CURE HSV

Herpes Cure Pipeline 4.0



Herpes Cure Advocacy

CURE HSV

Vision: A world free of herpes.

Mission: Promote the cure, treatment, and prevention of herpes simplex infections.

We do these things by accomplishing objectives:

- Influencing policy and its implementation in governmental agencies and non-governmental organizations
- Encourage and publicize R&D in government, academia, and industry
- Educate various stakeholders

Critical Issues

OASH/OIDP has a national strategy to address HSV - *a result of our advocacy!*

Herpes is not reportable - meaning available data is minimal and medical records incomplete.

Because data is lacking, the public health impact is difficult to assess. Medical research is slow and lacks strategic focus.

Herpes is strongly suspected as a contributing factor to Alzheimer's Disease and related neuro degenerative diseases.

Herpes is a driver of HIV with nearly 30% of new HIV cases directly attributable to genital herpes.

HSV Presents an Unmet Medical Need

CURE HSV

HSV

CHRONIC DISEASE
NO CURE

40,000 CASES
HERPES KERATITIS

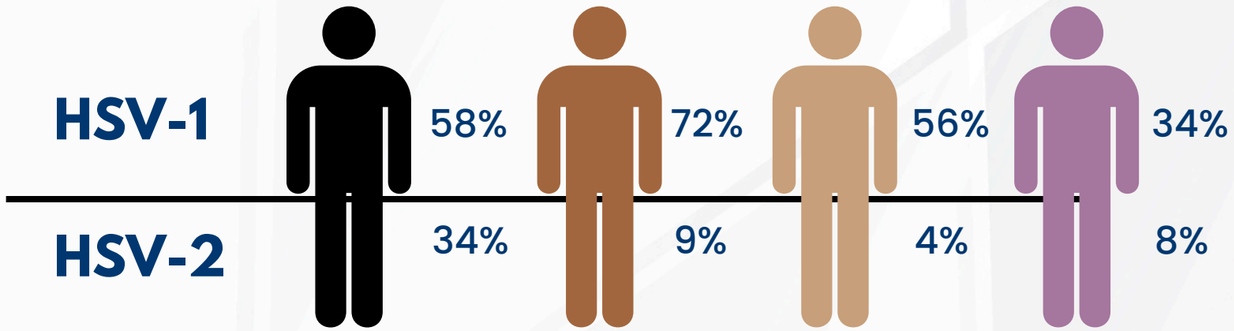
POTENTIAL LINK TO
ALZHEIMERS DISEASE

30% OF CHILDREN HAVE
HERPES BY AGE 5

60% MORTALITY RATE NEONATAL HSV

13% OF GLOBAL POPULATION W/HSV-2

67% OF GLOBAL POPULATION W/HSV-1



Herpes primarily impacts women, minorities, and LGBTQ populations.

REFERENCES:

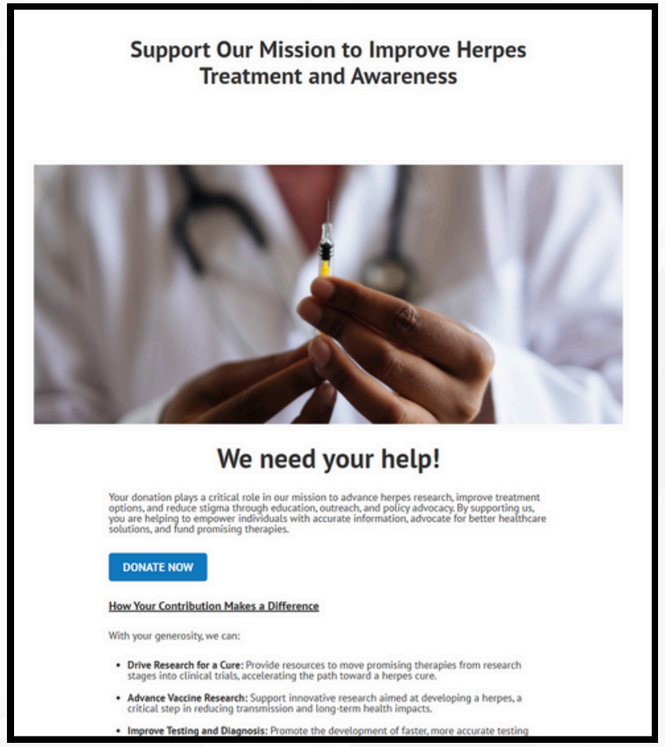
1. McQuillan G, Kruszon-Moran D, Flagg EW, Paulose-Ram R. Prevalence of herpes simplex virus type 1 and type 2 in persons aged 14–49: United States, 2015–2016. NCHS Data Brief, no 304. Hyattsville, MD: National Center for Health Statistics. 2018.
2. Donoval BA, Passaro DJ, Klausner JD. The public health imperative for a neonatal herpes simplex virus infection surveillance system. Sex Transm Dis. 2006 Mar;33(3):170-4. doi: 10.1097/01.olq.0000187203.27918.45. PMID: 16505733.
3. Renzi C, Douglas JM Jr, Foster M, Critchlow CW, Ashley-Morrow R, Buchbinder SP, Koblin BA, McKirnan DJ, Mayer KH, Celum CL. Herpes simplex virus type 2 infection as a risk factor for human immunodeficiency virus acquisition in men who have sex with men. J Infect Dis. 2003 Jan 1;187(1):19-25. doi: 10.1086/345867. PMID: 12508142.

