

PIPELINE 5.0 RELEASE EVENT

Herpes Cure Pipeline 5.0

October 7, 2026

SPEAKERS

Jeffrey D. Klausner, MD, MPH
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Luis M. Schang, MV, PhD

**Research progress, program attrition, and priorities for a broader
HSV pipeline**

Dr. Jeffrey Klausner



President, Herpes Cure Advocacy

- Dr. Jeffrey Klausner is an internationally renowned expert in sexually transmitted infections, including herpes.
- Dr. Klausner is a Clinical Professor of Medicine and Public Health at the Keck School of Medicine of the University of Southern California.
- From 1998-2009, Dr. Klausner was a Deputy Health Officer, Director of STD Prevention and Control Services at the San Francisco Department of Public Health, member of the UCSF School of Medicine faculty in the Divisions of AIDS and Infectious Diseases and Attending Physician at San Francisco General Hospital.

Herpes Cure Advocacy

Vision

A world free of herpes

Mission

Promote the cure, treatment, and prevention of herpes simplex infections

We advance that mission by:

- Influencing policy and implementation
- Encouraging and publicizing research and development
- Educating patients, clinicians, researchers, and decision-makers

HSV remains a major unmet medical need

2 out of 3

people under 50 globally
live with HSV-1

1 out of 7

people aged 15–49
globally live with HSV-2

No cure

and no prevention
currently exists

The burden is not only clinical

Recurrent symptoms, transmission concerns, stigma, anxiety and depression, relationship and sexual health effects, pregnancy-related risks, ocular and neurologic complications, and healthcare costs all reinforce the need for a cure.

Advances in therapeutics and vaccines

Gene therapy

Targets viral genetic material or infected-cell biology with the aim of durable control or cure

Therapeutic vaccine

Trains immunity to reduce recurrences, shedding, or disease severity

Prophylactic vaccine

Aims to prevent infection or clinical disease before exposure

Antiviral

Interferes with viral replication to reduce disease activity

Legend



Gene Therapy



Therapeutic/
Prophylactic
Vaccine



Antiviral

Clinical pipeline methodology

Included

Programs with ongoing or actively progressing clinical development:

- Recruiting or active
- Enrolling or dosing participants
- Advancing through an officially announced trial
- Moving through a regulatory process

Excluded

Programs without active clinical development:

- Completed studies awaiting financing
- No current clinical activity
- Discontinued development
- Historical programs without active progression

The pipeline is a current-state view—not an inventory of every historical HSV program.

Selected preclinical research of interest

HCA evaluated published literature and press releases to identify active programs with credible potential to progress into human studies.

Programs were included when they had:

- Accessible and verifiable information
- Reasonably supportive results
- Recent evidence of continued activity
- A plausible path toward clinical development

Programs were excluded when they had:

- Limited evidence of efficacy to treat or prevent herpes
- Undisclosed active matter
- Long-standing claims without advancement
- Inaccessible or outdated information

This is a selected view of work of interest—not a comprehensive catalog of all HSV research.

Dr. Lao-Tzu Allan-Blitz



Secretary and Treasurer, Herpes Cure Advocacy

- Dr. Lao-Tzu Allan-Blitz is an Assistant Professor of Medicine at the University of California, Los Angeles and the David Geffen School of Medicine.
- As a physician, he cares for both adults and children.
- Dr. Allan-Blitz's research focuses on addressing disparities in sexual health equity, combining laboratory-based diagnostic development with public health field implementation programs.

CLINICAL DEVELOPMENT AND SELECTED PRECLINICAL RESEARCH OF INTEREST

GENE THERAPY

Programs designed to target HSV genetic material

Fred Hutch meganuclease-based HSV gene editing



Fred Hutch Cancer Center (Jerome Lab)

HSV Gene-Editing Program

TARGET

**HSV-1 and HSV-2
latent infections**

CATEGORY

Gene therapy

CLINICAL TRIALS

Not yet announced

Meganuclease-based gene editing targets latent HSV in sensory ganglia

This technology uses in vivo gene-editing therapy (dual cuts to the viral genome) to target latent HSV-1 and HSV-2 infections in sensory ganglia using meganucleases delivered by multiple adeno-associated virus vectors. Mouse studies reported substantial reductions in latent HSV-1 and lower viral shedding, supporting continued work toward translational development.

