SCALABLE, SERUM-FREE CELL CULTURE PLATFORM FOR IMPROVED PRODUCTION OF DIVERSE LIVE VIRUS AND VIRAL VECTOR VACCINE CANDIDATES

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There is a continuing need for the development of flexible and robust cell culture platforms that can enable rapid, lower-cost, and highly scalable live virus vaccine development and production for outbreak or pandemic responses and for high dose-demand indications (large patient populations and/or high individual dose formulations). Live virus vaccines have been successfully developed for a wide variety of important viral diseases to date, but there can still be significant unmet medical need due to relatively high cost of goods (COGs) or due to developability challenges for new virus/vector constructs and the associated bioprocesses. To address these concerns, we have been evaluating a broadly applicable cell culture platform that requires only minimal process re-design to rapidly produce new viruses or replicating vectors at high titer and with promising line-of-sight to clinical supply and commercial scale manufacturing. Using this platform, we have demonstrated significant improvements in the production of a broad panel of viruses and replicative vectors including 7 examples across 3 different virus families (*Figure 1*), covering potential applications for 6 diverse infectious disease indications. For at least some viruses, the platform has also enabled a significant reduction in key impurities such as host cell DNA, including at least one case where use of the platform may entirely shift the developability profile of the product vector from unfavorable/challenging to feasible. The platform is also expected to add additional manufacturing flexibility and high end scalability relative to many legacy manufacturing technologies, and for some candidates and bioprocesses, also unlocks entirely new avenues for data-rich experimentation and characterization/control of the production process in situ and in real-time.

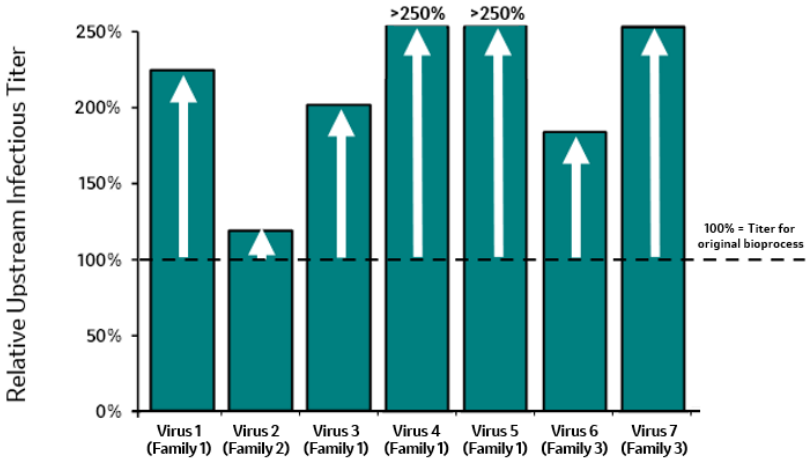

Figure 1 – Improvement in bioreactor infectious virus / replicative vector titers using adapted cell line and bioprocess platform (head-to-head comparison relative to original cell line and process)