



## **Talking Points for IAVI and Wellcome’s Call to Action: Expanding Access to Monoclonal Antibody-Based Products**

### ***Topline message***

Monoclonal antibodies (mAbs) have the potential to save and improve millions of lives but are generally unavailable to the world’s poorest people. We need to ensure that mAb-based products for infectious and non-communicable diseases can be accessed by all who need them, especially in low- and middle-income countries.

The goal of this call to action is to catalyze discussion, collaboration, and action among global health players to join forces to make global access to transformative monoclonal antibody products a reality.

**To facilitate the equitable access to mAbs for COVID-19, HIV, and other diseases, once they are shown to be efficacious, we must act now.**

### ***About the call to action***

- The call to action, entitled “Expanding Access to Monoclonal Antibody-Based Products” was commissioned by Wellcome and developed by IAVI, a nonprofit scientific research organization dedicated to addressing urgent, unmet global health challenges.
- The call to action couldn’t come at a more critical time: the novel coronavirus pandemic has triggered unprecedented collaboration to accelerate research and development for mAbs to prevent and treat COVID-19.
- While the science is promising, and more than 70 COVID-19 antibody programs are in development, tremendous barriers exist to making these antibodies widely available once they are shown to be effective. This call to action provides critical guidance for the global health community by identifying a way forward to equitable global access to COVID-19 mAbs and mAbs for many other diseases.
- Findings and recommendations in the call to action are built on examples of mAbs that have been used for treating and preventing multiple diseases, and include insights from more than 100 interviews with global stakeholders including product developers, global health organizations, manufacturers, regulators, funders, policy makers, healthcare providers and ministries of health

### ***Key messages***

- IAVI and Wellcome have issued a call to action to make monoclonal antibodies widely accessible to people who need them most.
- Though mAbs have revolutionized treatment for certain cancers and autoimmune diseases, and despite their promise in reining in the COVID-19 pandemic, monoclonal antibodies are not being developed and licensed so that they are and accessible to people in low- and middle-income countries (LMICs).
- Four parallel commitments are needed:



1. Increase awareness: spread the word that monoclonal antibodies save lives
  2. Expand availability: support broader registration of monoclonal antibodies across the globe
  3. Apply innovations: invest in and deploy new technologies to lower development costs
  4. Create new models: establish business models that enable different market approaches and promote access.
- These actions are achievable: a roadmap in the call to action details specific steps stakeholders must take to expand access to existing monoclonal antibodies and to pave the way for rapid development and introduction of future monoclonal antibody products.

### ***Key facts on mAbs***

- Antibodies are proteins generated by the immune system. They are one of the primary ways the body defends itself against disease.
- Monoclonal antibodies are antibodies expressed from identical immune cells that can be manufactured at commercial scale using living cells. They are powerful tools in treating and preventing disease.
- mAbs have been deployed, mainly in high-income countries, against many cancers, autoimmune diseases, and some infectious diseases. A growing pipeline of mAbs is being developed to address infectious and neglected diseases—including COVID-19 and HIV which are significant and escalating threats to global public health.
- In 2019, seven of the ten best-selling novel drugs globally were mAbs.
- mAbs are the largest class of biologic products in development.

### ***Key findings***

- Availability and affordability are two key factors impeding global access to licensed mAbs.
  - Monoclonal antibodies are more complex and expensive to develop and produce than small molecule generic drugs.
  - 80% of licensed mAbs are sold in the United States, Europe, and Canada. Only 20% of mAbs are sold in countries that make up 85% of the world's population
  - mAbs are unaffordable for most of the world's population.
  - In LMICs, few mAbs are licensed. India – which has the most registered mAbs for an LMIC – has 36, compared to the U.S. (112) and Europe (120)
  - When and where lower-priced biosimilar mAbs are available, they can increase access, but not sufficiently.
  - India represents one of the best-case scenarios with respect to the availability of mAbs in middle-income countries, largely because of its biosimilar manufacturing capacity and the competition among biosimilar products. Even so, fewer than 22% of the products in the U.S. market are available in India, and no mAbs for cancer therapy are currently available in the Indian public health system.
  - Companies focused on high-income country markets have little incentive to pursue lower-cost strategies to develop, manufacture, and deliver mAbs.



- Competition, regulation and other strategies that can lower mAb prices are not sufficient to make these products affordable globally.
- Advances in antibody optimization, manufacturing technologies, and packaging and delivery have the potential to lower mAb production costs and increase affordability.
- Creative intellectual property/licensing frameworks may help expand access to mAbs.
- Alternate business models, including public-private partnerships and industry-led access models, are emerging and should be prioritized to support mAb research and development, manufacturing and global access for non-communicable and infectious/neglected diseases.
- Engaging communities, healthcare providers, and policy makers will help ensure that future products are acceptable and feasible to implement in diverse settings.
- The call to action includes a roadmap with specific actions and partners suggested to achieve the goal of affordable global access to monoclonal antibody-based products.