SARS-CoV-2 Monoclonal Antibody Workshop: FDA Perspective

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Disclaimer

- The views expressed are those of the speaker and do not necessarily reflect official policy of the FDA.

Workshop Rationale

- We recognize the rapidity of changes in the SARS-CoV-2 variant landscape and its potential impact on the development of viable monoclonal antibody (mAb) products targeting the virus.
- We have convened this workshop to discuss whether there are novel, scientifically sound approaches that could help expedite mAb development thereby increasing the likelihood of making new mAb products that retain activity against circulating strains available to the public.

Workshop Rationale (2)

- For the purpose of this workshop, FDA is interested in hearing participants views on whether novel approaches to mAb development for COVID-19 could provide reliable and interpretable data to inform a preliminary assessment of benefit-risk for a product (e.g., whether the known and potential benefits of a product outweigh its known and potential risks).

Topics of Particular Interest

- Perspectives on the circumstances under which information can be leveraged from a prototype mAb product (that has demonstrated safety and efficacy in clinical trials) to support the development of a new monoclonal antibody product, and the information that should be collected in this situation.

Topics of Particular Interest (2)

- Perspectives on whether novel approaches to expedite the development and availability of monoclonal antibodies for COVID-19 should be limited to supporting indications for populations with an unmet medical need (e.g., prevention of COVID-19 in patients unlikely to adequately respond to COVID-19 vaccination), as these approaches may yield greater uncertainty with respect to anticipated efficacy.

Workshop Expectations

- FDA does not intend to provide a regulatory determination on the potential acceptability of a specific development pathway during this workshop.
- Consistent with our approach to other workshops, FDA will use the information provided today to help inform future discussions.

Thank You For Your Participation