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Preface

COVID-19: An unprecedented challenge and an opportunity for change



COVID-19 is among the most significant pandemics in recorded history, not only because of its public health impact but also due to its societal and economic effects. The unprecedented challenges caused by COVID-19 require the drug delivery community to acknowledge a new landscape in basic and clinical science and to establish new priorities. For example, a greater focus on developing novel therapeutics to counter infectious diseases is clearly warranted. While effective anti-SARS-CoV-2 therapies are urgently needed, new drugs to treat drug-resistance infections are also critical. Moreover, new pathogens are very likely to emerge, which will demand novel countermeasures. The COVID-19 pandemic has also underscored the need to rapidly develop and implement more efficient means of clinical translation and commercialization as exemplified by the remarkably rapid employment of mRNA vaccines. COVID-19 has further drawn attention to the need to validate therapeutic tools *via* the orchestrated expertise of basic researchers, clinicians, the pharmaceutical industry, and policy makers, in order to achieve effective outcomes. Considerations beyond scientific rationale alone are indispensable to address global challenges, which require a team-based strategy. Finally, efforts focused on developing novel therapeutics for challenging non-infectious diseases, such as cardiovascular disease, cancers, and degenerative neurological disorders, should not be dampened by the COVID-19 pandemic.

For more than two centuries, vaccines have greatly contributed to improving human welfare and extending lifespan, and their role in a modern society with substantially increased encounters among people is more impactful than ever. During the COVID-19 pandemic, vaccines have been desperately needed not only to protect people from the morbidity and mortality caused by SARS-CoV-2 but also to restore social and economic activity. As this theme issue of *Advanced Drug Delivery Reviews* goes to press, millions of people have already been vaccinated in a world-wide effect to combat COVID-19. The issue compiles excellent articles covering key aspects of COVID-19 prevention research and development, including theories and principles, design and formulation, and current technological and clinical updates, provided by experimental and computational biologists, chemists, bioengineers, pharmaceutical scientists, and clinicians. Kwon et al., briefly discuss COVID-19 pathology and provide an overview of SARS-CoV-2 virology and immunology leading to key considerations in developing effective COVID-19 vaccines. Forthall provides insights into the roles of cellular and humoral immunity in SARS-CoV-2 infection and prevention. Han et al. and McKay et al.

introduce *in silico* methods to predict SARS-CoV-2 epitopes used in developing effective COVID-19 vaccines and assessing immune responses and toxicity. Lai et al. discuss the use of anti-SARS-CoV-2 monoclonal antibodies to mitigate pulmonary morbidity in COVID-19, and Pollet et al. highlight recombinant protein vaccines with their clinical validation and employment in preventing COVID-19. Moon et al. and Slavcev et al. collectively discuss the COVID-19 vaccines that are based on nucleic acids encoding SARS-CoV-2 antigens, along with their promise and the remaining questions and challenges. Ainslie et al. and Gendelman et al. extensively cover COVID-19 vaccine formulations, particularly focusing on a broad range of nanocarriers, and Falo et al. present a novel microarray patch as an effective and safe approach to delivering COVID-19 vaccines. Finally, Wang et al. comprehensively summarize the preclinical and clinical status of COVID-19 vaccines and discuss what it takes to make them clinically successful.

The topic of COVID-19 vaccines is complex and broad, but it is certainly a promising area in which the drug delivery community will find pivotal roles and make significant contributions. The articles compiled in the COVID-19 vaccine theme issue represent merely a small fraction of our very rapidly accumulating and substantial knowledge on the topic, but we hope they will provide an entry way for attacking one of the biggest scientific and clinical challenges of our generation.

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