepoietin Alfa from the IgG4 moiety contributes to this extended pharmacokinetic profile. Following subcutaneous administration, mean serum concentrations of Efepoietin Alfa reached peak levels within 0-12 hours and subsequently declined in a biphasic pattern.

Injectability

HyFC prefilled injections are administered via subcutaneous or intramuscular injection. The needle is inserted into the designated site, and the medication is injected at a controlled rate

Safety

Clinical studies of Efesa Q2W show that 69.7% of the treated anemia in CKD-non-dialysis patients have experienced an AE (vs 64.5%).

Stability

hyFC technology products may allow long-term storage at cold storage with a shelf life of 1 year.

Storage conditions and cold-chain related features

Store in a refrigerator at temperatures between 2°C and 8°C. Avoid freezing. Protect from light and handle gently.

Potential application(s)

Therapeutic area(s)

Diabetes

Other(s) : "HPV, Autoimmune diseases, Organ Transplantation, CKD induced anemia, Obesity, Ocular degeneration and Neutropenia"

Oncology

Use case(s)

Treatment

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

Monthly, Every two weeks and Twice monthly

User acceptance

Not provided

Targeted user groups

Age Cohort

- Children
- Adolescents
- Adults
- Older Adults

Genders

- All

Pregnant individuals

No

Lactating individuals

No

Healthy individuals

Unspecified

Comment

Not provided

Potential associated API(s)

Interleukins

Class(es)

Antineoplastic agent

Development stage

Phase II

Clinical trial number(s)

NCT03144934

Foreseen/approved indication(s)

Lymphopenia, solid tumors, infectious disease

Foreseen user group

Not provided

Foreseen duration between application(s)

Twice monthly

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

Not provided

erythropoietin (EPO)

Class(es)

Erythropoiesis-stimulating agent

Development stage

Marketed

Clinical trial number(s)

NCT06466785

Foreseen/approved indication(s)

CKG induced Anemia

Foreseen user group

Chronic kidney diseases patients

Foreseen duration between application(s)

Every 2 weeks and 4 weeks

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

Efesa is approved in Indonesia by the Indonesian Food and Drug Adminstration (BPOM)

Human Growth Hormone Agonists

Class(es)

Pituitary Hormones and analogues

Development stage

Phase III

Clinical trial number(s)

Not provided

Foreseen/approved indication(s)

Pediatric & Adult growth hormone deficiency

Foreseen user group

Children, adolescents and adults with Growth hormone deficiency

Foreseen duration between application(s)

Twice monthly

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

Eftansomatropin alfa is currently in Phase 3 clinical study in China

Programmed cell death ligand 1 (PD-L1)

Class(es)

PDL1 inhibitors(Programmed death-ligand 1 inhibitors)

Development stage

Phase I

Clinical trial number(s)

NCT04298749

Foreseen/approved indication(s)

Autoimmune disease, and Organ Transplatation

Foreseen user group

Not provided

Foreseen duration between application(s)

Not provided

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

Not provided

Colony stimulating factors

Class(es)

Granulocyte colony-stimulating factor

Development stage

Phase I

Clinical trial number(s)

NCT01951027

Foreseen/approved indication(s)

Neutropenia

Foreseen user group

Not provided

Foreseen duration between application(s)

Not provided

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

Not provided

Glucagon-like peptide-1 (GLP-1) analogues (GLP-1)

Class(es)

GLP-1 and its analogues

Development stage

Phase I

Clinical trial number(s)

NCT03651466

Foreseen/approved indication(s)

Diabetes Mellitus and Obesity

Foreseen user group

Not provided

Foreseen duration between application(s)

Not provided

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

Not provided

Recombinant human thyroid-stimulating hormone (rhTSH)

Class(es)

Recombinant human thyroid stimulating hormone

Development stage

Phase I

Clinical trial number(s)

NCT03276988

Foreseen/approved indication(s)

