

New Vaccines against Infectious Diseases: Research and Development Status

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Disease	Type of vaccine	Pharmaceutical company or Research group	Stage of development
Diarrheal Diseases			
Cholera	Killed O1 and O139 whole cell vaccine, oral	Nha-Trang, Vietnam	Phase II (Demonstration trial)
	Live attenuated, oral	Finlay Institute, Cuba	Phase II
	Live attenuated, oral	Avant Immunotherap / BioSidus	Phase II
	Live attenuated O139 strains	Univ Maryland	Phase I
	Conjugate vaccine (O Ag)	Pasteur Institute	Preclinical
	DNA	Putra Univ, Malaysia	Preclinical
ETEC	Inactivated 5-valent whole cell + rCTB, oral	Göteborg Univ, Sweden/ Active Biotech Res/ GSK	Phase III
	Live attenuated recombinant <i>Shigella</i> - ETEC fimbriae/LT, oral	Univ Maryland,	Preclinical
	Live attenuated recombinant <i>S. typhi</i> - ETEC, oral	Microscience	Preclinical
	Live attenuated strains (<i>omp R</i> , <i>aro C</i> / <i>omp C</i> , <i>omp F</i> , <i>aro C</i>), oral	Cambridge Biostability	Phase I
	Encapsulated colonization factors	Univ Maryland	Phase I
	Colonization factor + LT, transcutaneous	US Navy/ Iomai	Phase II
Rotavirus	Lamb-derived, live attenuated, oral	Lanzhou Inst Biol Prod, China	Used in China; controlled Phase III pending
	Live human neonatal strain, oral	GSK	Licensure
	Live bovine/human 4-valent reassortant, oral	Merck	Phase III completed; licensure pending
	Live bovine/human multivalent reassortant	NIAID	Phase II
	Live human neonatal strain, oral	Australia	Phase I
	Live attenuated, human neonatal strains, oral	India and PATH	Phase I
	RV VLPs	Various research groups	Preclinical
Shigellosis	Conjugate vaccine (PEA-PS)	NIH	Phase II in children
	Ribosomal preparation	IVI/WRAIR	Preclinical
	Inactivated whole cell, oral	Antex	Phase I
	Live attenuated <i>S. flexneri/sonnei</i> , oral	Lanzhou Inst Biol Prod, China	Phase III
	Live attenuated <i>S. flexneri/dysenteriae</i> , oral	Pasteur Institute /WRAIR / IVI	Phase I/II
	Live attenuated <i>S. flexneri/dysenteriae</i> /ETEC fimbriae,	Univ Maryland	Phase I
	Live attenuated <i>S. sonnei</i> (Vir G), oral	Univ Maryland	Phase I

Typhoid Fever	rPAE- Vi conjugate vaccine	NIH /Sanofi-Pasteur	Phase II/ III
	Ty800 live attenuated strain, oral	Avant Immunotherapeutics	Phase II
	Live attenuated CVD908-htrA and CVD 909, oral	Univ Maryland / Acambis; Berna	Phase II
	Live attenuated, oral	Microscience, Avant Immunotherapeutics	Phase II
Respiratory Diseases			
Influenza virus	Inactivated H5N1 reassortant virus vaccine	Sanofi-Pasteur; Chiron / NIH; Kitasato Inst, Japan	Phase I pending
	Inactivated H9N2	GSK	Phase I in preparation
	Live attenuated, cold-adapted strains, nasal	MedImmune	Phase III completed; licensure pending
	Live attenuated, nasal	Merck / Biödiem	Preclinical
	Live attenuated, cell-culture, nasal	Vector, Russia	Preclinical
	Live attenuated H9N2 and H5N1 strains, nasal	MedImmune	Preclinical
	Proteosome	ID Biomedical	Phase II
	Synthetic peptides, nasal	Yeda/ BiondVax, Israel	Phase I in preparation
	DNA	CDC; Vical; PowderJect	Phase I
