Webinar

# Monoclonal antibodies for the treatment and prevention of diseases: why and how to expand global access

Ayesha Sitlani, Marcela Vieira

25 November 2020

## Q&A Session with the Participants

**16:03:10**
From Global Health Centre Research, Graduate Institute Geneva : Welcome to the webinar series of the Knowledge Network for Innovation and Access to Medicines, a project of the Global Health Centre, Graduate Institute of Geneva. Thank you for joining us. The recording and materials from the webinar will be made available at www.knowledgeportalia.org.

If you have any questions, please type them at the chat (don't forget to select send to "all panelists and attendees") or use the button "Raise Hand" (in the participants list) if you wish to pose the question orally.

The IAVI/Wellcome report "Expanding access to monoclonal antibody-based products: A global call to action" is available at https://www.iavi.org/news-resources/expanding-access-to-monoclonal-antibody-based-products-a-global-call-to-action

**16:08:06**
From Esther Sedano : Are monoclonal AB being used for HIV patients treatment?

**16:10:48**
From Shelly Malhotra : The mAb Ibalizumab is FDA approved as salvage therapy in patients whose viruses are resistant to multiple existing antiretroviral drugs. Additionally, there are several mAbs for HIV in the pipeline.

**16:14:55**
From Hester Kuipers : There is a full overview of mAbs in development for HIV prevention and treatment in the HIV supplement to the Access report (see link above)

**16:16:10**
From Esther Sedano : Thanks

**16:27:07**
From Anna Amiranda : Any batch produced by originators is biosimilar to the first batch, thus a copy, exactly like biosimilars are vs the originators.

**16:30:17**
From Giustino Adesso : Although monoclonal antibodies can be a good complement to vaccine therapy, in relation to Covid19, there is still no vaccine developed that is effective to generate immunity, only some (without complete information) to treat the disease. So, do not you think that it is even more justified to continue insisting with monoclonal antibodies to treat patients with covid19?

**16:36:14**
From Julien Potet : Do you agree with the estimate that manufacturing costs for mAbs are around $100 per gram (and potentially lower in the future)?

**16:37:03**
From Isabela Drummond : In your report, did you assess / looked into the disease burden in LMICs for some of these mabs and is it clear which could be priority areas?

**16:38:09**
From Isabelle Colmagne-Poulard : did you assess the cause for hindering those technological advancements over the life cycle of Mabs?

**16:38:25**
From Suerie Moon : Intriguing case of rabies post-exposure prophylaxis by Serum institute and others -- would you give us further details on how the product was initially developed, who did the R&D? Was it feasible to cover the R&D costs while also selling the final product at this relatively affordable price?

**16:39:31**
From Philippe Carteron de Balmont : Decreasing price does not push prescriptions as original companies having huge marketinga activities to maintain their market share by paying congresses trips  supports etc....

**16:39:48**
From Andrew Farlow : Great presentation. Thanks. But what means “new ways to to business”? Our biggest issue now is covid-19 time constraint… We can visualise great progress in 2 to 5 to 10 years, but that is too slow in a pandemic.  If there was one or two products focussed on, could a big push to scale up work within the time constraints we face (within the next year, etc.). This, for sure, would seem more of a mass market than many other applications (without downplaying all the challenges).

**16:41:41**
From Julien Potet : As far as I know (please correct me if I am wrong), R&D of RabiShield was by WHO (identification of épitopes) and MassBio (US not for profit). Then mAb was licensed by Serum Institute who conducted clinical trials.

**16:42:52**
From Shelly Malhotra : More on partnerships for Rabishield development: https://www.umassmed.edu/news/news-archives/2017/10/serum-institute-of-india-

launches-rabishield-developed-in-partnership-with-umms/. Example of the innovative public-private models highlighted in the report!

**16:42:58**
From Suerie Moon : @Julien, thank you for this add'l info, very interesting example of an alternate business model

**16:44:35**
From Aleksandr Belinskiy : While there are no "universal insurance" in USA, what percent of population in USA could afford to pay for mAb therapies (taking into account high deductible for many insurance plans, for those who has medical insurance)?

**16:46:23**
From José Daniel Rengifo Martínez : In your opinion, do IP rights establish a barrier to access to monoclonal antibodies? If so, what kind of measures can be taken by governments to improve access in relation to those barriers?

**16:47:08**
From Isabela Drummond : Which are best practices you have seen regarding companies establishing scalable patient access schemes?

**16:49:26**
From Rakesh Chaurasia : why regulators are having very conservative approach towards biosimilars. Is it due to safety concern or what

**16:50:29**
From Andrew Farlow : (my angle is affordability in developing countries so the need to get affordable quickly for such populations)

**16:50:30**
From Claire Baudot : Could you share the study you are mentioning Marcela please ?

**16:50:48**
From Suerie Moon : Claire Baudot asked for ref to UCL report Marcela mentioned, it is here: https://www.ucl.ac.uk/bartlett/public-purpose/publications/2018/oct/peoples-prescription

**16:55:54**
From Kirsten Myhr : Disappointing to listen to a talk defending originators' high prices and criticism of biosimilars. There are regulations in place for biosimilars and several are approved in e.g. in Europe. I hope there can be a seminar presenting another view

(Note from organizers: A previous webinar of the series presented a different view on biosimilars: “Regulation to accelerate access to biosimilars: Colombia's pioneering approach”)

**16:58:36**
From Lisa Gieber : WHO prequalified the first biosimilar medicine trastuzumab in Dec 2019

**16:58:52**
From Adrián Alonso Ruiz : Could you develop further the example of Synagis being developed by Utrecht Center for Affordable Biotherapeutics? how is it addressing affordability and availability?

**16:59:12**
From Giustino Adesso : Aleksandr, Amazon Pharmacy will be the option for no universal insurance...they told

**17:01:28**
From Els Torreele : the big advantage of mAb technology is that one can generate an unlimited number of different antibodies against one particular target (eg the covid spike protein), and many could be candidate drugs. So this is a fantastic opportunity for parallel innovation, including in LMIC (taking advantage of all the technological/miniaturizing progress), with many producers/innovators making their own product instead of thinking along originator -biosimilar lines (copying the small chemical and generics thinking). much more transformative - but it requires IP freedom to operate. any thoughts?

**17:04:58**
From Julien Potet : I agree that dose matters a lot in the case of mAbs. For example the dose of Inmazeb, the anti-Ebola mAb cocktail by Regeneron is huge : 150mg/kg. High dose means high manufacturing costs !

**17:07:59**
From Aleksandr Belinskiy : Thank your for a comment for accessibility of mAb therapies.

**17:08:19**
From Annette Gaudino : market analysis is relatively cheap for producers but challenging for civil society

**17:08:24**
From Annette Gaudino : we should demand producers do this work rather than burden civil society

**17:08:25**
From Suerie Moon : Thank you, Dr. Sitlani, great talk. Thank you Marcela for the great moderation.

**17:08:38**
From Giustino Adesso : gracias marcela