Your Support Matters

Your donation plays a critical role in our mission to advance herpes research and improve treatment options through education, outreach, and policy advocacy.

By supporting us, you are helping to empower individuals with accurate information, advocate for better healthcare solutions, and fund promising therapies.

Donate Now



Support Our Mission to Improve Herpes Treatment and Awareness

We need your help!

Your donation plays a critical role in our mission to advance herpes research, improve treatment options, and reduce stigma through education, outreach, and policy advocacy. By supporting us, you are helping to empower individuals with accurate information, advocate for better healthcare solutions, and fund promising therapies.

DONATE NOW

How Your Contribution Makes a Difference

With your generosity, we can:

- **Drive Research for a Cure:** Provide resources to move promising therapies from research stages into clinical trials, accelerating the path toward a herpes cure.
- **Advance Vaccine Research:** Support innovative research aimed at developing a herpes, a critical step in reducing transmission and long-term health impacts.
- **Improve Testing and Diagnosis:** Promote the development of faster, more accurate testing

Pipeline

Despite affecting billions globally and carrying a substantial health and economic burden, herpes simplex virus (HSV) remains critically underfunded in research and development (R&D) when compared to other infectious diseases and therapeutic areas.

New Technology

Fortunately, the landscape is beginning to change. Advances in gene therapy, mRNA technology, and antivirals are generating new interest in HSV research and development.

Gene-editing technologies like CRISPR-Cas9 and other approaches are being explored to target the latent HSV genome, which hides in nerve cells and reactivates over time.

The success of COVID-19 mRNA vaccines has inspired similar technology platforms to be tested against other viruses, including HSV.

Rather than only targeting the virus, immunotherapies aim to enhance the body's own immune system to keep HSV dormant or eliminate infected cells.

These long-acting therapies aim to reduce the frequency of genital herpes outbreaks, including those caused by drug-resistant strains, with the potential for once-weekly or even monthly dosing.

