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Rapid Development of Ronapreve, a Monoclonal Antibody Cocktail for Covid-19

Mohammed Shameem
Vice President, Preclinical Development,
Regeneron Pharmaceuticals, Inc　New York, USA

2021年12月17日(金)
10：00〜11 ：30
Zoomでのオンライン講演 * This lecture will be given in English.
https://md.kumamoto-u.ac.jp/course/view.php?id=84771

Zoom meeting ID と Password は、Moodle から確認出来ます
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講演概要

Ronapreve™ (REGEN-COV™) is a cocktail antibody product comprising of two monoclonal antibodies (casirivimab and imdevimab) discovered and developed by Regeneron for the treatment and prophylaxis of mild to moderate forms of covid-19 infection in non-hospitalized patients [1, 2]. Both antibodies within the cocktail recognize mutually exclusive and non-overlapping epitopes on the receptor binding domain of the spike protein present on the surface of SARS-COV-2 virus. The cocktail approach was developed by design to prevent rapid mutational escape of SARS-CoV-2 virus seen with individual antibodies [3]. Regeneron's core technologies and business practices uniquely positioned the company to rapidly respond to the pandemic. Regeneron has built and applied a suite of proprietary platform technologies (VelociSuite®) that offer high throughput and rapid cell line development capability amenable for robust drug discovery and development. The cell lines display reliable bioreactor performance by utilizing proprietary media and platform production processes. A platform high concentration formulation, manufacturing processes, analytical characterization approach to accelerate CMC development and technology transfers ultimately enabled manufacturing readiness to fulfill large clinical and commercial demands [4]. Correspondingly, the absence of comprehensive product specific stability data, multiple product transfers, global raw material shortages, and workforce challenges were manageable because of true platform approaches, high employee morale and robust business processes. Modeling product stability data from research studies under accelerated stress conditions were used to predict degradation under long-term storage conditions. The process performance qualification (PPQ) activities and commercial readiness was based on efficient process development, effective risk assessments, understanding of facility operation, and emphasis on continuous process verification. After the initial product development was complete, Regeneron partnered with Roche to increase global supply and manage the international markets and regulatory compliance.

＊There is no e-learning for this seminar.

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