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OVERCOMING PROCESS INTENSIFICATION CHALLENGES TO DELIVER A MANUFACTURABLE AND COMPETITIVE INTEGRATED CONTINUOUS BIOMANUFACTURING PLATFORM

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Groups in both industry and academia have achieved high densities and productivities in perfusion cell culture processes. At Sanofi, we have demonstrated perfusion densities greater than 100 million cells/mL (with associated high productivities) at a cell-specific perfusion rate of only 20 pL/cell/day. This process intensification reduces the footprint of upstream unit operations as well as capital and operating expenses of manufacturing facilities. The continuous nature of perfusion cell culture also creates opportunities for integration of continuous downstream operations, leading to further process intensifications and volume reductions.

In this presentation, we will discuss our work on several upstream challenges that must be overcome to create a manufacturable, continuous bioprocessing platform. These will include (1) mitigation strategies for the large shear forces accompanying the high sparge rates necessary to sustain a high-density culture, (2) efforts to minimize the economic and logistical burden of media cost and consumption in perfusion cell culture, (3) the challenge of maintaining consistent product quality over long durations and (4) scale-up of these intensified processes to 50-L and 500-L manufacturing-scale systems.

We can address each of these areas to create an efficient, competitive cell culture platform that generates high cell viabilities and excellent product quality at manufacturing scales. We will demonstrate real-world examples of both enzyme and antibody-producing processes, showing that such a platform can reliably deliver good results across diverse products.