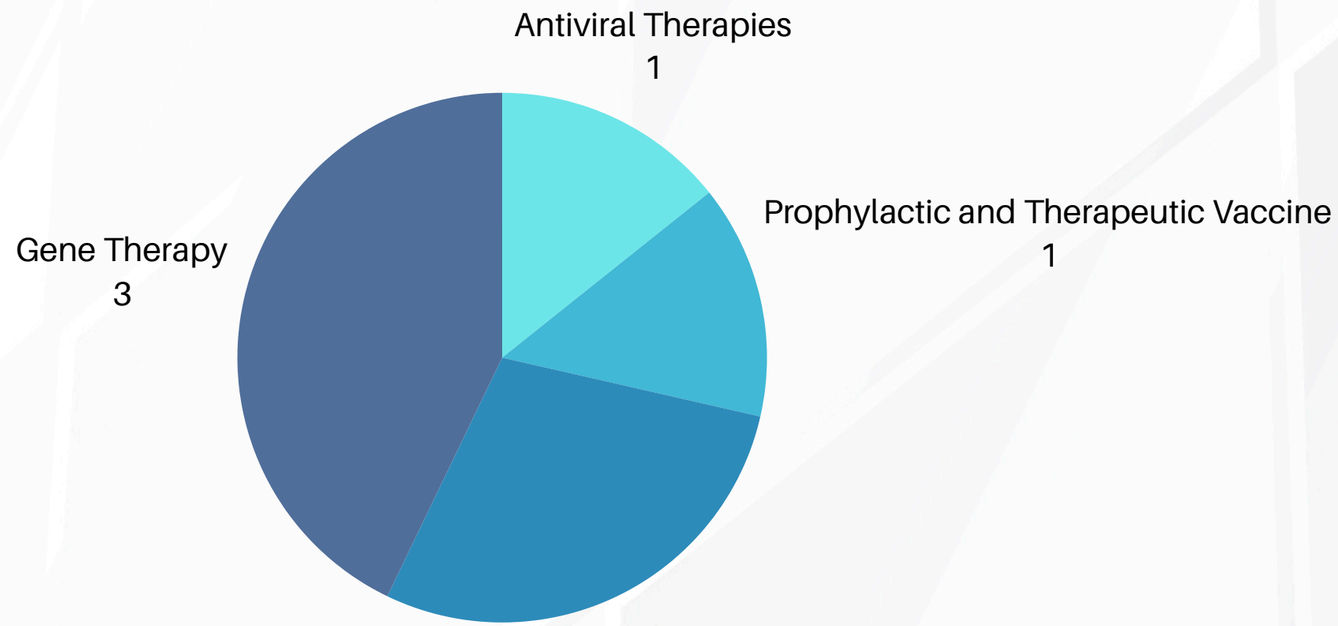
Herpes Cure Pipeline Methodology

Methodology to develop the preclinical pipeline: In the Pipeline 4.0, to select preclinical projects, Herpes Cure Advocacy focused on **active** and **new** programs that have demonstrated likelihood of progressing to clinical trials in humans.

We defined projects with likelihood of progressing as those documented by accessible and verifiable information and reasonably supportive results.

We avoided programs with a very low likelihood of progressing to clinical trials as those with limited evidence of efficacy to treat herpes and those not properly supported by recent or accessible information.

Technologies in HCA’s Preclinical Pipeline



Herpes Cure Pipeline 4.0 (Preclinical)

List of Preclinical

Fred Hutch / Caladan Therapeutics

Excision Biosciences

Rational Vaccines

Shanghai BD Gene

Symbio Pharma

Simplexia

An undisclosed team is working to return Genocea / GEN-003 to the clinic.

Herpes Cure Advocacy focused on active and new programs that have demonstrated likelihood of progressing to clinical trials in humans.

Herpes Cure Pipeline 4.0

Categories of Therapies

Antiviral therapy is a type of treatment that uses medications to fight viral infections. These drugs work by interfering with the virus’s ability to replicate (make more copies of itself) in the body, which helps reduce the severity and duration of the illness.

Therapeutic gene therapy is a medical treatment that involves altering a person's genes to treat or prevent disease. The goal is to correct or replace faulty genes or to introduce new genes to help the body fight or manage a condition.

A vaccine is a biological preparation that helps protect you from infectious diseases by training your immune system to recognize and fight specific pathogens—like viruses or bacteria—without making you sick.