MOST RECENT UPDATE (SEPTEMBER 2024)

The team published their novel gene drive strategy of engineering HSV to carry genetic modifications that can spread through viral populations, potentially disabling the virus's ability to cause disease.

BD111 has advanced into Phase 2a



Shanghai BDgene
BD111

TARGET

HSV-1 stromal keratitis

CURRENT PHASE

Phase 2a

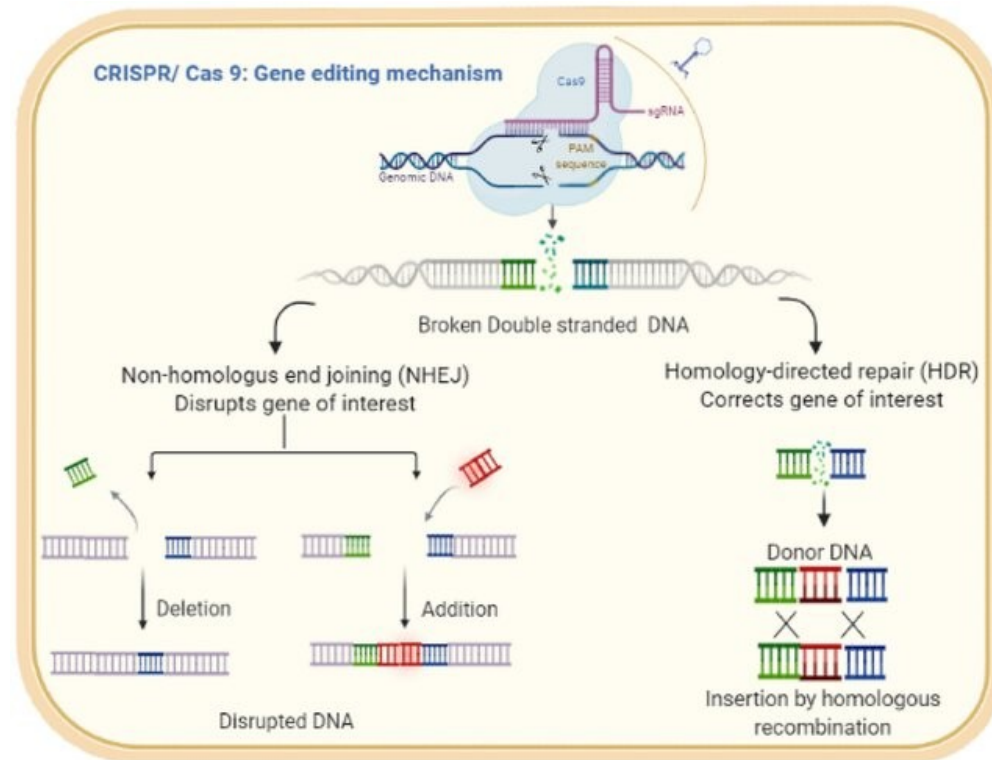
CATEGORY

Gene therapy

PHASE 2A INITIATED

April 2025

BD111 uses virus-like particles to deliver Cas9 mRNA and guide RNA, targeting essential HSV-1 genes



MOST RECENT UPDATE (APRIL 2025)

The Phase 2a clinical trial initiated, evaluating BD111 in combination with standard therapy versus standard therapy alone in patients with HSV-1 stromal keratitis.

