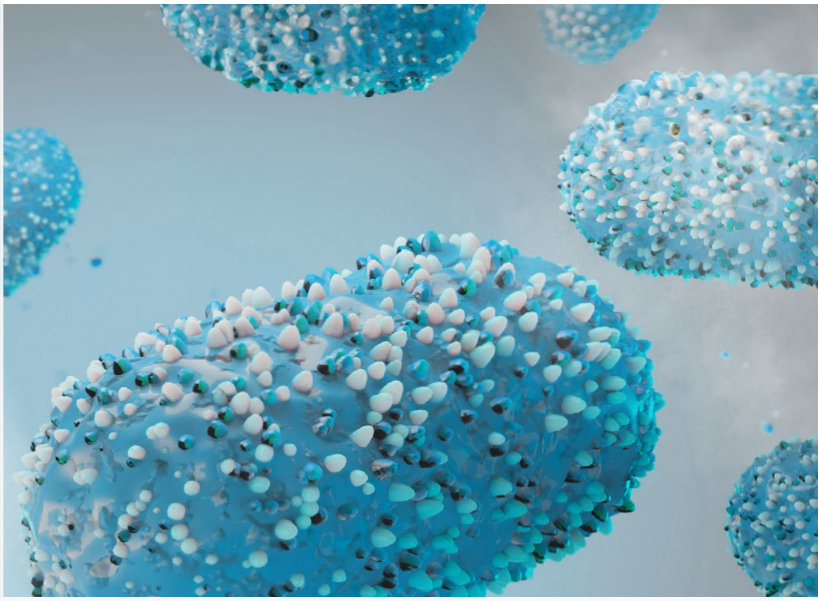
Southern Research
MOVING SCIENCE

Southern Research Successfully Tests BioNTech MPXV Vaccine in NHPs



BACKGROUND/OVERVIEW:

Monkeypox virus (MPXV), the causative agent of mpox disease, is a member of the genus orthopoxvirus, which includes variola virus (VARV)—the causative agent of smallpox. Mpox is a re-emerging viral disease that frequently manifests as a self-limiting infection with symptoms including fever, headache, fatigue, lymphadenopathy, and skin lesions. Although mpox in humans is considered less severe than disease associated with smallpox, fatality rates of up to 10% have been reported with outbreaks caused by the virulent central African clade I MPXV. Per the Center for Disease Control and Prevention (CDC), the National Notifiable Disease Surveillance System reported an outbreak of mpox disease in the year of 2022 that led to more than 93,497 cases worldwide spanning 118 countries—many (7) of which have not been previously considered to be mpox endemic. Although MPXV was known to be predominantly endemic in West and Central Africa, recent large-scale human-to-human transmission caused the World Health Organization to declare it a public health emergency of international concern. In addition, some of the strains of MPXV are select agents which have the potential to pose a severe threat to public health and safety as well as incite concern for bioterrorism. Currently, there is a very limited number and supply of vaccines that can protect humans against mpox disease—hence further therapeutic interventions are required. Many research laboratories (academic and non-academic) throughout the globe are working to develop vaccines and therapeutic agents against MPXV. Southern Research (SR) is supporting the mission readiness to counter emerging viral infections as part of our pandemic preparedness plan.

THE CHALLENGE:

German biotechnology company BioNTech SE approached Southern Research to test the efficacy of their prophylactic (mRNA vaccine) against highly pathogenic MPXV Zaire strain in non-human primates (NHPs). Because of the select agent nature of this pathogen, the sponsors required a Tier-1 Biological Safety Level-3 (BSL-3) facility with an approved select agent program to conduct experiments on NHPs. In addition, the project also required MPXV subject matter experts (SMEs) with high level expertise in virology, immunology, and animal models—especially NHPs.

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THE SOLUTION:

SR has teams that specialize in screening, testing, and AI-driven optimization of small molecules *in vitro* as well as testing the efficacy of candidates (both vaccines and therapeutics) in animal models (including both small and large animals) against multiple viruses, including select agents like MPXV. Many pharmaceutical companies do not have the infrastructure and skilled personnel to test vaccine efficacy against wild type monkeypox viruses. Also, there are currently very few CROs that have these unique infrastructures and capabilities that can support efficacy testing of vaccines and therapeutics in BSL-3 laboratories as well as toxicity studies in small and large animals against select agents. BioNTech's team evaluated SR's capabilities, including the dedicated team of Study Directors (SDs), Project Managers (PMs), highly skilled technicians, scientists performing *in vivo* procedures, veterinary staff, and anatomic pathologists. The study required evaluation of immunogenicity (both humoral and cell-mediated immunity) as well as efficacy of their candidate vaccine, and the client was seeking the highest testing quality. SR's scientific staff advised on study design and assays to evaluate the efficacy of the study. The project management team arranged meetings with all stakeholders involved. Through honest discussion and continued updates from the SDs and PMs, the study moved smoothly from study initiation to journal publication.

RESULTS:

These studies were performed under BSL-3 conditions evaluating the efficacy of a vaccine against highly pathogenic, lethal MPXV, Zaire strain challenge in NHPs. While the study was ongoing, the funding agencies provided feedback to BioNTech, and SR accommodated all recommended changes in discussion with the client with minimal turnaround time – highlighting SR's client-focused approach and ability to individualize studies based on clients' needs. The BioNTech team was briefed throughout the in-life part of the study with real-time data. The study was highly successful; findings from the Monkeypox vaccine studies were published in the leading journal, Cell. The open real-time communication of data allowed the client team to present the results to stakeholders and team members in their internal meetings. The continuous real-time updates from the dedicated SR team allowed the client to accelerate the planning of their next steps and new studies.