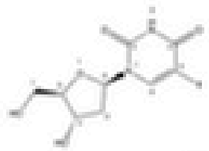
CURE HSV

Antiviral Therapies

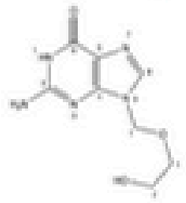
The challenges ahead

NUCLEOSIDES

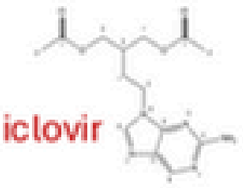
Idoxuridine



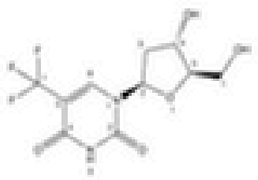
Acyclovir



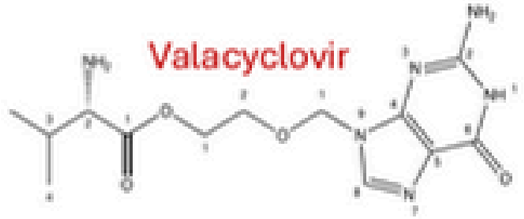
Famciclovir



Trifluoruridine



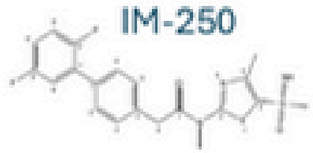
Valacyclovir



HELICASE/PRIMASE INHIBITORS

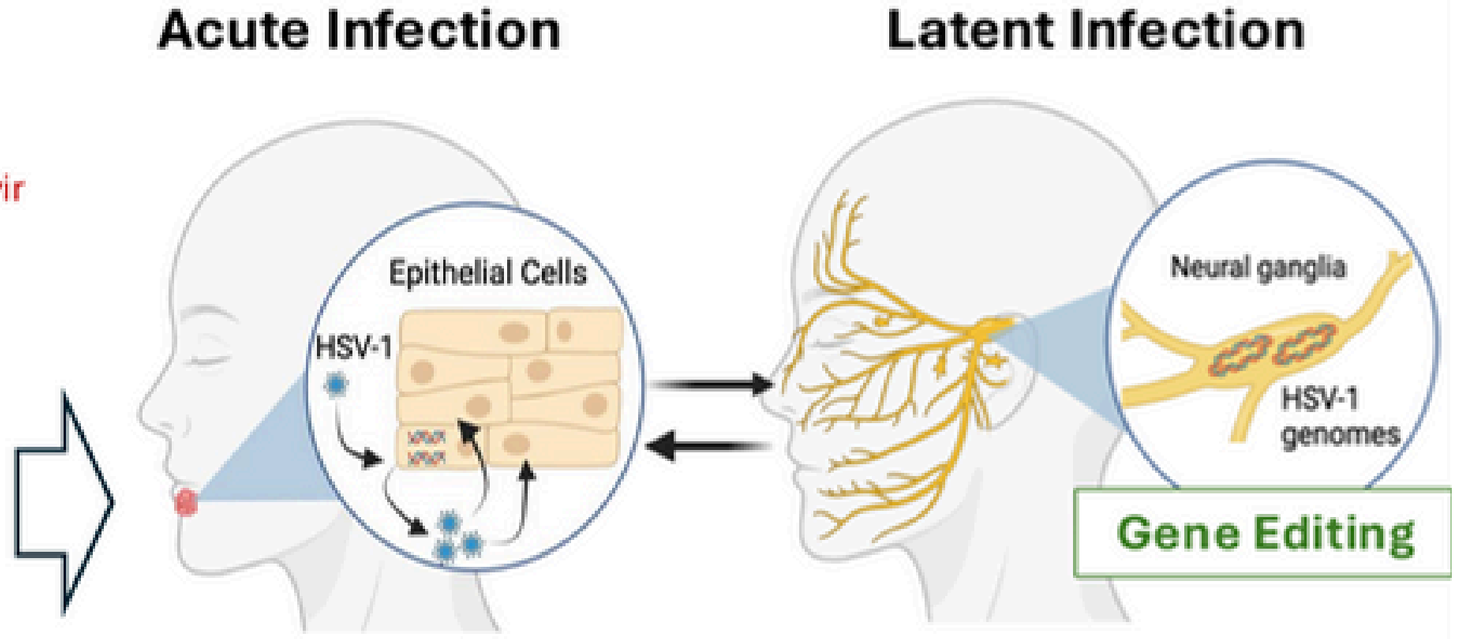
Pritelivir

IM-250



ABI-5366 ABI-1179

(structures not disclosed)



• *Viral transcription*	• *Restricted viral transcription*
• *Protein expression*	• *No protein expression*
• *DNA and virus replication*	• *No DNA or viral replication*
• *Cell death-inflammation*	• *No cell death*
• *Immune responses*	• *Immune responses?*
• ***SYMPTOMS***	• ***ASYMPTOMATIC***

Herpes Cure Pipeline 4.0

Organization.: Aicuris
Asset:
Target: HSV-1 + HSV-2
Current Phase: Phase 3
Category: Antiviral
Study Initiated: 2017
Expected completion: November 2025
Website: https://www.aicuris.com/
Clinical Trial Site: https://clinicaltrials.gov/study/NCT03073967
EXPANDED ACCESS: https://clinicaltrials.gov/study/NCT05844436

- Pritelivir is a novel antiviral developed by AiCuris that targets HSV-1 and HSV-2 by inhibiting the helicase-primase complex, effective even against acyclovir-resistant strains.
- Clinical trials show it reduces viral shedding, lesions, and pain, with strong results in immunocompromised patients.
- It received Breakthrough Therapy designation from the FDA and is currently in Phase 3 trials to confirm its safety and effectiveness.