EBT-104 reduces latent HSV-1 in a keratitis model



Excision BioTherapeutics EBT-104

TARGET

HSV-1 keratitis

CATEGORY

Gene therapy

CLINICAL TRIALS

Not yet announced

Dual-guide CRISPR editing reduced latent HSV-1 and ocular shedding

This technology uses in-vivo gene-editing therapy (CRISPR/Cas9-based) with dual guide RNA to reduce HSV-1 and HSV-2 infection in corneas using adeno-associated virus vectors systemically or locally. In a rabbit keratitis model, EBT-104 reduced latent virus and nearly eliminated ocular shedding without detectable off-target editing.

MOST RECENT UPDATE (MAY 2025)

Excision reported the rabbit keratitis findings at the American Society of Gene & Cell Therapy Annual Meeting.

Shanghai BDgene’s HSV-2 program exits in Pipeline 5.0



Shanghai BDgene Preclinical HSV-2 Program

TARGET

Genital herpes
(latent infection)

CATEGORY

Gene therapy

The preclinical HSV-2 program no longer meets Herpes Cure Advocacy’s preclinical pipeline selection criteria

For the past few years, BDgene has listed a preclinical gene-editing program for genital herpes, but we have not seen any program-specific development updates. Therefore, publicly accessible evidence has not shown sufficient recent advancement to retain the preclinical program among the selected preclinical programs of interest.

Platform	Indication	Development	Pre-clinical	IIT	IND	Phase I-III
BD-VLP	HSK-BD111					
	Huntington's Disease-BD112					
	Glaucoma-BD113					
	HPV-BD114					
	Genital Herpes					
	Cancer Vaccine/CARvac					

THERAPEUTIC / PROPHYLACTIC VACCINES

Programs designed to reduce recurrence, shedding, and disease severity or prevent infection

Prevention and therapy require different immune outcomes

PREVENTION

Stop or minimize infection or disease before it begins

Often depends on strong neutralizing antibody responses at the point of exposure

THERAPY

Reduce recurrence, shedding, or severity after infection

Likely requires durable T-cell responses and effective immunity at sites of latency and reactivation

Different goals may require different antigens, platforms, and measures of success.

BNT163 has produced encouraging early immune-response data



BioNTech
BNT163

TARGET

HSV-2 infection

CURRENT PHASE

Phase 1

CATEGORY

Prophylactic vaccine

ESTIMATED COMPLETION

October 2026

The trivalent mRNA vaccine remains active in Phase 1

BNT163 encodes three HSV-2 glycoproteins—gC, gD, and gE—and is being evaluated in healthy volunteers and people with recurrent genital herpes. The study examines safety, tolerability, immunogenicity, and preliminary efficacy.

MOST RECENT UPDATE (OCTOBER 2025)

Interim data indicated acceptable tolerability and induced binding and neutralizing antibodies against HSV-2.

GSK3943104 did not advance after Phase 2



TARGET

HSV-2 disease

CATEGORY

Therapeutic vaccine

PROGRAM DECISION

Discontinued
September 2024

The primary efficacy endpoint was not met, and there were no safety concerns noted

GSK3943104 was an adjuvanted recombinant protein therapeutic vaccine evaluated in a Phase 1/2 proof-of-concept trial. The exact composition and specific target antigen components of GSK3943104 have not been publicly disclosed. The trial did not reduce recurrent genital herpes episodes or delay time to first recurrence sufficiently to support advancement.

MOST RECENT UPDATE (SEPTEMBER 2024)

GSK ended development and did not advance the candidate to Phase 3.

Moderna discontinued mRNA-1608 after Phase 1/2



TARGET

HSV-2 disease

CATEGORY

Therapeutic vaccine

PROGRAM DECISION

Discontinued November 2025

The completed program will not advance into Phase 3

mRNA-1608 was designed to generate neutralizing and functional antibody responses together with cell-mediated immunity in adults with recurrent genital herpes. mRNA-1608 encoded five specific HSV-2 proteins: three glycoprotein antigens (gB, gC, and gD) and two immediate-early regulatory proteins (ICP0 and ICP4). Moderna completed the Phase 1/2 study before ending the program through portfolio prioritization.

