Coronavirus vaccine program

IAVI and Merck are responding to the coronavirus pandemic by leveraging their extensive vaccine development expertise to develop a vaccine to prevent COVID-19.

Built on established, effective technology for accelerated development and approval

IAVI researchers began working on a coronavirus vaccine candidate in early 2020 when it became clear that coronavirus disease 2019 (COVID-19) was spreading globally, and that the organization had expertise needed to contribute to the response. In May 2020, Merck, known as MSD outside the United States and Canada, and IAVI announced their collaboration to work together at an accelerated pace to develop the vaccine.

The partnership’s coronavirus vaccine candidate is built on the same technology as Merck’s highly effective Ebola virus vaccine ERVEBO® (Ebola Zaire Vaccine, Live) that was recently approved by the European Commission, the U.S. Food & Drug Administration, and regulators in several African countries. The use of an established vaccine technology could potentially speed development, clinical testing, and approval of the vaccine candidate in the midst of the continuing global public health threat of COVID-19.

The coronavirus vaccine program leverages IAVI’s expertise in recombinant vesicular stomatitis virus (rVSV) vector technology that it has developed through its rVSV HIV vaccine candidate and its viral hemorrhagic fever vaccine candidates in preclinical development. rVSV is the vector used in ERVEBO®.

“One of the major countermeasures that we have to address [emerging infectious diseases] is the ... development, rapidly and efficiently, of vaccines against these pathogens.”

Anthony Fauci, M.D., Director, U.S. National Institute of Allergy and Infectious Diseases

In addition to the potential of generating a strong immune response, this coronavirus vaccine candidate may share other characteristics with ERVEBO® that make it well suited for use in an outbreak: immunity may be generated relatively quickly, and only one dose of vaccine may be required. Additionally, IAVI and Merck will investigate oral administration of the vaccine candidate as well as intramuscular injection, which could accelerate vaccine production and facilitate global access. Oral immunization with the rVSV-vectored Ebola vaccine was evaluated in animals and found to be as effective as intramuscular immunization in preventing disease.

For the rVSV-based coronavirus vaccine candidate, named rVSVΔG-SARS-CoV-2, IAVI scientists have replaced the VSV gene coding for the VSV surface protein with a gene coding for the surface protein of SARS-CoV-2, the virus that causes COVID-19. If the vaccine candidate is shown to be safe and stimulates immune responses in animals in preclinical studies, a Phase I clinical trial, followed by large-scale safety and efficacy evaluation in humans, would occur as soon as possible to support licensure and global access. An accelerated development plan, based on the rVSV platform technology, has been discussed with regulators.

IAVI/Merck Coronavirus Vaccine Candidate

- Based on rVSV vector used to develop the Ebola vaccine that was 100% efficacious in a trial in Guinea
- Potential 1 dose formulation
- Oral and IM administration being tested
- Using the rVSV platform technology, an accelerated plan is being discussed with regulators
- Accelerated production of vaccine for clinical trials
- Scalable technology for high-volume commercial production

IAVI and Merck are responding to the coronavirus pandemic by leveraging their extensive vaccine development expertise to develop a vaccine to prevent COVID-19.
Innovative partnership model

IAVI and Merck will work together to advance the development and global clinical evaluation of the SARS-CoV-2 vaccine candidate. The vaccine candidate is in preclinical development, and clinical studies are planned to start later in 2020. Merck will lead regulatory filings globally. Both organizations will collaborate to develop the vaccine and make it accessible and affordable globally, if approved. IAVI and Merck have already begun to prepare for eventual large-scale vaccine production.

The Government of Japan has announced its commitment to contribute to IAVI’s work on COVID-19 vaccines.

IAVI’s Vaccine Design and Development Lab in New York

Much of the research and development on IAVI’s rVSV platform is performed at the IAVI Vaccine Design and Development Lab (DDL). The DDL is located at the bioscience center (BioBAT) in the historic Brooklyn Army Terminal in New York. Since its founding in 2008 the IAVI DDL has become one of the world’s leading viral vector vaccine research and development labs, known for innovation and generation of novel vaccine design concepts.

The IAVI DDL’s Biosafety Level (BSL) 2 laboratories are outfitted for molecular cloning, cell culture, virology, protein chemistry, and immunology research.

### IAVI’s Emerging Infectious Diseases Vaccine Candidates

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<thead>
<tr>
<th>Vaccine</th>
<th>Funder/Partner</th>
<th>Stage</th>
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<tbody>
<tr>
<td>SARS Coronavirus 2 rVSVΔG-SARS-CoV-2</td>
<td>Merck, with funding from the Biomedical Advanced Research and Development Authority (BARDA); Government of Japan, in partnership with the World Bank</td>
<td>Preclinical</td>
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<td>Lassa Fever Virus rVSVΔG-LASV-GPC*</td>
<td>CEPI</td>
<td>Preclinical</td>
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<td>Marburg Virus rVSVΔG-MARV-GP*</td>
<td>U.S. Department of Defense, Defense Threat Reduction Agency</td>
<td>Preclinical</td>
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<tr>
<td>Ebola Sudan Virus rVSVΔG-SUDV-GP*</td>
<td>Pursuing funds</td>
<td>Preclinical</td>
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*Technology licensed from the Public Health Agency of Canada. Partners: Batavia Biosciences; Center for Global Infectious Disease Research; George Washington University; IAVI-Institute of Clinical Research (Kenya); Kenema Government Hospital (Sierra Leone); La Jolla Institute for Immunology; Merck & Co., Inc.; MRC/UVRI and LSHTM Uganda Research Unit; National Public Health Institute of Liberia; Projet San Francisco/Center for Family Health Research (Rwanda); Ragon Institute of MIT, MGH, and Harvard; Tulane University; University of Texas Medical Branch.

Sources available at iavi.org/fact-sheets-sources

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