Herpes Cure Pipeline 4.0

CURE HSV

assemblybio

Organization: Assembly Biosciences
Asset: ABI-5366
Current Phase: Phase 1 a/b
Target: HSV-2
Category: Antiviral
Study Initiated: 2024
Estimated Completion: 2025
Website: https://www.assemblybio.com/
Clinical Trial: https://clinicaltrials.gov/study/NCT06385327

Description:

- ABI-5366 is a long-acting investigational HSV-2 helicase inhibitor showing strong antiviral activity against both HSV-1 and HSV-2.
- Its long half-life and low clearance suggest potential for infrequent dosing, possibly monthly administration.
- A Phase 1a/b trial launched in June 2024 showed good tolerability and supported its long-acting profile in early results.

Herpes Cure Pipeline 4.0

CURE HSV

assemblybio

Organization: Assembly Biosciences
Asset: ABI-1179
Current Phase: Phase 1a/b
Target: HSV-2
Category: Antiviral
Study Initiated: 2024
Estimated Completion: 2025
Website: https://www.assemblybio.com/
Clinical Trial: https://clinicaltrials.gov/study/NCT06698575

Description:

- ABI-1179 is a long-acting oral HSV-2 helicase inhibitor being developed for recurrent genital herpes.
- Phase 1a trials showed a favorable safety profile and a ~4-day half-life, supporting potential once-weekly dosing.
- Even at low doses, it exceeded target plasma levels, leading to the launch of Phase 1b efficacy trials.

Herpes Cure Pipeline 4.0

CURE HSV

innovative molecules
IMPROVING LIFE

Organization: Innovative Molecules
Asset: IM-250
Target: HSV-2
Category: Antiviral
Phase 1 Study Initiated: 2023
Phase 1 Study Completion: May 2024
Website: https://www.innovativemolecules.com/
Clinical Trial: https://clinicaltrials.gov/study/NCT06435507

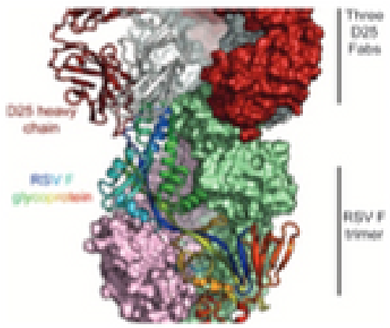
Description:

- IM-250 is an oral, selective HSV helicase-primase inhibitor that blocks viral DNA replication.
- It works by targeting the helicase-primase complex in HSV-1 and HSV-2 through a potentially uncompetitive mechanism.
- IM-250 is effective against acyclovir-resistant strains, offering a potential option for drug-resistant HSV infections.

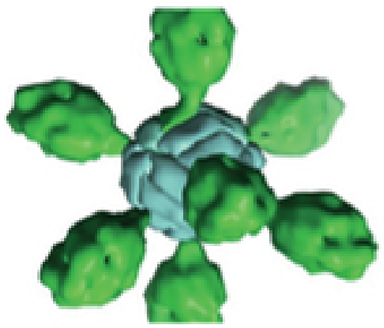
CURE HSV

Vaccines

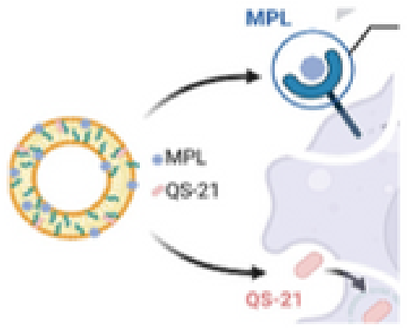
New technologies have enabled new vaccines



