Monoclonal Antibodies as Therapeutics Against SARS-CoV-2

From Development to Regulatory Approval

Sept. 30 [8:30 pm EST]
Oct. 1 [9:30 am KST]

Event Program

KWiSE Forum Series

Agenda

8:30-9:00 pm EST
9:30-10:00 am KST

Neutralizing Effect of CT-P59 against SARS-CoV-2 Variants
Dr. Soo-Young Lee, Celltrion Inc.

9:00-9:30 pm EST
10:00-10:30 am KST

Monoclonal Antibodies Targeting SARS-CoV-2
Dr. Su-Young Choi, FDA

9:30-10:00 pm EST
10:30-11:00 am KST

Discussion/Q&A
Moderator: Dr. Youngmi Ji, NIDCR/NIH

Neutralizing Effect of CT-P59 Against SARS-CoV-2 Variants

Dr. Soo-Young Lee

Abstract: CT-P59 is a fully human mAb isolated from a SARS-CoV-2 convalescent patient. CT-P59 interferes with the SARS-CoV-2 RBD-ACE2 interaction, so that it can neutralize SARS-CoV.

SARS-CoV-2 variants such as D614G, and the UK variant can be significantly neutralized by CT-P59. Although CT-P59 showed a reduction in vitro neutralization activity, the reduced effect in in vitro neutralization of CT-P59 could not affect in vivo therapeutic potency against beta, gamma and delta variant in the respiratory tract, especially with clinical dose. Both in vitro and in vivo studies continue to evaluate the antiviral activity of CT-P59 against constantly emerging variants such as delta plus or Lamda.

Monoclonal Antibodies Targeting SARS-CoV-2

Dr. Su-Young Choi

Abstract: There are many monoclonal antibodies (mAbs) being developed for the treatment and prophylaxis of COVID-19 and several of them demonstrated clinically meaningful benefits in certain populations/indications. The majority of anti-viral monoclonal antibody products currently being developed target the spike protein, which the virus utilizes to enter host cells. Currently, three mAb products (bamlanivimab and etesevimab administered together, casirivimab and imdevimab administered together, and sotrovimab) have been authorized by FDA for emergency use for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms) with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progression to severe COVID-19, including hospitalization or death.

In addition, FDA also authorized the use of casirivimab and imdevimab administered together for post-exposure prophylaxis (prevention) for COVID-19 in adults and pediatric individuals (12 years of age and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19, including hospitalization or death.

This presentation will provide a brief introduction of the emergency use authorization, the overview of the three products currently authorized for emergency use, and ongoing discussion topics regarding the use of anti-SARS-CoV-2 mAbs for the treatment and prophylaxis of COVID-19.

Dr. Soo-Young Lee

Vice President, Celltrion Inc.

Dr. Soo-Young Lee is currently Vice President of Celltrion Inc. In addition, Dr. Lee also serves as head of the New Drug Research Division, head of Research Management Development, and head of New Drug and Vaccine Development at Celltrion.

Dr. Lee joined Celltrion Inc. in 2003, wherein he has been deeply involved in upstream process development, specifically in scaling lab to commercial production of various biosimilar monoclonal antibodies (mAbs) and new targets. He has extensive experience in a diverse range of biosimilar projects, including vaccine development.

Dr. Lee has also developed therapeutic mAbs for several infectious diseases including the flu, Hepatitis B, rabies, and MERS. In 2020, he spearheaded research of therapeutic mAbs against SARS-CoV-2 based on this prior research experience. He has more recently branched out into digital healthcare and microbiomes in 2021. Dr. Lee received his PhD from the Department of Bioengineering at Inha University, South Korea.

Dr. Su-Young Choi

Team leader, OCP, CDER, FDA

Dr. Su-Young Choi is currently a clinical pharmacology team leader for antiviral products, Office of Clinical Pharmacology, Office of Translational Sciences, Center for Drug Evaluation and Research, US Food and Drug Administration. She is primarily responsible for leading scientific and regulatory assessments on clinical pharmacology aspects of antiviral drug development.

Particularly, she has been extensively involved in the research and regulation of investigational products being developed for emerging viral infections counter-terrorism such as COVID-19, smallpox, or Ebola where clinical pharmacology often plays pivotal role for critical decisions with extremely limited information. She has presented at various conferences and has numerous publications addressing clinical pharmacology principles for drug development for antiviral products. Dr. Choi obtained her Pharm.D. and Ph.D. at the University of Illinois at Chicago.

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This event was hosted by the KWiSE NIH and DC Chapters And sponsored by the Korea Foundation.

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