MOST RECENT UPDATE (NOVEMBER 2025)

Moderna announced that the program had been discontinued and would not advance to Phase 3 as part of a broader portfolio-prioritization decision.

Simplexia prepares its HSV-2 vaccine for clinical development



Simplexia

Glycoprotein G-2 Vaccine Candidate

TARGET

**HSV-2 infection
or disease**

CATEGORY

**Therapeutic and
prophylactic vaccine**

NEXT STEP

Phase 1/2a planned

A glycoprotein G-2 vaccine program is preparing for interventional development

Simplexia is advancing an HSV-2 vaccine program centered on glycoprotein G-2. The company initiated a non-interventional preparation study in July 2026 to support a planned Phase 1/2a clinical program.

MOST RECENT UPDATE (JULY 2026)

Simplexia initiated SIMCT-001, an exploratory study intended to prepare for future interventional testing.

UC Irvine advances tissue-targeted immunity for recurrent HSV



University of California, Irvine (BenMohamed Lab)

Prime/Pull/Keep Vaccine Strategy

TARGET

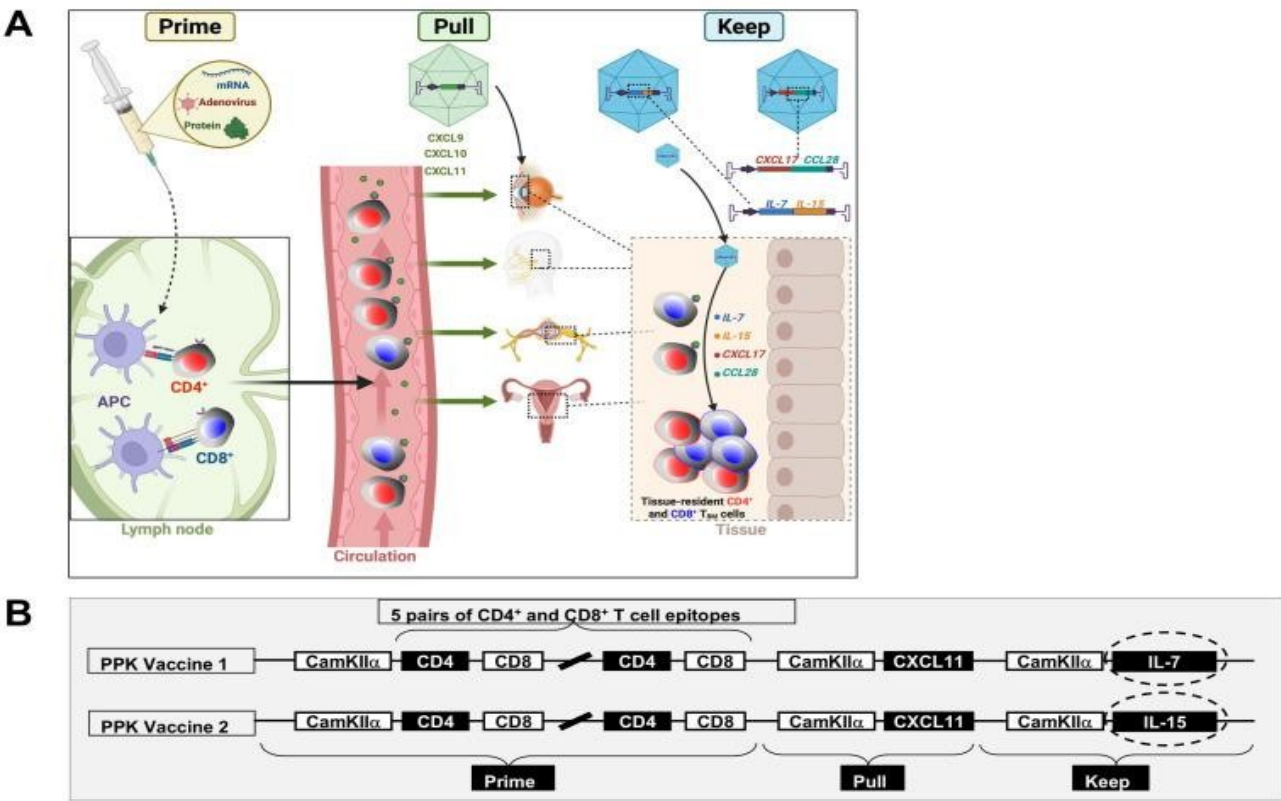
HSV-2 disease

CATEGORY

Therapeutic vaccine

CLINICAL TRIALS

Not yet announced



MOST RECENT UPDATE (JUNE 2026)

A five-year, \$3.93 million NIH R01 award supports continued development.

Rational Vaccines exits in Pipeline 5.0



Rational Vaccines RVX201

TARGET

HSV-2 disease

CATEGORY

Therapeutic vaccine

The live-attenuated program no longer meets Herpes Cure Advocacy’s preclinical selection criteria

RVX201 is a live-attenuated HSV-2 vaccine candidate designed to reduce the frequency and severity of recurrent genital lesions by eliciting a robust immune response. The program was previously included among preclinical work of interest, but publicly accessible evidence has not shown sufficient recent advancement to retain the preclinical program among the selected preclinical programs of interest.

MOST RECENT UPDATE (July 2022)

Rational Vaccines reported that RVX201 demonstrated therapeutic efficacy against recurrent HSV-2 disease in a guinea pig model.

Dr. Luis Schang



Board Member at Large, Herpes Cure Advocacy

