ACM Biolabs Announces Positive Topline Results from a Phase I Trial of SARS-CoV-2 Booster Vaccine ACM-001

2023-09-13
Provides clinical validation for ACM Biolab's Tunable Platform (ATP™), ACM Biolab's proprietary polymer-based delivery platform. ACM-001 was well tolerated at the recommended dose levels with no serious adverse events and encouraging early immunogenicity data. ACM is in partnering discussions to provide new drug delivery solutions that address the most significant challenges faced using lipid nanoparticle-based (LNP) delivery systems.

ACM Biolabs, a biotechnology company using its next-generation polymer-based delivery platform to develop new nano formulations for use in multiple therapeutic fields, today announced positive topline results from a Phase I trial of ACM-001, the Company's first clinical-stage development program.

ACM-001 is an adjuvanted booster vaccine for SARS-CoV-2, the virus responsible for COVID-19. It comprises a spike-protein component from the immune-evasive beta SARS-CoV-2 variant and an immunostimulant, CpG 7909, formulated using the Company's polymer-based delivery technology, ACM Biolabs' Tunable Platform (ATP™).

The trial, which was conducted in thirty-six subjects at six sites in Australia, showed that the vaccine candidate was safe and well-tolerated at the recommended dose level for both standard intramuscular injection as well as mucosal delivery. Promising early immunogenicity data indicate that the intramuscular vaccine initiated a broadly active antibody response targeting previous variants as well as currently circulating omicron strains.

Vaccine developers face many, widely known challenges using lipid nanoparticles (LNPs). These include ultra-low cold storage (-60°C to -90°C) throughout the supply chain and an inflexible processing time. ATP™ has the potential to overcome many of these challenges and ACM Biolabs also benefits from a clear and robust IP position underpinning its technology.

Further data to be presented at a key industry medical conference over the coming months and published in a peer-reviewed scientific journal.

Madhavan Nallani, Ph.D., Chief Executive Officer of ACM Biolabs, commented: "This is excellent news for ACM Biolabs as it substantially de-risks our core technology and enables us to progress all our formulations in discovery and development. We have received a lot of interest in our technology from partners who we believe will find the data valuable as we advance projects with them."

Pierre Vandepapelière, M.D., Ph.D., Chief Medical Officer of ACM Biolabs, added: "These positive Phase I results provide clinical validation for ATP™, our flexible proprietary delivery platform. It means we can move forward with confidence and explore the full potential of the technology in multiple therapeutic areas including vaccines. What excites us the most is the broader neutralization upon vaccine administration suggests the high quality of antibodies generated by targeting immune cells. On behalf of ACM, I would like to thank all study participants and staff members at the clinical sites."

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