bnAbs for HIV prevention

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As of April 2022
Contents

The burden of HIV

The case for bnAbs

Global Access
HIV
An Unmet Need

• The HIV pandemic continues to **cause extensive morbidity and mortality** globally and is a top public health priority

• Despite progress in reaching 73% of people living with HIV with antiretroviral therapy, gaps in HIV prevention and treatment contributed to **1.5 million new infections and 680,000 HIV-related deaths in 2020**

• **Adolescent girls and young women** (AGYW) in low- and middle-income countries (LMICs), especially in sub-Saharan Africa (sSA) remain **disproportionately affected**

• **Young children** accounted for **150,000 new HIV infections**, the vast majority during infancy
**HIV Prevention Toolbox**

A single product or approach will not stop the pandemic.

<table>
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<tr>
<th>STI Treatment</th>
<th>Medical Male Circumcision</th>
<th>HIV Testing and Counseling</th>
<th>Microbicides</th>
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<td>Treatment/Prevention of Drug/Alcohol Abuse</td>
<td>Clean Syringes</td>
<td>HIV Prevention Toolbox</td>
<td>PrEP</td>
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<td>Education/Behavior Modification</td>
<td>Blood Supply Screening</td>
<td>Treatment as Prevention</td>
<td>Condoms</td>
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*We need a diversity of prevention options and programs to address the diverse needs of individuals at risk for HIV infection.*
HIV bnAbs for prevention (and treatment)

CASE FOR ADDING ENHANCED BNABS TO PREVENTION TOOLBOX

LONG-ACTING
- Reduced frequency of administration

MECHANISM OF PROTECTION
- AMP trials provided a proof of concept for use of bnAbs for prevention of HIV
- Protection at the site of infection
- Elimination of infected cells distally from the site of infection

LOW TOXICITY
- Very few cases of adverse side effects, generally well-tolerated

DISCREET
- Subcutaneous delivery every 3 to 4 months for next generation ebNAbs

We need a diversity of prevention options and programs to address the diverse needs of individuals at risk for HIV infection.
Potential role of ebnAbs to prevent vertical transmission

- Favorable potential **dosing schedules**
- Lower **COGS** for the pediatric indication
- **Cost effectiveness**; bNAbs for infant prophylaxis would offer good value in various sub-Saharan African settings and implementation scenarios (Alba, et al. forthcoming)
- Potential to align with schedule for **routine pediatric vaccines**
- Plan is to initiate a **Phase 1 in Q1 2023**, followed by initiating the Pediatric Program in sub-Saharan Africa once an adult dosing schedule (2024)
- Access work to define a use case, potential demand, acceptability, & implementation strategies for infant indication is underway
Approach for global access to HIV bnAbs

Defining a pathway to global access
- Stakeholder-informed target product profile (PPC)
- Ensuring end user acceptability & feasibility
- Determining cost effectiveness
- Demand forecasting and generation
- Defining access pathways
- Integration into policy, financing & procurement platforms
- Advocacy to generate political will

Affordable and accessible bnAbs for prevention
- Evaluating platforms to reduce manufacturing COGs
- Formulation studies to enable SQ injections
- Low cost regional manufacturer

Highly potent bnAbs w/ extended half-life
- Discovery of highly potent HIV bnAbs
- Optimization of existing HIV bnAbs for enhanced potency
- Optimization of bnAbs for extended half-life
IAVI has Created a Public-Private Partnership to Advance an HIV bnAb Prevention Product and Collectively Map Out a Pathway to Global Access

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<tr>
<th><strong>USAID-PEPFAR and IAVI Strategic Partnership</strong></th>
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<th><strong>IAVI-Serum Institute Collaboration Agreement</strong></th>
<th><strong>Expanding Access to Monoclonal Antibodies: A Global Call to Action</strong></th>
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<td>✓ Development experience</td>
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<td>✓ Antibody R&amp;D for HIV prevention in African/global communities</td>
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**Expanding Access to Monoclonal Antibodies: A Global Call to Action**
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**HIV antibody guidance documents**
- Collaboration on Preferred product characteristics (PPC), Vaccine Value Profile
Summary

• The HIV pandemic continues to cause extensive morbidity and mortality globally and is a top public health priority
• There is a good case for adding long acting and potent bnAbs to the HIV prevention toolkit
• Alongside our product development, activities to enable broad access to bnAbs post-licensure are ongoing and include plans for prevention of vertical transmission and use by pregnant women
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