- Dr. Luis Schang is a molecular virologist interested in the interactions between viruses and cells, interactions which determine the outcomes of the infection and, consequently, pathogenicity.
- His laboratory works to identify small molecules that inhibit the infectivity or replication of multiple viruses and then use these compounds as probes to find commonalities among mostly unrelated viruses.
- Dr. Schang is a Professor of Chemical Virology at Cornell University and the past president of the International Society for Antiviral Research (ISAR).

CLINICAL DEVELOPMENT AND SELECTED PRECLINICAL RESEARCH OF INTEREST

ANTIVIRALS

Programs designed to interrupt HSV replication and reduce disease activity

Pritelivir is now under FDA Priority Review



AiCuris

Pritelivir

TARGET

**HSV-1 and HSV-2
infection**

CURRENT PHASE

**New Drug
Application Under
FDA Priority Review**

CATEGORY

Antiviral

FDA DECISION EXPECTED

Q4 2026

The most advanced new therapy in the Pipeline 5.0 landscape

Pritelivir inhibits the HSV helicase–primase complex, essential for HSV DNA replication, and remains active against strains resistant to standard therapies like acyclovir and its derivatives. Its pivotal Phase 3 program focused on immunocompromised patients with refractory HSV infection. Phase 3 study regimen: 400 mg oral loading dose on Day 1, followed by 100 mg orally once daily. Proposed FDA indication: refractory HSV infection, with or without resistance, in immunocompromised patients

MOST RECENT UPDATE (APRIL 2026)

FDA granted Priority Review after the pivotal Phase 3 trial met its primary endpoint.

GS-5366 supports long-acting HSV suppression



Gilead Sciences / Assembly Biosciences

GS-5366

TARGET

HSV-2 infection

CURRENT PHASE

Phase 2 being planned

CATEGORY

Antiviral

PHASE 1B COMPLETED

February 2026

Weekly—and exploratory monthly—dosing produced antiviral activity

GS-5366 is a long-acting oral helicase–primase inhibitor originally developed by Assembly Biosciences. Phase 1b results showed reductions in viral shedding, high viral-load shedding, and genital lesion rates, with a pharmacokinetic profile supporting infrequent dosing.

