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## BIOMANUFACTURING TECHNOLOGY ADVANCES ENABLE RAPID RESPONSE TO DISEASE OUTBREAKS

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## Key Words: Flexibility, Scalability, Intensification, Low-cost, Low-footprint

Outbreaks can have devastating socio-economic and mental health impacts if the spread of disease is not stopped. Particularly in the case of COVID-19 which has claimed thousands of lives across the globe, the importance of rapid response to disease outbreaks is paramount. In the past, response to pandemics was following very long licensing and development timeframes, whereas in the case of COVID-19 the response was immediate while approval and manufacturing timeframes were much shorter. The global COVID-19 pandemic has highlighted the important role that scalable and flexible manufacturing solutions play in enabling rapid response to new disease outbreaks. In this unprecedent situation the industry joined forces and accelerated the development of new vaccine candidates to rapidly respond to the pandemic. Following this the next hurdle was to ensure that scaling up the production capacity to respond to the global immunization demand was feasible. Indeed, manufacturing capacity often acts as a bottleneck in rapid development programs. Traditional manufacturing processes are highly complex, require extensive process development efforts, and tend to suffer from a lack of scalability to rapidly reach commercial scale capacity. Considering the short timelines, vaccines are developed and scale-up at risk, with companies deploying manufacturing facilities at very early stage. Therefore, it is important that manufacturers can rapidly adapt their existing equipment and facilities for alternative drug candidates. This requires manufacturers to have facilities and equipment that are truly flexible and can be adapted for different drug candidates and processes.

This is where platform technologies can play a major role. Advances in integrated and automated manufacturing technologies result in cost-effective, scalable, and highly productive processes. Those technologies are considered as flexible by design as they can accommodate various expression systems, vaccine applications and capacity requirements. This presentation will focus on the breakthrough structured fixed-bed bioreactors and an integrated and automated manufacturing platform that can enable cost-effective and flexible multiproduct facilities with capacities of up to billions of vaccines per year in a reduced footprint and reduced capex.