	M2-HBc VLPs	Apovia / Univ Gent	Preclinical
	M2-N. meningitidis OMP and M2-KLH	Merck	Preclinical
Parainfluenza virus type 3 (PIV-3)	Live chimeric human / bovine PIV-3 reassortant	NIH; MedImmune	Phase I
	Live chimeric RSV / human PIV-3 / bovine PIV-3 reassortant, nasal	MedImmune	Preclinical
	Virosomes	Berna	Preclinical
Respiratory Syncytial Virus (RSV)	F protein subunit vaccines (PFP-2, PFP-3)	Wyeth	Phase II/III (children with CF); Phase II (pregnant mothers)
	F/G/ M proteins subunit vaccine	Sanofi-Pasteur	Phase II
	Live attenuated, cold-adapted <i>ts</i> strain, nasal	Wyeth/NIAID	Inactive
	Genetically engineered live attenuated vaccines	Wyeth/NIAID	Phase I
	Live chimeric RSV / human PIV-3 / bovine PIV-3, nasal	MedImmune	Preclinical
	Virosomes	Berna	Preclinical
Severe acute respiratory syndrome (SARS)	Whole inactivated virus	Sinovac, China;	Phase I
		Sanofi-Pasteur; Chiron; Baxter	Preclinical
	Live recombinant MVA-S protein	Rockefeller Univ	Preclinical
	Live recombinant Ad-S protein	Crucell	Preclinical
	S, S/M, or S/M/N subunit vaccines	Various academical institutions	Preclinical

Streptococcus pneumoniae (pneumococcal disease)	Conjugate 9-valent vaccine	Wyeth	End of Phase III
	Conjugate 11-valent vaccine	Sanofi-Pasteur;	Phase III
		GSK	Phase III completed (old formulation) / Phase II (improved formulation)
	BVH3/11V fusion protein	ID BioMedical	Phase I completed
	PspA+PsaA	Sanofi-Pasteur	Phase I in adults
	Pneumolysin, PspA, adhesins, PiaA, PiuA, etc, subunit or DNA vaccines	Various academic institutions	Preclinical / Phase I
Tuberculosis	Modified BCGs :		
	-BCG30 (Ag85B)	UCLA	Phase I
	-BCG::RD1	Pasteur Institute	Preclinical
	-BCG: Δ ure C-Hly	Max Planck Institute	Prep for Phase I
	Live attenuated <i>M. tuber- culosis</i> Pho P mutant	Pasteur Institute/ Univ Zaragoza	Preclinical
	Live attenuated mc2 6020 / 6030 strains	Albert Einstein Coll Med, NY	Prep for Phase I
	Live, recombinant MVA-Ag85A	Oxford Univ	Phase I completed (BCG - primed volunteers)
	Live, recombinant Ad-Ag85A	Crucell / Aeras; GlobalTB Vaccine Foundation	Preclinical
	Mtb32 / Mtb39 fusion protein subunit vaccine	IDRI-Corixa / GSK	Phase I (BCG-primed volunteers)
	ESAT-6 / Ag85B fusion protein subunit vaccine	SSI	Prep for Phase I
	Mtb72F in AS02A subunit vaccine	GSK	Phase I
	Multi-epitope peptide, mycolic acid, others	Intercell; others	Preclinical / Phase I
	Bacterial Diseases		
Anthrax	Protective antigen (PA) subunit vaccine	BioPort; Vaxgen	Phase I/II
	Live recombinant (MVA, <i>Salmonella</i> , <i>V. cholerae</i> ...)	Avant Immunotherapeutics;	Phase I
		others	Preclinical
Neisseria meningitidis (Groups A,C, Y, W135)	Group A PS conjugate	Serum Institute of India	Phase I
	Trivalent A, C,W135 PS	GSK	Phase II
	Tetravalent PS conjugate	Sanofi-Pasteur	Licensure
	Heptavalent DPT-HepB-Hib-MenA/C conjugate	GSK	Phase II
Neisseria meningitidis (Group B)	NZ Por A outer membrane vesicles	GSK	Phase II
		Chiron / Auckland Univ	Phase III/IV
	New membrane protein subunit vaccines	Chiron ; Microscience	Preclinical / Phase I