MOST RECENT UPDATE (MAY 2026)

Gilead Sciences is advancing the long-acting HSV-2 antiviral toward Phase 2 clinical development.

GS-1179 is advancing toward Phase 2



Gilead Sciences / Assembly Biosciences

GS-1179

TARGET

HSV-2 infection

CURRENT PHASE

Phase 2 being planned

CATEGORY

Antiviral

PHASE 2 INITIATION EXPECTED

By year-end 2026

Once-weekly dosing delivered substantial virologic and lesion-rate reductions

GS-1179 is a long-acting oral HSV-2 helicase–primase inhibitor. Phase 1b results supported weekly dosing, and Gilead selected the program to advance into Phase 2 in recurrent genital herpes, with broader prevention settings also under consideration.

MOST RECENT UPDATE (AUGUST 2026)

Gilead selected GS-1179 for Phase 2 advancement after taking control of the program in December 2025.

Adibelvivir entered Phase 2a proof-of-concept testing



Innovative Molecules

Adibelvivir

TARGET

HSV-1 and HSV-2 infections

CURRENT PHASE

Phase 2a

CATEGORY

Antiviral

PHASE 2A INITIATED

June 2026

A differentiated oral helicase–primase inhibitor has moved beyond Phase 1

Adibelvivir is an orally available helicase–primase inhibitor active against HSV-1 and HSV-2, including acyclovir-resistant strains. The Phase 2a study evaluates safety, antiviral activity, viral shedding, pharmacokinetics, and clinical efficacy in recurrent genital herpes.

MOST RECENT UPDATE (JUNE 2026)

The first patient was dosed in the Phase 2a trial.

SymBio Pharma advances HSV-1-related research with intravenous brincidofovir



SymBio Pharma
SyB V-1901

TARGET

HSV-1 replication

CATEGORY

Antiviral

CLINICAL TRIALS

Not yet announced

Brincidofovir suppresses HSV-1 activity in a human brain-tissue model

SyB V-1901 is an intravenous formulation of the broad-spectrum antiviral brincidofovir. In a human brain-tissue model, treatment suppressed HSV-1-induced changes associated with Alzheimer’s disease, supporting further development for HSV-1-associated neurodegenerative disease.

MOST RECENT UPDATE (DECEMBER 2025)

SymBio obtained exclusive global rights from Tufts University to develop intravenous brincidofovir for Alzheimer’s disease and mild cognitive impairment based on the HSV-1 research.