Differentiated thyroid carcinoma

Foreseen user group

Patients who are undergoing Total or Partial Thyroidectomy

Foreseen duration between application(s)

Not provided

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

Not provided

glucagon-like peptide-2 (GLP-2)

Class(es)

Glucagon-like peptide-2 (GLP-2) analogs

Development stage

Phase I

Clinical trial number(s)

Not provided

Foreseen/approved indication(s)

Short Bowel Syndrome

Foreseen user group

Not provided

Foreseen duration between application(s)

Not provided

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

Not provided

Interleukins

Class(es)

Interleukin-7

Development stage

Phase II

Clinical trial number(s)

NCT03478995

Foreseen/approved indication(s)

Fibrotic/metastatic cancers

Foreseen user group

Not provided

Foreseen duration between application(s)

Every three or six weeks

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

Not provided

Vascular Endothelial Growth Factor inhibitors (VEGF/VEGFR)

Class(es)

VEGR inhibitors

Development stage

Phase I

Clinical trial number(s)

Not provided

Foreseen/approved indication(s)

Neovascular (Wet) Age-Related Macular Degeneration

Foreseen user group

Not provided

Foreseen duration between application(s)

Not provided

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

Not provided

Programmed cell death ligand 1 (PD-L1)

Class(es)

PD-L1 inhibitors

Development stage

Phase I

Clinical trial number(s)

Not provided

Foreseen/approved indication(s)

Autoimmune disease and Organ Transplantion

Foreseen user group

Not provided

Foreseen duration between application(s)

Not provided

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

Not provided

Patent info

Description

Formulation of modified interleukin-7 fusion protein

Brief description

Provided is a pharmaceutical formulation comprising a modified IL-7 protein. More particularly, it comprises (a) a modified IL-7 fusion protein; (b) a basal buffer with a concentration of 10 to 50 mM; (c) a sugar with a concentration of 2.5 to 5 w/v %; and (d) a surfactant with a concentration of 0.05 to 6 w/v %. Such pharmaceutical formulation of a modified IL-7 fusion protein does not show aggregates formation, but shows protective effects on proteins under stress conditions such as oxidation or agitation, and thus can effectively be used for the treatment of a patient.

Representative patent

US11548927B2

Category

Formulation

Patent holder

Genexine Inc

Exclusivity

Not provided

Expiration date

November 2, 2036

Status

Active

Description

Modified interleukin-7 protein

Brief description

The present invention provides a modified interleukin-7 and a use thereof. The modified IL-7 or an IL-7 fusion protein of the present invention comprising the same can be obtained in high yield, and biologically active in viral infection and cancer models. Therefore, they can be used for the prevention and treatment of various diseases.Genexine Inc

Representative patent

US20190106471A1

Category

Not provided

Patent holder

Genexine Inc

Exclusivity

Not provided

Expiration date

October 26, 2036

Status

Active

Description

Human interleukin-1 receptor antagonist—hybrid Fc fusion protein

Brief description

The present disclosure provides a fusion protein comprising IL-1 receptor antagonist fused to a hybrid Fc. Particularly the present disclosure relates to a fusion protein comprising IL-1 receptor antagonist fused to a human immunoglobulin hybrid Fc fragment. In one embodiment, the hybrid Fc fragment comprises IgD and IgG4. Also provided is a pharmaceutical composition comprising the present fusion protein, which are useful for treating autoimmune disease including rheumatoid arthritis, inflammatory bowel disease (Crohn's disease, ulcerative colitis), psoriasis and diabetes and the like. The present fusion protein with excellent efficacy and reduced side effects is qualified for clinical development as therapeutic antibodies to treat autoimmune disease.

