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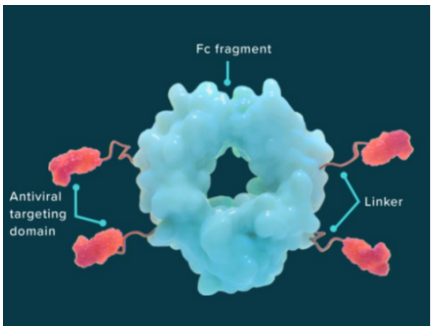


Drug Fragment Conjugate (DFC)

Based on public information

Developer(s)

Cidara Therapeutics

https://www.cidara.com/

United States of America

Cidara Therapeutics has developed a drug development pipeline platform called CloudBreak which is based on API conjugation with antibody fragment conjugate. This Drug Fc conjugate is a targeted immunotherapy that inhibits specific disease targets while simultaneously engaging the immune system. Cidara's portfolio includes novel therapeutics targeting viral infections and solid tumors.

Sponsor(s)

No sponsor indicated

Partnerships

Janseen Pharmaceuticals

https://www.janssen.com

Technology information

Type of technology

Peptide of Human Antibody Fragment (Fc) coupled with drug molecule

Administration route

Subcutaneous, Intramuscular

Development state and regulatory approval

Active Pharmaceutical Ingredient (API)

Temsavir

Development Stage

Pre-clinical

Regulatory Approval

Not provided

Description

Drug Fc Conjugate is a long acting technology that acts as a single-molecule cocktail by coupling targeted small molecules and peptides to a human antibody fragment (Fc). These conjugates bind to the target receptors for an extended period while simultaneously engaging with the immune system of the human body, allowing them to both treat and prevent disease. DFC also has the potential to carry multiple targeting drug molecules.

Technology highlight

• Ability to target cryptic sites & has small molecule binding pockets • Targeted pharmacological action with low systematic exposure • Long half-life, similar to monoclonal antibody • Multivalent target engagement of DFC increases potency of API and reduces resistance potential • Extracellular targeted action

Technology main components

Drug -Fc Conjugate cocktail consists of (i) API, (ii) peptide fusions, and (iii) a human antibody fragment specific to the targeted disease (Fc MOIETY).

Information on the raw materials sourcing, availability and anticipated price

Not provided

Delivery device(s)

No delivery device

APIs compatibility profile

API desired features

Water-soluble molecules

Water-insoluble molecules

Small molecules

The DFC technology targets small molecules like Influenza neuroaminidase inhibitors (such as oseltamivir, zanamivir, peramivir, and laninamivir), CD73 inhibitors, CCR antagonists and GP120 inhibitors (such as temsavir).

Additional solubility data

Not provided

Additional stability data

Not provided

API loading: Maximum drug quantity to be loaded

Not provided

API co-administration

Not provided

LogP

Not provided

Scale-up and manufacturing prospects

Scale-up prospects

WuXi XDC partnered with Cidara Therapeutics to manufacture DFC formulations. WuXi recently established a new manufacturing facility with the capacity to produce 200-2000 litres of DFC formulation per batch.

Tentative equipment list for manufacturing

Not provided

Manufacturing

Manufacturing of DFC formulation has low COGS.

Specific analytical instrument required for characterization of formulation

HPLC analytical procedure is used for the gross content and assay of reconstituted solution tests in the drug product specification

Clinical trials

CD388.SQ.2.02

Identifier

NCT05523089

Link

https://clinicaltrials.gov/study/NCT05523089

Phase

Phase II

Status

Completed

Sponsor

Cidara Therapeutics Inc.

More details

The purpose of this study is to evaluate the preventative antiviral activity of CD388, as compared to saline placebo, when administered as a single dose to healthy adult participants in a human viral challenge model of influenza.

Purpose

The Effectiveness of CD388 to Prevent Flu in an Influenza Challenge Model in Healthy Adults

Interventions

Intervention 1

Saline placebo

Intervention 2

CD388

Countries

United Kingdom

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2022-09-09

Anticipated Date of Last Follow-up

2023-07-28

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2023-07-17

Actual Completion Date

2023-07-17

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. Written informed consent signed and dated by the participant and the PI/investigator obtained before any assessment is performed. 2. Adult male or female aged between 18 and 55 years old, inclusive, on the day prior to signing the consent form. 3. A total body weight ≥50 kilograms (kg) and body mass index (BMI) ≥18 kg/meter squared (m\^2) and ≤35kg/m\^2. 4. In good health with no history, or current evidence, of clinically significant medical conditions, and no clinically significant test abnormalities that will interfere with participant safety, as defined by medical history, physical examination (including vital signs), electrocardiogram (ECG), and routine laboratory tests as determined by the Principal Investigator (PI)/investigator. 5. Participants will have a d

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

59

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

CD388.IM.SQ.1.01

Identifier

NCT05285137

Link

https://clinicaltrials.gov/study/NCT05285137

Phase

Phase I

Status

Completed

Sponsor

Cidara Therapeutics Inc.

