

Passive and Active Immunization

- Passive immunization
 - Transfer of preformed antibody produced externally to provide protection to the recipient
 - Provides temporary protection that wanes with time
 - Transfer of maternal antibody across the placenta that provides protection in early infancy is an example of passive immunization
- Active immunization
 - Administration of specific components of an infectious agent that elicit an immune response in the recipient
 - Immunology memory provides prolonged protection that may be lifelong
 - Traditional vaccines provide active immunization



Monoclonal antibodies for prevention of infectious diseases

- With development of long-acting monoclonal antibodies (mAbs), there is an opportunity to provide protection beyond what can be provided by traditional vaccines
- Especially valuable when
 - Full protection is needed without delay
 - A traditional vaccine is not available
- For some indications, a long-acting mAb might provide “long enough” protection
 - For a respiratory disease season
 - For a critical part of a pregnancy
 - For prevention of travel-related infection

TARGET PATHOGEN ANTIBODY	PRECLINICAL	PHASE I	PHASE II	PHASE III
Chikungunya mRNA-1944		Moderna NCT03829384		
Ebola GamEMab		Gamaleya Research Institute of Epidemiology and Microbiology NCT03428347 NCT03015181		
Gamezumab		Gamaleya Research Institute of Epidemiology and Microbiology NCT04592549		
Ansuvimab			ANRS, Emerging Infectious Diseases (INSERM) NCT04822376	
Malaria TB31F			PATH NCT04238889	
VRC-MALMAB0100-00-AB (CIS43LS)		NIH NCT04208332	NIH NCT04329104	
VRC 614 (L9LS)		NIH NCT05019729	NIH NCT05400655 NCT05304611	
Rabies SYN023		Synermore Biologics Co., Ltd. NCT04495589	Synermore Biologics Co., Ltd. NCT02056746 NCT03061555	Synermore Biologics Co., Ltd. NCT04844484
RSV Nirsevimab (MEDI8897)				Astra Zeneca / Sanofi Pasteur EUCTR2019-000114-11-LV EUCTR2019-000201-89-BE NCT03959485 NCT03979313
MK-1654			Merck NCT04787373	
MRI RSM01		Gates Medical Research Institute NCT05118385		
Staphylococcus aureus Suvratzumab (MEDI4893)				Aridis Pharmaceuticals Inc NCT05331685
SARS-CoV-2 ADM03820		Ology Bioservices NCT04592549	Ology Bioservices NCT05142527	
MTx-COVAB36		Memo Therapeutics AG NCT05351437		
dMAb AZD5396 and dMAb AZD8076		Astra Zeneca, Inovio Pharmaceuticals, the Wistar Institute (DNA-encoded mAbs) NCT05293249		
Yellow fever TY014		Tysana Pte Ltd NCT03778786		
Zika dMAb-ZK190 and INO-A022		Inovio Pharmaceuticals (DNA-encoded mAbs) NCT03831503		

CDC's Approach to Prioritizing Long-Acting Monoclonal Antibodies for Prevention of Infectious Diseases

CDC will prioritize for ACIP consideration those long-acting monoclonal antibodies for prevention of infectious diseases that are:

- Expected to address conditions that result in a significant burden of disease to the public's health;
- Not expected to present significant implementation issues – at least from the perspective of mode of administration, storage and handling, and frequency of administration -- for immunization providers; and
- Expected to be priced at a level allowing for incorporation into immunization programs.