Representative patent

US8883134B2

Category

Formulation

Patent holder

Genexine Co Ltd Handok Pharmaceuticals Co Ltd

Exclusivity

Not provided

Expiration date

October 19, 2031

Status

Active

Description

Immunoglobulin fusion proteins

Brief description

Disclosed are fusion proteins comprising a biologically active molecule and an immunoglobulin (Ig) Fc domain which is linked to the biologically active molecule. The Fc domain is a hybrid human Fc domain of (i) IgG1, IgG2 or IgG4 or (ii) IgG4 and IgD. The hybrid Fc is useful as a carrier of biologically active molecules.

Representative patent

US7867491B2

Category

Treatment

Patent holder

Genexine Co., Ltd.,

Exclusivity

Not provided

Expiration date

May 30, 2028

Status

Active

Supporting material

Publications

** Kim, Y. J., Koh, E. M., Song, C. H., Byun, M. S., Choi, Y. R., Jeon, E. J., Hwang, K., Kim, S. K., Yang, S. I., & Jung, K. J. (2021). Preclinical immunogenicity testing using anti-drug antibody analysis of GX-G3, Fc-fused recombinant human granulocyte colony-stimulating factor, in rat and monkey models. Scientific reports, 11(1), 12004. https://doi.org/10.1038/s41598-021-91360-7 **

We optimized and validated analytical tools by adopting validation parameters for immunogenicity assessment. Using these validated tools, we analyzed serum samples from rats and monkeys injected subcutaneously with GX-G3 (1, 3 or 10 mg/kg once a week for 4 weeks followed by a 4-week recovery period) to determine immunogenicity response and toxicokinetic parameters with serum concentration of GX-G3. Several rats and monkeys were determined to be positive for anti-GX-G3 antibodies. Moreover, the immunogenicity response of GX-G3 was lower in monkeys than in rats, which was relevant to show less inhibition of toxicokinetic profiles in monkeys, at least 1 mg/kg administered group, compared to rats. These results suggested the establishment and validation for analyzing anti-GX-G3 antibodies and measurement of serum levels of GX-G3 and anti-GX-G3 antibodies, which were related to toxicokinetic profiles. Taken together, this study provides immunogenicity assessment which is closely implicated with a toxicokinetic study of GX-G3 in 4-week repeated administrated toxicological studies.

** Choi, Y. J., Hur, S. Y., Kim, T. J., Hong, S. R., Lee, J. K., Cho, C. H., Park, K. S., Woo, J. W., Sung, Y. C., Suh, Y. S., & Park, J. S. (2020). A Phase II, Prospective, Randomized, Multicenter, Open-Label Study of GX-188E, an HPV DNA Vaccine, in Patients with Cervical**

**Intraepithelial Neoplasia 3. Clinical cancer research : an official journal of the American Association for Cancer Research, 26(7), 1616–1623. https://doi.org/10.1158/1078-0432.CCR-19-1513 **

We conducted a prospective, randomized, multicenter, open-label, phase II clinical trial of GX-188E in CIN3 patients positive for human papillomavirus (HPV) type 16/18. The primary endpoint was to determine the histopathologic regression to ≤CIN1 at visit seven (V7; 20 weeks after the first GX-188E injection), and an extension study was pursued until visit 8 (V8; 36 weeks after the first GX-188E injection). HPV-sequencing analysis and an *ex vivo* IFNγ ELISpot assay were performed using the collected cervical biopsy and blood samples from patients.

In total, 72 patients were enrolled and underwent randomization. Of them, 64 patients were included in per-protocol analysis (V7) and 52 in extension analysis (V8). Our data showed 52% (33/64) of patients at V7 and 67% (35/52) of patients at V8 presented histopathologic regression after receiving the GX-188E injection. We found that 73% (V7) and 77% (V8) of the patients with histologic regression showed HPV clearance.

