Gating Criteria for SARS-CoV-2 mAbs Moving into Phase II Studies—Abbreviated			
	Minimum Criteria for Selection	**No-Go Criteria**	**Supporting Data**
Ascending Dose Study	• No toxicity or other major safety concerns seen within a practical dose range for assumed efficacy	• Toxicity seen within assumed efficacy dose range	• Details of ascending dose study and outcomes
Phase I Dose Finding Study ***(If planning to enter Phase II of ACTIV studies)***	• Completed a dose-finding study or other Phase I study • Plans defined and shared for a Phase I dose finding study that will allow the company to select no more than two doses to enter the ACTIV trials	• No Phase I clinical plans given	• Phase I Clinical Testing Plan *(Should be evaluated for soundness and should be assumed to have positive results for the purpose of evaluation for moving forward)* • Can be requested from company after initial information submission if not provided
Safety	• Clinically acceptable safety profile with no evidence of ADE • SAE not higher than is seen with SoC	• SAEs higher than seen with placebo in Phase I • Substantial off target binding • ADA in Phase I that limits exposure or impacts safety	• Safety data from a Phase I study
Phase I Plan	• Provided detailed Phase I Plan that covers the clinical safety capture, ascending dose study, and dose finding study	• No Phase I clinical plans given	• Phase I Plan
Meeting with FDA	• Have had conversation / consultation with the FDA	• No indication FDA submission	• FDA Conversations shared or at the very least dates of the FDA submissions and feedback received

"Nice-to-Have" Gating Criteria for SARS-CoV-2 mAbs		
	Minimum Criteria for Selection	**Supporting Data**
Specificity to Virus	• Ab that binds SARS-CoV-2 and does not bind human proteins • Optional: Cross reactivity data on close virus species.	• Live virus neutralization of SARS-CoV-2 and lack of binding to different human tissue (adult, child, and fetal) including cardiac tissue
Likely Duration of Therapeutic Dose in Acceptable Animal Models *(Most Important for ACTIV-2)*	• One week or greater for treatment • Predictable PK from a relevant species • PK data generated from a relevant species	• One week or less for treatment
Time to Resistance	• Virus does not escape antibody neutralization within 2 weeks	• In vitro, animal, or human data to support no emergence of viral resistance
Cross Resistance	• Antibody active against immune escape variants	• In vitro antiviral activity and affinity
Epitope *(Additional Information)*	• Antibody binds unique epitope from other antibodies already being studied in the platform trial • No antagonism with other antibodies in a cocktail	• In vitro experiment to determine if the test antibody has a synergistic, additive, antagonistic or neutral effect when assayed in combination with other antibodies
Fc Functionality	• ADCC/phagocytosis/Antibody trafficking; not sure what characteristics are the most favorable for Fc function trafficking in the body for treatment or prevention and may differ between the two	• Mutations to knockout Fc functions have been added; lgG subtype; in vitro assays to determine ADCC; animal model antibody distribution studies to determine antibody distribution/location in the body
Host Response to Antibody	• Ab that is not recognized by the recipient immune system, lack of immunogenicity	• In vitro ADA assay measurements
In Vivo Potency Against	• One week or greater for treatment • Predictable PK from a relevant species	• Relevant animal model • PK data generated from a relevant species