More details

The purpose of this first-in-human study is to determine the safety and tolerability profile of CD388 Injection, as compared to saline placebo, when administered as a single dose to healthy adult subjects by injection either in the muscle or under the skin.

Purpose

Study of CD388 Intramuscular or Subcutaneous Administration in Healthy Subjects

Interventions

Intervention 1

CD388

Intervention 2

Saline placebo

Countries

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2022-03-14

Anticipated Date of Last Follow-up

2023-11-09

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2023-10-27

Actual Completion Date

2023-10-27

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: 1. Willing and able to provide written informed consent. 2. Males and females 18 to 65 years of age, inclusive. 3. A female subject must meet one of the following criteria: 1. If of childbearing potential - agrees to use a highly effective, preferably user-independent method of contraception (failure rate of \<1 percent per year when used consistently and correctly) for at least 30 days prior to screening and agrees to remain on a highly effective method until 205 days after last dose of study medication. Examples of highly-effective methods of contraception include: abstinence from heterosexual intercourse; hormonal contraceptives (birth control pills, injectable/implant/insertable hormonal birth control products, transdermal patch); intrauterine device (with or w

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

78

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

CD388.SQ.1.03

Identifier

NCT05619536

Link

https://clinicaltrials.gov/study/NCT05619536

Phase

Phase I

Status

Completed

Sponsor

Cidara Therapeutics Inc.

More details

The purpose of this study is to determine the safety and tolerability profile of CD388 Injection, as compared to saline placebo, when dosed by subcutaneous (SQ) administration as a single dose to healthy Japanese adult subjects.

Purpose

Study of CD388 Subcutaneous Administration in Healthy Japanese Subjects

Interventions

Intervention 1

CD388

Intervention 2

Saline placebo

Countries

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2022-10-18

Anticipated Date of Last Follow-up

2023-07-28

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2023-07-14

Actual Completion Date

2023-07-14

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: 1. Must be of Japanese descent with Japanese parents and grandparents, as determined by subject's verbal report. 2. Willing and able to provide written informed consent. 3. Males and females 18 to 65 years of age, inclusive. 4. A female subject must meet one of the following criteria: 1. If of childbearing potential - agrees to use a highly effective, preferably user-independent method of contraception (failure rate of \<1 percent per year when used consistently and correctly) for at least 30 days prior to screening and agrees to remain on a highly effective method until 7 months after last dose of study medication, whichever is longer. Examples of highly-effective methods of contraception include: abstinence from heterosexual intercourse; hormonal contraceptives (

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

28

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

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
- Other(s)

Targeted action

Release properties

Small molecule conjugates in DFC exhibit selective targeting towards enzyme active sites and receptors. The distribution of the active pharmaceutical ingredient (API) is influenced by the molecular size of the DFC, with smaller sizes facilitating faster tissue penetration. The API is released from the Fc domain at the target site in a cumulative manner, optimizing therapeutic efficacy through sustained and controlled delivery for a longer period of time.

Injectability

Preclinical and clinical studies focused on DFC drug candidates administered via intramuscular (IM) and subcutaneous (SQ) routes. For administration, a 25-gauge or larger bore needle is used.

Safety

Interim analysis of Phase 2a studies of CD-388 shows that the drug was well-tolerated with no treatment emergent adverse events (TEAE) or serious adverse events (SAE) in 28 subjects who received CD-388.

Stability

Not provided

Storage conditions and cold-chain related features

The formulation should be stored at 20°C–25°C. It can also be stored at 5°C–25°C for up to 24 hours.

Potential application(s)

Therapeutic area(s)

Other(s) : "Influenza A & C infection"

Oncology

HIV

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

Weekly, Single dose administration

User acceptance

Not provided

Targeted user groups

Age Cohort

- Adults
- Older Adults

Genders

- All

Pregnant individuals

No

Lactating individuals

No

Healthy individuals

Unspecified

Comment

Not provided

Potential associated API(s)

Temsavir

Class(es)

Antiretroviral

Development stage

Pre-clinical

Clinical trial number(s)

Not provided

Foreseen/approved indication(s)

HIV

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

Compositions and Methods for The Treatment of Viral Infections

Brief description

This patent pertains to antiviral drug conjugates and methods for inhibiting viral growth and treating viral infections that involves administering an effective amount of the conjugate, population of conjugates, or pharmaceutical composition to the subject. These conjugates contain monomers or dimers of a moiety that inhibit influenza virus neuraminidase, conjugated to Fc monomers, Fc domains, Fc-binding peptides, albumin proteins, or albumin protein-binding peptides. The neuraminidase inhibitor targets neuraminidase on the viral particle's surface, while the Fc domains bind to FcyRs on immune cells, activating phagocytosis and effector functions. These drug conjugates have enhanced antiviral activity.