The antiviral pipeline needs more targets and new chemistry

Most current and emerging HSV drugs converge on one viral function

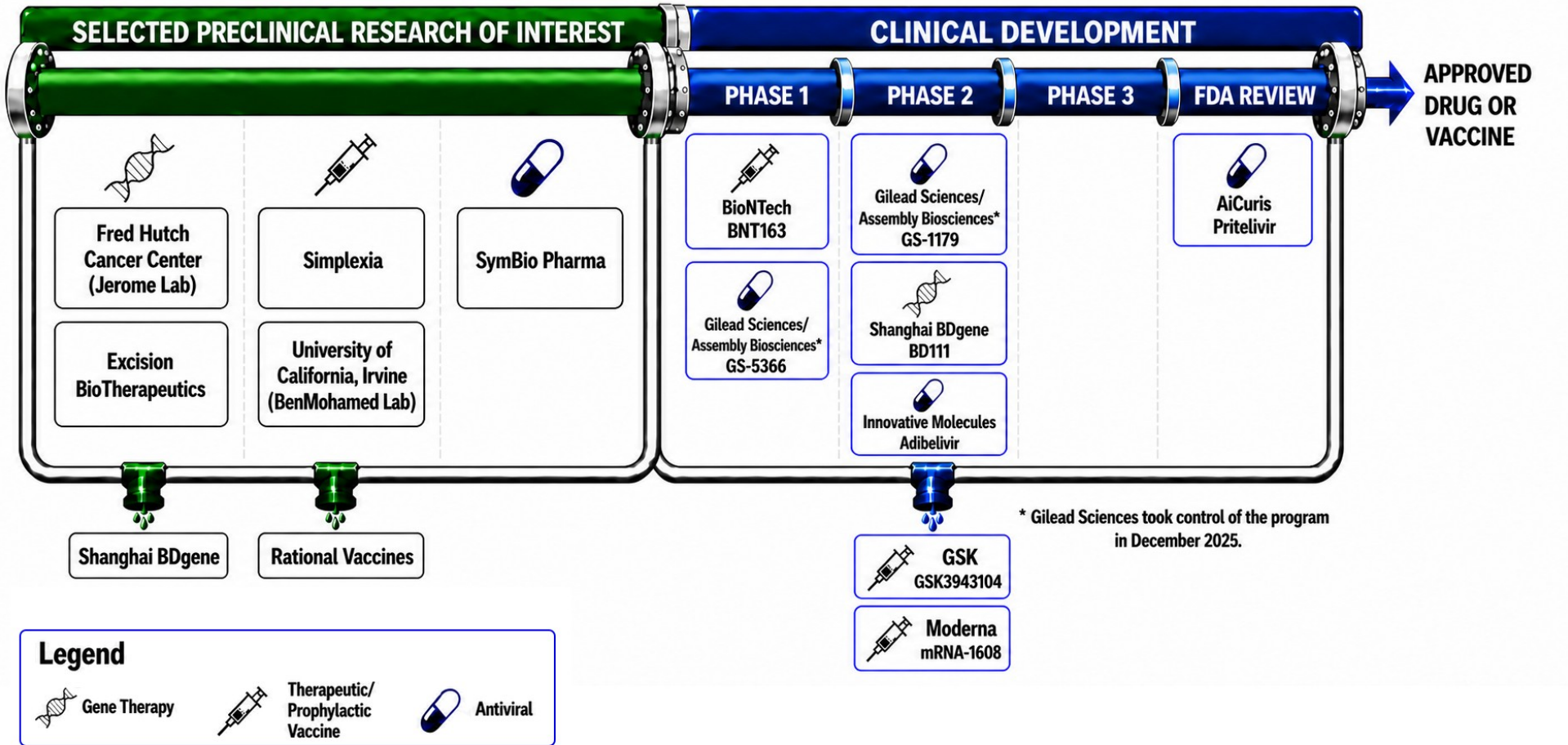
**Thymidine kinase =>
DNA polymerase**

Helicase–primase complex

Viral DNA replication

A more resilient pipeline requires new biological targets, new chemistry, and multiple therapeutic approaches—not only additional candidates against the same mechanisms.

Pipeline 5.0 shows both progress and attrition



New technologies are expanding the HSV toolkit

1

Gene editing

Targets latent viral DNA in sensory ganglia, where HSV persists between reactivations

2

mRNA vaccines

Enable rapid antigen design and combined antibody and cell-mediated immune responses

3

Tissue-targeted immunity

Seeks to generate and retain protective immune cells at sites of latency and reactivation

4

Long-acting antivirals

Aim to suppress replication with weekly or potentially less frequent dosing

Progress continues, but the pipeline still needs more approaches and early-stage programs.

Progress is real, but the pipeline is still too narrow

- **Sustain investment across prevention, treatment, and cure, with an emphasis on broadening the pipeline**
- **Expand beyond the dominant antiviral targets and chemistries**
- **Advance preventive and therapeutic vaccines with differentiated strategies**
- **Develop effective, longer-acting, and more convenient therapies that improve daily life**

A broader pipeline creates more chances for durable control and ultimately cure

Your support matters

Donations strengthen education, outreach, policy advocacy, and the visibility of promising HSV research

By supporting Herpes Cure Advocacy, you help empower people with accurate information, advocate for better healthcare solutions, and sustain pressure for research investment.

**PLEASE SCAN
THE QR CODE
TO DONATE!**