** Youn, J. W., Hur, S. Y., Woo, J. W., Kim, Y. M., Lim, M. C., Park, S. Y., Seo, S. S., No, J. H., Kim, B. G., Lee, J. K., Shin, S. J., Kim, K., Chaney, M. F., Choi, Y. J., Suh, Y. S., Park, J. S., & Sung, Y. C. (2020). Pembrolizumab plus GX-188E therapeutic DNA vaccine in patients with HPV-16-positive or HPV-18-positive advanced cervical cancer: interim results of a single-arm, phase 2 trial. The Lancet. Oncology, 21(12), 1653–1660. https://doi.org/10.1016/S1470-2045(20)30486-1 **

In this open-label, single-arm, phase 2 trial, patients with recurrent or advanced, inoperable cervical cancer, who were aged 18 years or older with Eastern Cooperative Oncology Group performance status of 0 or 1 and histologically confirmed recurrent or advanced HPV-positive (HPV-16 or HPV-18) cervical cancer, and who had progressed after available standard-of-care therapy were recruited from seven hospitals in South Korea. Patients received intramuscular 2 mg GX-188E at weeks 1, 2, 4, 7, 13, and 19, with one optional dose at week 46 that was at the investigator's discretion, and intravenous pembrolizumab 200 mg every 3 weeks for up to 2 years or until disease progression. The primary endpoint was the overall response rate within 24 weeks assessed by the investigator using Response Evaluation Criteria in Solid Tumors version 1.1 in patients who received at least 45 days of treatment 45 days of treatment with at least one post-baseline tumour assessment, and this is the report of a planned interim analysis. This trial is registered with ClinicalTrials.gov, NCT03444376 .

** Yang, S. H., Yang, S. I., & Chung, Y. K. (2012). A long-acting erythropoietin fused with noncytolytic human Fc for the treatment of anemia. Archives of pharmacal research, 35(5), 757–759. https://doi.org/10.1007/s12272-012-0500-5 **

The Fc fusion technology has been introduced to generate long-acting antagonistic drugs such as Enbrel, Orencia and Amevive. Here, Genexine created a novel noncytolytic hybrid Fc (hyFc) as a carrier of agonistic protein drugs using naturally existing IgD and IgG4 Fcs without any mutation in the hyFc region. The erythropoietin (EPO) fused with hyFc exhibited little binding activity to FcγR and C1q molecules that are main mediators for death of target cells. The EPO-hyFc showed higher in vitro and in vivo bioactivities than EPOIgG1 Fc and highly glycosylated EPO (Aranesp). Phase I clinical trial with EPO-hyFc is currently undergoing in Korea.