Plague	F1-V fusion protein subunit vaccine	DynPort Vaccine	Phase I
	Live recombinant <i>Salmonella</i> –F1-V	Avant Immunotherapeutics	Phase I

Group A <i>Streptococcus</i>	26-valent M protein N-terminal epitopes + conserved protein Spa	ID Biomedical	Phase II
	J14 moiety fusion peptide combined with 7-valent determinants on polymer backbone	Queensland Inst of Med Res, Australia	Ready to enter Phase I
	C-terminal half of M protein expressed as a fusion protein on surface of <i>Streptococcus gordonii</i>	Rockefeller Univ, New- York/ SIGA Technologies	Phase I
	Carbohydrate	Rockefeller Univ, New-York	Pre-clinical
	C5a peptidase	Minnesota Univ/Wyeth	Preclinical
	Stb1 subunit vaccine	Gesellschaft Biotechnologis- che Forschung, Germany	Preclinical
	Exotoxin A and C toxoids	Various groups	Preclinical
	Recombinant fusion peptide containing N-terminal M protein fragments from Group A Strep serotypes 1, 3, 5, 6, 19, and 24	Center for Vaccine Development, Baltimore, USA	Phase I
Group B <i>Streptococcus</i>	Conjugate Ia, Ib vaccine	NIH	Phase I
	Conjugate III vaccine	NIH ; Baxter	Phase I (pregnant women)
	New membrane protein subunit vaccines	Microscience; Intercell	Preclinical
Sexually Transmitted Diseases			
<i>Chlamydia trachomatis</i>	Membrane protein (OMP) subunit vaccine	Antex Biologics	Phase II
	Conserved surface-exposed polymorphic membrane protein D (PmpD)	NIAID, NIH, USA	Preclinical
Herpes simplex type 2 (HSV-2)	gD2 subunit with AS04 adjuvant	GSK / NIH	Phase III (HSV seronegative women)
	Live attenuated ICP8 DISC virus vaccine	Xenova	Phase I/II
	Other live attenuated, replication - competent virus vaccines	Avant; AuRix	Phase I; Phase II
HIV / AIDS	Aldithriol- or NEM-inactivated whole virus	NCI	Preclinical
	Trimeric ΔV2 gp140 subunit vaccine;	Chiron	Phase I
	Disulfide -bound (SOS) trimeric gp140 subunit	Progenics	Preclinical
	Single chain CD4 mimic-gp120 subunit vaccine	Univ Maryland;	Preclinical
	Gp41 subunit vaccines	Vienna Univ; Mymetics; Merck; research groups	Preclinical
	Live, recombinant ALVAC-env/gag/pol/ nef + recombinant clade	Sanofi-Pasteur / WRAIR / VaxGen / Ministry of Health of Thailand	Phase III (Drug users)
	Live, recombinant MVA	Therion / IAVI; Aaron Diamon / IAVI	Phase I
	Live, recombinant non-replicative Ad5-gag /pol/ nef	Merck / NIAID	Phase II
		Vaccine Res Ctr (NIH)	Prep for Phase II with DNA prime
	Other live, non replicative Ad recombinants (Ad6, Ad35...)	IAVI/Crucell; Beth Israel Deaconess Med Ctr; Merck	Preclinical
	Live, recombinant attenuated measles virus vaccine	Pasteur Institute / GSK	Prep for Phase I
	Live recombinant fowlpox virus (clade E)	AVC (Australia)	Phase I (with DNA prime)
	DNA+ NYVAC (clade C)	Eurovac consortium (EU)	Phase I

	Other live recombinant vaccines (BCG, VEEV, AAV, <i>Salmonella</i> , VSV...)	NIH Japan; Alphavax; Targeted Genetics / IAVI ; Univ Maryland; Wyeth ...	Preclinical / Phase I
	DNA vaccines	Parexel; Wyeth / Univ Pennsylvania; Vical; Istituto Sup di Sanita	Phase I
	Gag-B. anthracis LF fusion protein subunit vaccine	Avant / WRAIR	Phase I