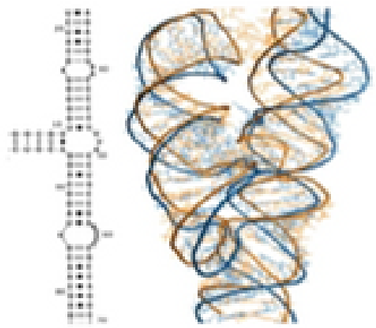
Protein structure & engineering



Virus-like particles



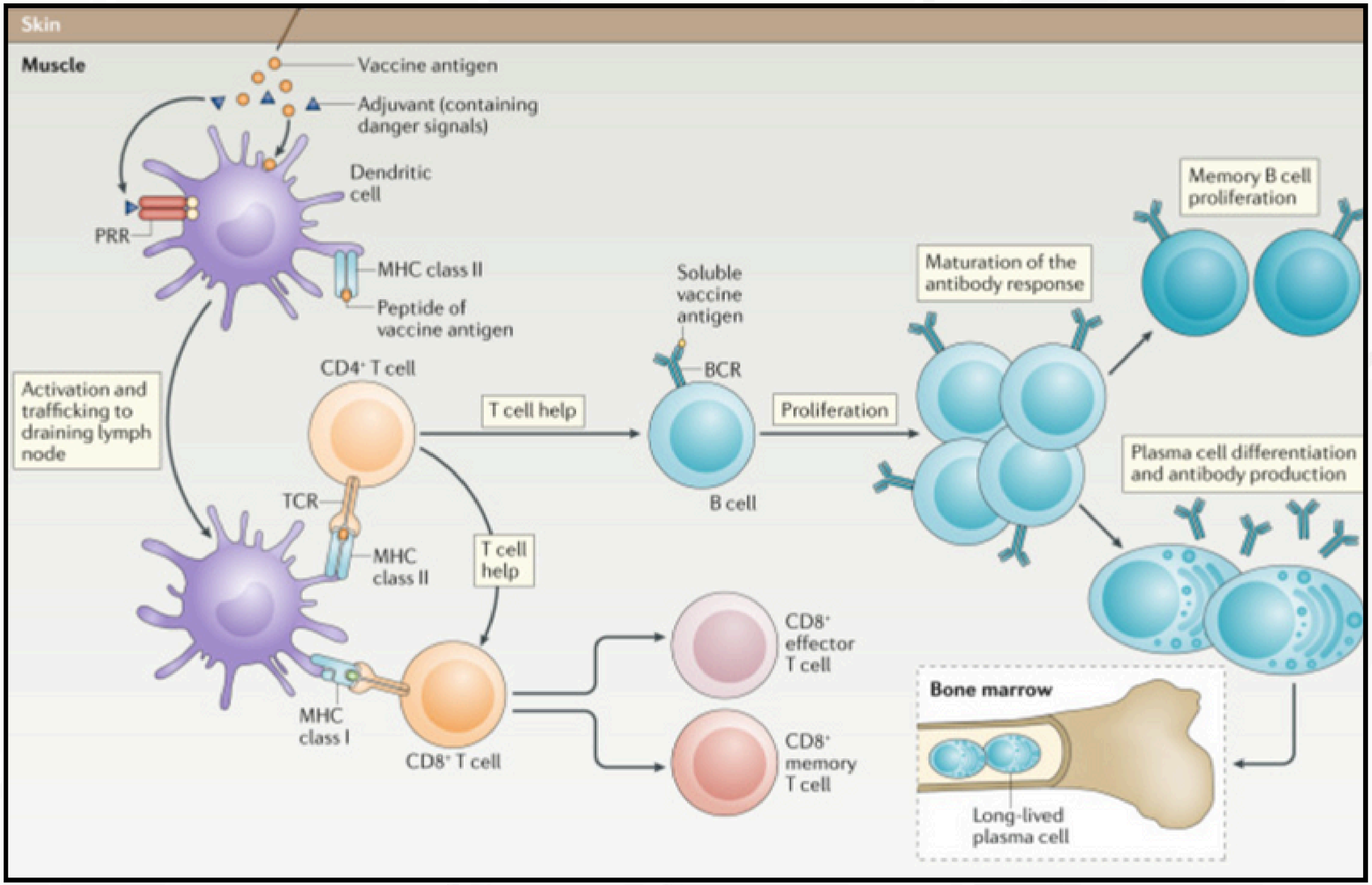
Adjuvants



mRNA

Disease	Companies	Technology	Opportunities for improvemen
RSV	Pfizer, GSK	Stabilized pre-fusion F protein	
Shingles	GSK	gE plus powerful adjuvant ASO1	Tolerability
COVID19	Moderna, Pfizer, BioNTech	mRNA vaccines	Tolerability & durability
COVID19	SK Biosciences, Icosavax, Nova	Nanoparticle vaccines	Programmability

Prophylaxis and therapy against HSV require different mechanisms of action, and probably different vaccines