Additional documents

- Corporate Presentation
- Press Release

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

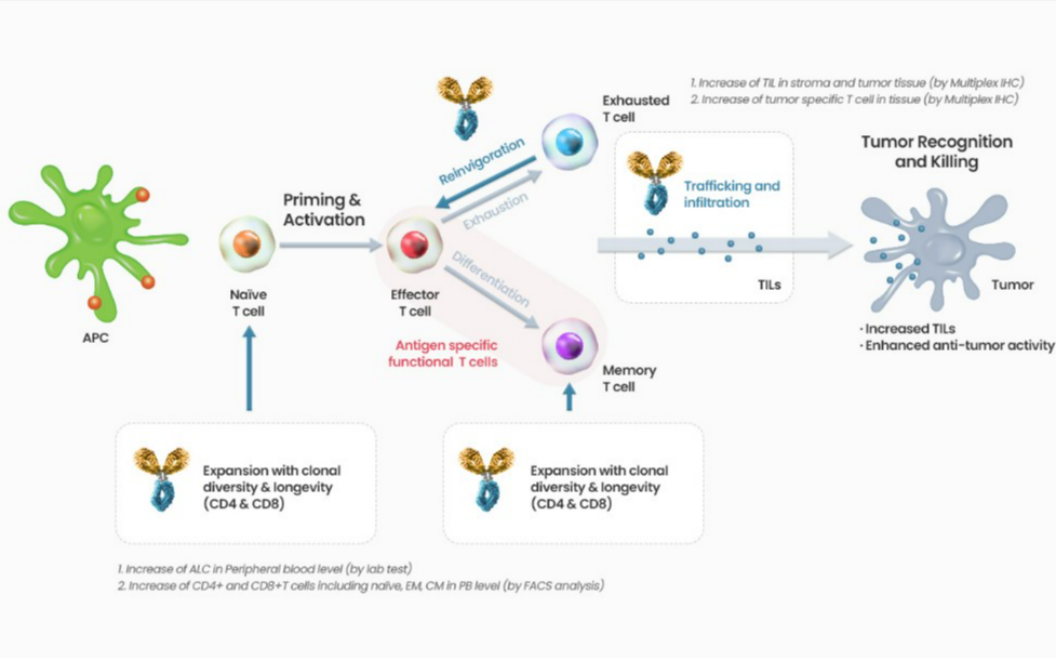
Work with MPP to expand access in LMICs

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

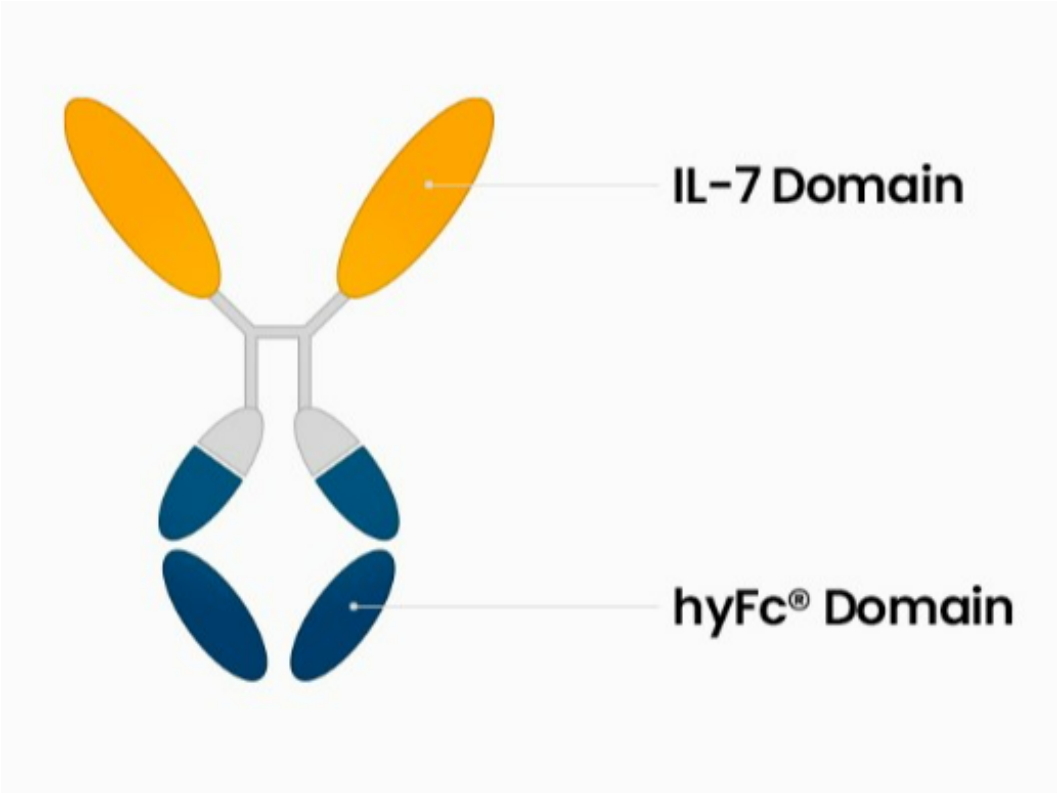
Comment & Information

Illustrations



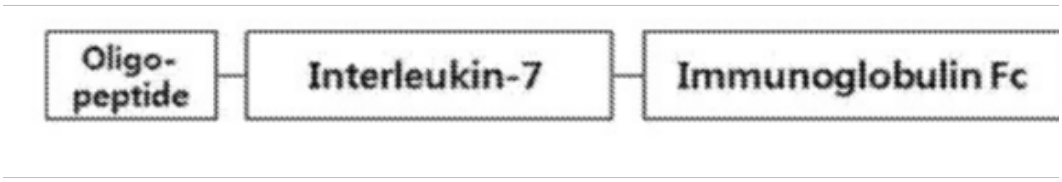
Pharmacodynamics of Gx-i7 inside the cells i.e., hyFc IL-alfa acts on IL-7 receptors, increasing CD4 and CD8 T cells (Naive & memory subtype)

Genexine. (n.d.). GX-I7 pipeline. Genexine. Retrieved September 3, 2024, from http://www.genexine.com/en/pipeline/gx-i7