	Tat-Nef fusion protein +Env subunit vaccine	GSK	Prep for Phase I
	Polyepitopic polypeptides	Epimmune; Wyeth / Duke Univ; GAIA	Preclinical / Phase I
	Tat, Rev, Nef subunit vaccine	AVIP consortium (EU)	Phase I
	Gag, Pol, Nef lipopeptides	ANRS/NIAID	Phase II (suspended)
	CCR5 peptides ; CCR5-hsp70 fusion protein	Guy's Hospital, London ; Maryland Univ ; Various groups	Preclinical
Vector-borne Diseases			
Dengue Fever	Live attenuated, 4-valent vaccine	Sanofi-Pasteur / Mahidol	Phase II (pediatric)
	Live chimeric 4-valent Dengue/Yellow Fever vaccine	Acambis / Sanofi-Pasteur	Phase I (adults)
	Live attenuated (3 ⁺ NCR), 4-valent vaccine	NIH	Phase I (as monovalent)
	Live attenuated DV-2 and DV-2/1, -2/3, -2/4 chimeric vaccines	CDC	Preclinical
	Tetravalent chimeric, F mutant	US FDA	Preclinical
	4-valent E-NS1 fusion protein subunit vaccine	Hawaii Biotech	Preclinical
	Other vaccines (DNA, recombinant MVA...)	NIH	Preclinical
Japanese Encephalitis	Inactivated Vero cell-grown SA14--14-2 strain	Intercell	Phase II/III (adults)
	Inactivated Vero cell-grown Beijing strain	Biken, Kaketsuken	Phase II/III
	Live, chimeric SA14 -14-2/Yellow Fever vaccine	Acambis	Phase II in adults
	Live MVA recombinant	Bavarian Nordic	Preclinical
West Nile virus	Live, chimeric WNV/ Dengue (DV-4) vaccine	NIH	Prep for Phase I
	Live, chimeric WNV/ Yellow Fever vaccine	Acambis	Phase I/II
	Inactivated virus vaccine	Crucell	Preclinical
	Glycoprotein subunit vaccine	Hawaii Biotech	Preclinical
	DNA vaccine, VLPs, others	Several institutions	Preclinical
Parasitic Diseases			
Hookworm Disease	ASP2 subunit vaccine	Human Hookworm Vaccine Initiative	Phase I
Leishmaniasis	Live attenuated / drug-sensitive strains	Various laboratories	Preclinical
	Killed promastigotes with BCG and alum	Razi Institute	Phase II
		BIOMM (Brazil)	Phase I/II
	LeIF/ LmSTI-1/ TSA fusion protein subunit vaccine	IDRI/Corixa	Phase I/Ib
	DNA, subunit vaccines (gp63, LeIF, PSA2, LACK antigen,...)	Various laboratories	Preclinical

Malaria	RTS,S: Hybrid <i>P. falciparum</i> CSP-HBsAg particles + AS02 adjuvant	GSK / WRAIR/MVI	Phase IIb
	<u>Pre-erythrocyte stage</u>		
	CSP C-ter peptide + Montanide ISA 720	Dictagen / Lausanne Univ	Phase Ib
	ICC-1132: Hybrid CSP multiepitope-HBc VLPs	Apovia/MVI	Phase II
	DNA vaccines (including MuStDO-5: CSP/LSA-1/ LSA-3/EXP1/TRAP)	US Navy/ Vical	Phase I
	Live recombinant FPV- or MVA-CSP + LSA-1 epitope	Oxford Univ/ Oxxon/MVI	Phase Ib
	Live recombinant MVA-multiepitope string + TRAP	Oxford Univ/Oxxon	Phase Ib
	Live recombinant Ad-CSP	Crucell/GSK/WRAIR/NIAID	Phase Ia
	Other live recombinant vaccines (MVA, cold-adapted influenza virus)-CSP	Oxford Univ; NYU;	Preclinical
	LSA-3 (long peptides; lipopeptide;recombinant)	Pasteur Institute/WRAIR/ GSK	Phase Ia
	LSA-1, SALSAs, other liver-stage antigens	Hawaii Biotech; Epimmune	Preclinical
	MSP-1 42 kD + AS02	GSK/WRAIR/MVI	Phase Ib/ II
	<u>Blood-stage</u>		
	AMA-1	MVDU; NIAID	Phase Ib
	PfCP 2.9: MSP-1-AMA-1 fusion protein (yeast) + Montanide ISA 720	Sec Military Med Univ Shanghai/Wanxing Pharmaceuticals/ WHO	Phase I