Prevention of infection usually relies on a strong antibody response

- Varivax against varicella, Merck

Therapeutic immunization relies on T cells

- Shingrix against shingles, GSK

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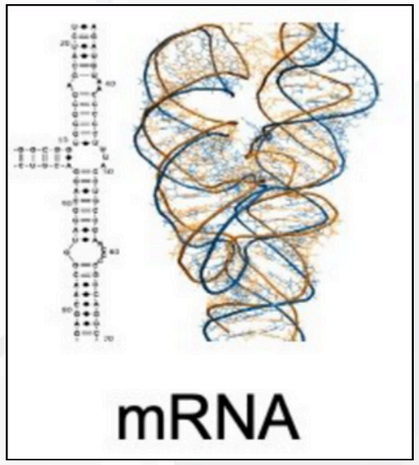
CURE HSV

moderna

Organization: Moderna
Asset: MRNA-1608
Target: HSV-2
Category: Therapeutic Vaccine
Phase 1 Study Initiated: September 2023
Status: Active (Not recruiting)
Phase 1 Study Completion: April 2025 (Estimated)
Website: https://www.modernatx.com/
Clinical Trial Link: https://clinicaltrials.gov/study/NCT06033261



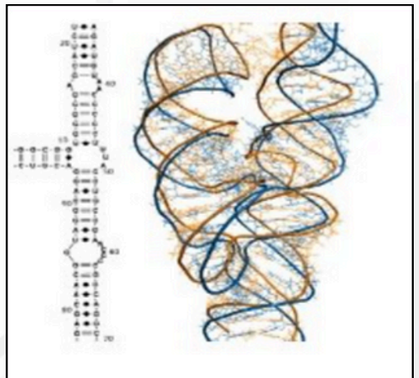
Description:

- N = 365
- mRNA, 2 doses at 0 and 2 months
- mRNA-1608 is Moderna’s investigational mRNA vaccine targeting HSV-2, designed to trigger strong antibody and cell-mediated immune responses, with potential cross-protection against HSV-1.
- A Phase 1/2 trial began in December 2022 to assess safety, tolerability, and immunogenicity in adults aged 18–55 with recurrent genital herpes.
- The study is fully enrolled with 300 participants, and primary completion is expected by mid-2025.

Herpes Cure Pipeline 4.0

CURE HSV

BIONTECH



Organization: Biontech
Asset: BNT-163
Target: HSV-2
Category: Prophylactic / Therapeutic Vaccine
Study Initiated: 2022
Status: Active and Recruiting
Study Completed: Expected 2025
Website: https://www.biontech.com/int/en
Clinical Trial: https://clinicaltrials.gov/study/NCT05432583

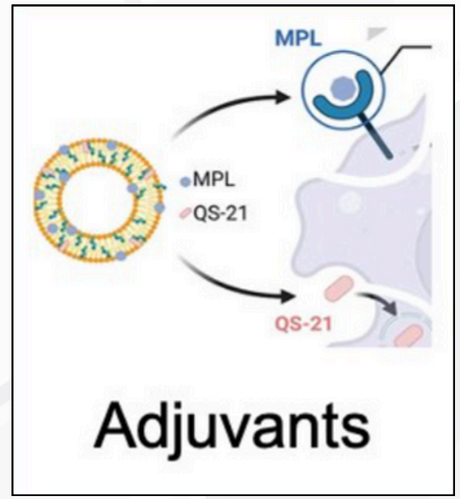
Description:

- mRNA, gC2 gD2 gE2
- 3 doses escalation study
- N ~ 308
- BNT163 is an investigational mRNA vaccine by BioNTech aimed at preventing genital lesions from HSV-2 and potentially HSV-1.
- The Phase 1 trial, launched in December 2022, evaluates safety, tolerability, and immune response across three parts: dose escalation, expanded evaluation, and testing in individuals with recurrent HSV-2.
- Approximately 100 healthy adults (ages 18–55) are being enrolled; the study is ongoing with primary completion expected in 2025.

Herpes Cure Pipeline 4.0

CURE HSV

Organization: GSK
Asset: GSK3943104
Target: HSV-2
Category: Therapeutic Vaccine
Current Phase: Combined Phase 1 / 2
Status: Active not recruiting
Phase 1/2 Study Initiated: 2022
Estimated Completion: 2025 (will not progress to phase 3)
Website: https://www.gsk.com/en-gb/
Clinical Trial: https://clinicaltrials.gov/study/NCT05298254?rank=1



Description:

- Protein(s) X + adjuvant
- GSK3943104 was an investigational therapeutic vaccine developed to reduce recurrent genital herpes caused by HSV.
- In a Phase I/II trial, participants received two doses of the non-adjuvanted vaccine or placebo on days 1 and 29.
- Despite good safety results, the vaccine did not meet efficacy goals, and GSK discontinued its development.


