Antibodies for HIV prevention

IAVI and partners are applying their expertise gained from HIV vaccine research to produce what could be a breakthrough in the fight against HIV/AIDS: an injection of broadly neutralizing antibodies (bnAbs) to prevent HIV infection.

We need new options for HIV prevention

Worldwide, 38 million people are living with HIV, and HIV/AIDS killed 680,000 people in 2020. Despite advances in treatment and prevention, notably through the broad availability of antiretroviral drugs, about 1.5 million people contracted HIV in 2020. We need additional tools that can work for people unable to benefit from today’s interventions. That’s why IAVI is committed to developing vaccines and antibodies as options for HIV prevention.

HIV prevention isn’t reaching the most vulnerable

Although some highly effective HIV prevention tools are available, the epidemic continues. This is partly due to the challenges people face when trying to consistently adhere to effective prevention options. But it’s also because certain populations — men who have sex with men, people who inject drugs, sex workers, and adolescent girls and young women, who account for a large proportion of all new infections — are less likely to access existing treatment and prevention services as a result of stigma and discrimination. We need new ways to stop the spread of HIV, ones that are likely to be embraced by the people most at risk of HIV infection.

The basics of HIV bnAbs

- bnAbs are broadly neutralizing HIV antibodies. They develop naturally in some people after many years of HIV infection.
- bnAbs have been shown to neutralize a wide range of HIV variants in the lab.
- Antibodies have revolutionized treatment for certain cancers and immune disorders, and are beginning to be applied more broadly to fighting infectious diseases.
- Scientists are making HIV bnAbs in the lab and engineering them to extend how long they last and make them more potent.

The potential of bnAbs to prevent HIV

- They would block multiple strains of HIV.
- They are likely to be safe and well tolerated.
- They could be given in a simple, discreet injection.
- They could prevent infection for up to six months.

HIV/AIDS and bnAbs by the numbers

<table>
<thead>
<tr>
<th>HIV/AIDS and bnAbs by the numbers</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>38 million people are living with HIV/AIDS</td>
<td>200+ broadly neutralizing HIV antibodies discovered</td>
</tr>
<tr>
<td>1.5 million people contracted HIV in 2020</td>
<td>6 months of protection likely with 1 dose of bnAbs</td>
</tr>
<tr>
<td>$29 billion is needed for global HIV/AIDS response by 2025</td>
<td>2 clinical trials of HIV bnAbs sponsored by IAVI are ongoing</td>
</tr>
</tbody>
</table>

Sources available at iavi.org/fact-sheets-sources
Ensuring bnAbs are globally accessible and affordable

IAVI and partners are working across the continuum of product development to ensure that bnAbs, once shown to be efficacious, will be promptly, globally, and affordably accessible to the people who need them. The partners are accomplishing this by:

- Building user preferences and local community needs into product development plans from the very beginning of the process.
- Working with low-cost manufacturers and supporting innovations in production and delivery.
- Collaborating with regulatory bodies and policy makers across the world to make sure pathways exist for rapid registration, adoption, and distribution of bnAbs.
- Expanding public-private partnerships to develop and commercialize affordable antibodies for global and sustainable access.

### Partnerships drive discovery and development

IAVI scientists have identified more than 80 bnAbs from our HIV epidemiology studies and have developed a powerful set of tools for antibody optimization. Our scientific collaborators, Scripps Research and the U.S. National Institutes of Health (NIH) Vaccine Research Center (VRC) and Division of AIDS (DAIDS) at the National Institute of Allergy and Infectious Diseases (NIAID), are global leaders in antibody discovery and development. IAVI scientists and scientists at University of Oslo and Translational Health Science and Technology institute, with support from the Research Council of Norway’s Globvac program, are collaborating to engineer HIV antibodies to extend their duration of effect. Together, and enabled by IAVI’s support from the U.S. Agency for International Development (USAID), these scientific partners will advance the most promising antibodies and antibody combinations into clinical trials.

Serum Institute of India, our respected industry partner known globally for manufacturing high-quality affordable, advanced biologics, will develop an affordable approach to manufacturing an easy-to-use, injectable HIV antibody product.

The Wellcome Trust and Merck have supported IAVI authorship of two comprehensive reports to stimulate global calls-to-action to accelerate the development of affordable and accessible antibody products for global health. And IAVI is working with the World Health Organization to establish guidelines for eventual regulatory approval of an HIV antibody-based intervention.

These partners have expertise spanning the continuum of product development and access — antibody discovery, clinical trials, manufacturing, regulatory review, policy development, and acceptability for at-risk populations.

### IAVI’s bnAb pipeline

<table>
<thead>
<tr>
<th>Clinical Trials</th>
<th>Partners</th>
</tr>
</thead>
<tbody>
<tr>
<td>T003</td>
<td>Beth Israel Deaconess Medical Center, NIH, VRC</td>
</tr>
<tr>
<td>C100</td>
<td>BMGF, Rockefeller University, University of Washington</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Preclinical Programs</th>
<th>Partners</th>
</tr>
</thead>
<tbody>
<tr>
<td>Next-generation bnAbs and bnAb combinations</td>
<td>USAID, Scripps Research, NIH/NIAID, VRC &amp; DAIDS, Serum Institute of India, University of Oslo</td>
</tr>
</tbody>
</table>

IAVI gratefully acknowledges the generous support provided by the following major donors:

As of October 2023