



PIPELINE OF CURES, THERAPIES AND VACCINES AGAINST HERPES SIMPLEX

Key: HSV 1 HSV 2 HSV 1 & 2 HSV-1 Keratitis

Updated: 2022_Mar_20

GENE EDIT

Research Entity and Product Name	Research Focus	Product Type	Research Phases						
			Initial Exploratory	Pre-Clinical (animals)	IND Enabling / Approved	Phase I (Safety)	Phase II (Safety & Dosing)	Phase III (Safety & Efficacy)	Study completion
Fred Hutch Cancer Center <i>The work of Dr. Keith Jerome & Dr. Martine Aubert</i> DONATION PAGE	Sterilizing cure	In-vivo gene-edit therapy to eliminate the latent HSV1 and HSV2 infection in sensory ganglia. Meganucleases delivered by multiple AAVs.	Completed	In progress - mice & guinea pigs - Next update expected Mar/Apr 2022		Targeting late 2023			
Excision BioTherapeutics <i>EBT-104</i> WEBSITE	Therapeutic	CRISPR-based gene editing therapy (gRNA); Cas9 delivered by AAV or non-viral vectors to make a dual cut in the viral genome to prevent replication	Completed	Pre-clinical studies in progress	Plan to file for IND request in 1Q 2023				
Shanghai Bdgene Co. <i>BD 111</i> WEBSITE	Therapeutic / Sterilizing cure	CRISPR-based gene editing cure to treat refractory HSV1 keratitis (i.e., corneal infection) of the eyes. Administered by corneal injection.	Completed	Completed	N/A for trials in China. Now seeking IND approval in the U.S. given early success in the Phase I/II trial in China.	Began Phase I/II trial in China in Nov 2020 with successful primary completion in Nov 2021; early results indicate success, but full report is still pending with study completion expected in May 2022 LINK			
Shanghai Bdgene Co. <i>"Viral Disease HSV-2"</i> WEBSITE	Therapeutic / Sterilizing cure	HSV2 therapy based on their proprietary mRNA gene edit, as BD111	Completed	Pre-clinical studies in progress in China					

THERAPEUTIC VACCINES

Sanofi Pasteur <i>HSV-529, which is SP0148 on their pipeline</i> WEBSITE	Therapeutic Vaccine	Replication defective vaccine	Completed	Completed	Completed	Completed the first in 2018 and the second in May 2021 LINK	Completion expected May 2024, but they WILL BE TERMINATING THEIR HSV RESEARCH (No longer viable given newer technologies being applied elsewhere)		
Sanofi Pasteur & Immune Design/Merck <i>G-103</i>	Therapeutic Vaccine	Sub-unit vaccine (purified antigen)	Completed	Completed	Completed	Combined into the 2nd HSV-529 Phase I above			
Redbiotech Two candidates: <i>RBT-3 & RBT-25</i> WEBSITE	Therapeutic Vaccine	Sub-unit vaccine (T-cell based antigen engineering)	Completed	Completed guinea pig trials	Status still unknown Sent message for an update				
SL Vaxigen (Korea) <i>SL-V20</i> WEBSITE	Therapeutic Vaccine	DNA plasmid	Completed	Completed	Completed with Korean FDA	Recruiting for Phase I trial in Korea has been completed – start date TBD			
Rational Vaccines <i>RVx-201</i> WEBSITE	Therapeutic Vaccine	Live attenuated (weakened) virus vaccine	Completed	Completed	Late 2021 filing in process for US trials Received Innovation Passport in UK for fast track 3-5 years to market.	Expected to start in the US in 2022 May start sooner than in US due to fast track status.			
UPenn led by Dr. Harvey Friedman DONATION PAGE	Therapeutic vaccine	mRNA vaccine	In progress						