GSK provides update on phase I/II therapeutic herpes simplex virus (HSV) vaccine trial

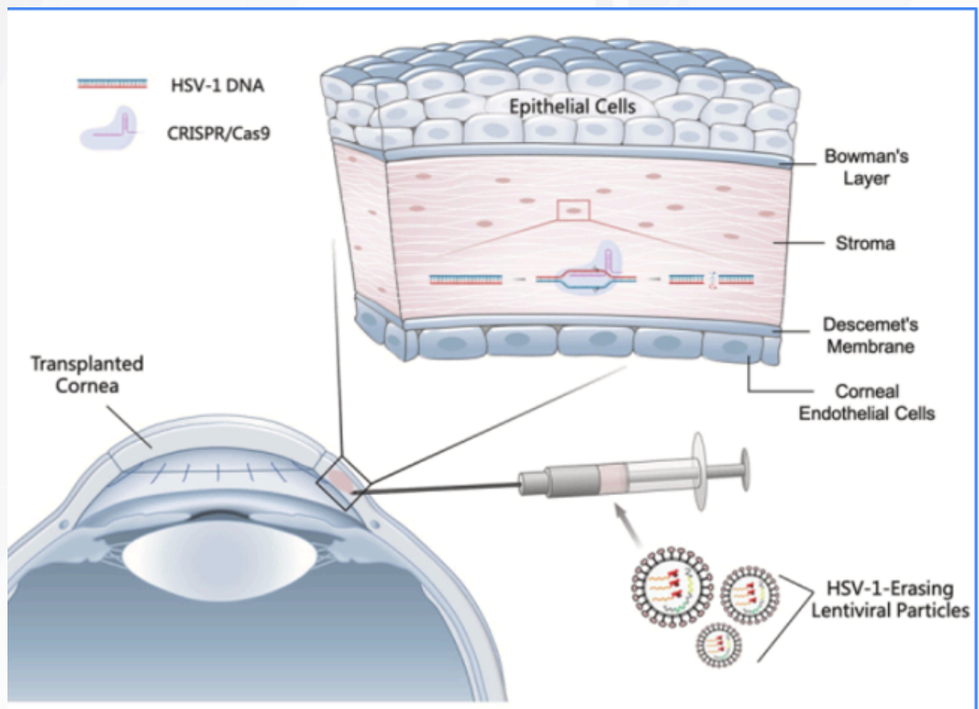
CURE HSV

Gene Therapy

Herpes Cure Pipeline 4.0

CURE HSV

本导基因 BDGENE



Organization: Shanghai BD Gene
Asset: BD-111
Phase: Phase 1
Target: HSV-1 Keratitis
Category: Therapeutic Gene therapy
Phase 1 Study Initiated: September 2023
Phase 1 Study completion: September 2025 (Estimated)
W**ebsite**: https://www.bdgenetherapeutics.com/en/
Clinical Trial Website: https://clinicaltrials.gov/study/NCT06474416
Description:

- Therapeutic phase 1
- Open label single dose lentivirus delivering CRISPR/Cas9, 4 escalating dose groups of 4 patients
- Adults with HSV-1 stromal keratitis (N~16)
- Last update 06/2024, recruiting

CURE HSV

Contact Us

267-797-7139

info@herpescureadvocacy.com

45 E. City Ave Unit 754
Bala Cynwyd, PA 19004

herpescureadvocacy.com

SILENT NO MORE

We need a cure today.
Because patients are waiting.

CURE HSV

Appendix

Herpes Cure Pipeline 4.0
Preclinical Project List

List of Preclinical

1. Fred Hutch / Caladan Therapeutics
2. Excision Biosciences
3. Rational Vaccines
4. Shanghai BD Gene
5. Symbio Pharma
6. Simplexia
7. An undisclosed team is working to return Genocea / GEN-003 to the clinic.

List of Active Clinical Trials

1. Aicuris
2. Assembly Biosciences/Gilead 1
3. Assembly Biosciences/Gilead 2
4. BioNTech / UPenn
5. GSK (Terminating after this Phase)
6. Innovative Molecules
7. Moderna
8. Shanghai BD Gene

Herpes Cure Pipeline 4.0

Currently Inactive Projects

- Genocea
- GSK (2010)
- Heidelberg Immunotherapies
- United biopharma
- X-Vax
- Eurocine
- Sanofi