Representative patent

WO2021046549A8

Category

treatment

Patent holder

Cidara Therapeutics, Inc

Exclusivity

Not provided

Expiration date

September 8, 2040

Status

Not provided

Description

Composition and Methods of treating Human Immunodeficiency Virus

Brief description

Conjugates containing viral gp120 receptor inhibitors (e.g., temsavir, BMS-818251, DMJ-ll-121, BNM-IV-147, or analogues thereof) linked to an Fc monomer, an Fc domain, an Fc-binding peptide, an albumin protein, or an albumin-binding peptide are used in the treatment of viral infections. These conjugates are particularly useful in the treatment of HIV infections.

Representative patent

WO2020252393A1

Category

Not provided

Patent holder

Cidara Therapeutics, Inc

Exclusivity

Not provided

Expiration date

June 12, 2040

Status

Not provided

Description

Compositions and Methods for the Treatment of Bacterial infections

Brief description

Conjugates with an Fc domain covalently bonded to one or more monomers or dimers of cyclic heptapeptides are among the compositions and methods used to treat bacterial infections. These small-molecule conjugates have the potential to treat gram-negative bacterial infections.

Representative patent

US20230190950A1

Category

Not provided

Patent holder

Cidara Therapeutics, Inc

Exclusivity

Not provided

Expiration date

December 20, 2037

Status

Not provided

Supporting material

Publications

There are no publication

Additional documents

- Corporate Presentation of Cidara Therapeutics
- Cidara Drug-Fc -Conjugates (DFCs): A New Approach To Treatment Of Cancer

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

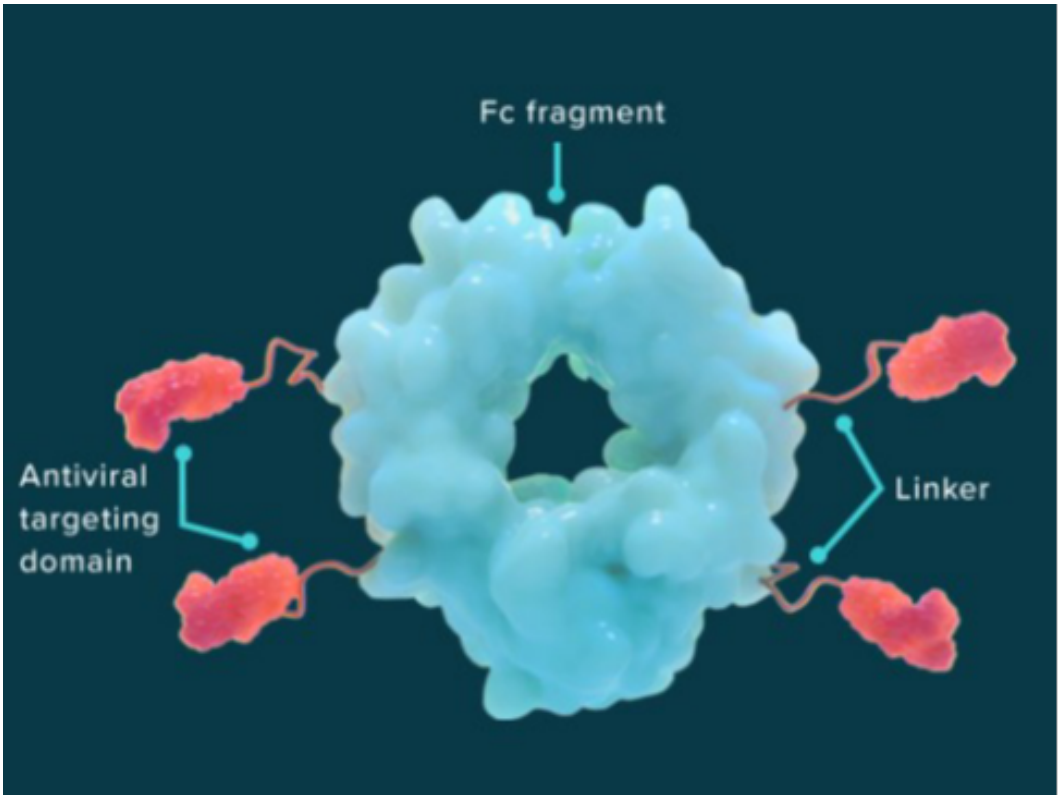
Work with MPP to expand access in LMICs

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



Drug Fragment Conjugate

Corporate presentation. (n.d.). https://www.cidara.com/wp-content/uploads/2023/09/Cidara-Corporate-Deck-September-2023.pdf