PROPHYLACTIC VACCINES

Moderna <i>mRNA-1608</i> WEBSITE	Prophylactic vaccine expected to also have therapeutic benefit	mRNA vaccine Expected to have cross protection against HSV1	Complete	In progress					
Rational Vaccines <i>RVx-2001</i> WEBSITE	Prophylactic vaccine	Live attenuated (weakened) virus vaccine	Completed	May be ongoing parallel to IND filing	In progress according to pipeline page				
Rational Vaccines <i>RVx-1001</i> WEBSITE	Prophylactic vaccine	Live attenuated (weakened) virus vaccine	Completed	May be ongoing parallel to IND filing	In progress according to pipeline page				
X-Vax Technology <i>Delta gD-2 vaccine</i> WEBSITE	Prophylactic vaccine + potential to be therapeutic under investigation	Vaccine with HSV2 genetically deleted for Glycoprotein-D	Completed	Completed trials in mice & guinea pigs	In progress	Expect to start in 2024			
BioNTech <i>Collaboration w/UPenn led by Dr. Harvey Friedman</i> WEBSITE	Prophylactic vaccine	mRNA vaccine	Completed	Completed in mice (HSV 1&2) and guinea pigs (HSV-2)	In progress	Expected to start late 2022			
Blue Willow <i>NE HSV-2</i> WEBSITE	Prophylactic and Therapeutic vaccine	Intranasal vaccine using nanoemulsion adjuvant	Completed	Complete	In progress and nearly complete	Expected to start 2022 or 2023			
Thyreos Vaccines <i>R2</i> WEBSITE	Prophylactic vaccine	Neutered recombinant viruses	In progress. Sent message for an update						

ANTIVIRALS & OTHER THERAPIES

Squarex <i>SADBE</i> WEBSITE	Topical immuno-sensitizer	Topical immunomodulator applied on inner upper arm (currently used to treat HPV)	Completed	Completed	Completed	Completed LINK	Completed LINK	Seeking investors to support Phase III trials – progress slow at \$235k raised of over \$20Mn needed	
United BioPharma <i>UB – 621</i> WEBSITE <i>Trial # NCT04714060 (safety & efficacy against recurrent genital infection)</i>	Monoclonal antibody	Subcutaneous injection There are three trials planned as noted to the left by trial number. While the trials are focused on genital HSV-2, their website indicates that this treatment should also be effective against HSV-1.	Completed	Completed	Completed	Completed	Completed	Estimated start October 2021, so appears delayed. Not yet recruiting. Emailed UB for an update. LINK	
<i>Trial # NCT04979975 (repeat dose tolerance and effectiveness)</i>			Completed	Completed	Completed	Completed	Completed	Estimated start December 2022. (3 year trial) Not yet recruiting. LINK	
<i>Trial # NCT003595995 (efficacy to reduce genital shedding)</i>			Completed	Completed	Completed	Completed	Completed	Estimated start June 1, 2022. (1 year trial) LINK	
Heidelberg ImmunoTherapeutics <i>HDIT101</i> WEBSITE	Monoclonal antibody	Intravenous infusion	Completed	Completed	Completed	Completed	Completed Nov 2022 Awaiting results LINK		
Heidelberg ImmunoTherapeutics <i>HDIT101</i> WEBSITE	Monoclonal antibody	Topical formulation for orolabial lesions	Completed	Completed	Completed	Completed	RECRUITING IN GERMANY estimated primary completion Oct 2022; study completion in Oct 2023 LINK		
AiCuris <i>Pritelivir (AIC316)</i> WEBSITE	Antiviral	HSV Helicase-Primase inhibitor	Completed	Completed	Completed	Completed	Completed – immune compromised people only LINK	RECRUITING IN U.S. LINK (immune compromised) estimated primary completion Nov 2023; study completion in Mar 2024 LINK	
Innovative Molecules <i>IM 250</i> WEBSITE	Antiviral	HSV Helicase-Primase inhibitor, small molecule	Completed	In progress					
Nanoviricides <i>HerpeCide Program™</i> WEBSITE Overview: LINK	Antiviral (virus-binding nanoparticles) <i>Leading with Shingles treatment & HSV to follow</i>	Skin cream for cold sores	Completed	Optimization testing (advanced)					
		Skin cream for genital sores	Completed						
		Keratitis eye drops / gel	Completed	Initial testing					
		HSV-2 retinal necrosis injection treatment	Completed	Initial testing					
Maxwell Biosciences <i>MXB-005</i> WEBSITE	Antiviral CLAROMER™	Peptoids (small molecule viral neutralizer)	Completed	In progress					