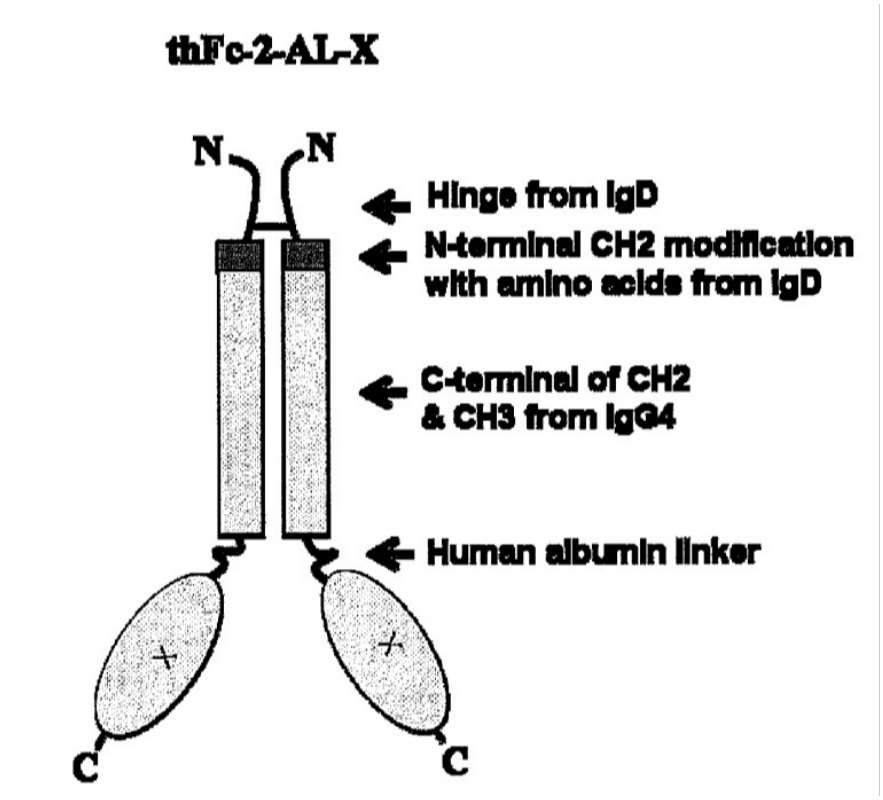
hyFC engineered IL-7 composed of IgG4 and IgD

Genexine. (n.d.). GX-I7 pipeline. Genexine. Retrieved September 3, 2024, from http://www.genexine.com/en/pipeline/gx-i7



Oligopeptide linkage with IL-7 and IG Fc

U.S. Patent No. US20230279069A1. (2023). Title of the patent. https://patentimages.storage.googleapis.com/00/57/97/83cbd38d28301a/US20230279069A1



The N terminals of IgD is linked to the compound by a human albumin linker

U.S. Patent No. US7867491B2. (2011). Title of the patent. https://patentimages.storage.googleapis.com/e1/19/d5/2a007ff60f6fe0/US7867491.pdf