	Other MSP-1 derivatives (peptides, <i>Salmonella</i> or BCG recombinants,...)	NIAID; Hawaii Biotech; AECOM; Univ Maryland	Preclinical to Phase I
	MSP-3 long peptides	Pasteur Institute/ AMANET/EMVI	Phase Ib
	GLURP long peptide	EMVI/SSI	Phase I
	MSP-3-GLURP hybrid long peptide + Montanide ISA 720	EMVI/SSI	Phase I
	MSP-4, -5	Monash	Preclinical
Combination B: MSP-1, -2, RESA + Montanide	Queensland Med Res Institute/WEHRI	Phase II	
SE36	Osaka Univ/Biken	Phase I	
Other blood-stage antigens (EBA-175,EBP2, MAEBL, RAP-2, EMP-1, DBL- α ..)	Various groups	Preclinical	
<u>Sexual stage</u>			
PfS25 (yeast)	NIH	Phase I	
PvS25 and other sexual-stage antigens	NIH	Preclinical	
Schistosomiasis	<i>S. haematobium</i> 28kD GST subunit vaccine	Lille Pasteur Institute	Phase II
	<i>S. mansoni</i> paramyosin + TPI multiepitope	Bachem/USAID/SVDP	Preclinical
	<i>S. mansoni</i> Sm14	FioCruz	Preclinical
Hepatitis and Cancers			
<i>Helicobacter pylori</i>	Whole cell vaccine with mutant LT adjuvant	Chiron; Antex	Phase I / II
Hepatitis B	HBc VLP+ cochleates, nasal	CIGB	Phase I
	HBV polyepitope vaccine	Innogenetics	Phase I
	HBsAg DNA vaccine	Pasteur Institute	Phase I
	DNA coding for T-cell epitopes	Genencor	Phase I

Hepatitis C	Recombinant E1/E2 + MF59 subunit vaccine	Chiron	Phase I
	Recombinant E1 glycoprotein subunit vaccine	Innogenetics	Phase II (therapy); Pre clinical for prevention
	HCCAg/E1/E2 VLPs	NIH	Preclinical
	HCCAg + ISCOMs	CSL, Australia /Chiron	Phase II
	Live recombinant MVA-NS3-NS4-NS5 antigens vaccine	Transgene/BioMerieux	Preclinical
	Multipitope synthetic peptides in virosomes	Pevion	Preclinical
	Multigene recombinant Adenovirus	GenPhar	Preclinical
	Multiantigen DNA, peptides, others	Epimmune/Innogenetics, Merix..	Preclinical
Hepatitis E	56 kD ORF-2 protein VLPs (baculovirus)	GSK/WRAIR	Phase II/III
	DNA vaccine (ORF-2)	US Navy	Preclinical
	Live swine virus vaccine	NIH	Preclinical
Human papillomavirus	HPV-6,-11,-16,-18 L1 protein VLPs, yeast	Merck	Phase III completed; licensure pending
	HPV-16,-18 L1 protein VLPs, baculovirus	GSK	Phase III
	Live, recombinant <i>Salmonella</i> -HPV-16 L1 protein (VLP), oral	Univ Lausanne (Switzerland)	Preclinical
	HPV-16 L1 VLPs, tobacco; same, potato	Univ Cape Town; Xian Jiaotong Univ (China); Inst for Plant Research,	Preclinical
	HPV-16 L1 VLPs / IL-2	Pochon Univ (S.Korea)	Preclinical
	Recombinant AAV-HPV16 L1 / GMCSF	Nat Defense Med Center, Taiwan	Preclinical
	HPV-16 L1 DNA vaccine	Swedish Institute for Infectious Diseases Control	Preclinical
	HPV-16 L1 DNA / RANTES	Pundang General Hospital (S. Korea)	Phase I
	HPV-16 L2 peptides, nasal	Tokyo Univ	Preclinical
Epstein-Barr Virus	Gp350 subunit vaccine	MedImmune/GSK/Henogen	Phase II
	EBNA-3A peptide	CSL, Australia	Phase I (discontinued)
	Live MVA –LMP2A recombinant	GSF, Germany	Preclinical
Enteroviruses			
Poliovirus	Whole inactivated Sabin strains (IPV)	JPRI, Japan;	Phase III/licensure
		Kunming Institute Med Biol, China; Panacea Biotech, India	Preclinical /Phase I
	Monovalent Sabin type 1 (OPV)	Sanofi-Pasteur; Panacea Biotech, India	Licensure