DETERMINISTIC CELL PROCESSING RECOVERS >2-FOLD MORE CELLS, AND UP TO 5-FOLD MORE NAÏVE T CELLS, AS COMPARED TO CENTRIFUGALLY PREPARED CELLS.

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Key Words: Automation; Autologous; Cell Isolation; CAR-T; Standardization

There are still significant manufacturing challenges impeding the rapid adoption of advanced therapies. The first day of leukapheresis product processing typically requires ~5 steps (~4-6 hours) and incurs significant cell loss prior to cell selection and/or activation steps. Here, we present data from our Curate® cell processing system, a single step process that yields >2 fold more cells with comparable or better quality in under an hour.

Use of deterministic cell separation (DCS) to simultaneously size, separate and wash leucocytes delivering the highest recoveries, without loss of T-cell subtypes, unlike density-based approaches. We present the results of DCS processing using 23 normal donor leukopacks using a prototype platform (Figure 1). All DCS samples were processed in ~40 minutes, with an additional ~10 minutes of hands-on time to make fluid connections.

On average, inclusive of aggregate removal by prefiltering, DCS yielded ~90% WBC recovery, 94% RBC removal, and 98% PLT (platelet) removal from undiluted Leukopack samples in comparison to ~45% WBC recovery from split density gradient prepared samples. Further, DCS resulted in a RBC/WBC ratio of 0.1 vs. 1.4 for Ficoll. Similarly, PLT/WBC ratios were 0.89 vs. 7.17 for DCS and Ficoll, respectively. In addition, Curate prepared cells recovered ~2-fold more CD3+ T cells and importantly for T-cell therapy generation, more naïve CD4+ cells as compared to the split samples prepared by density centrifugation.

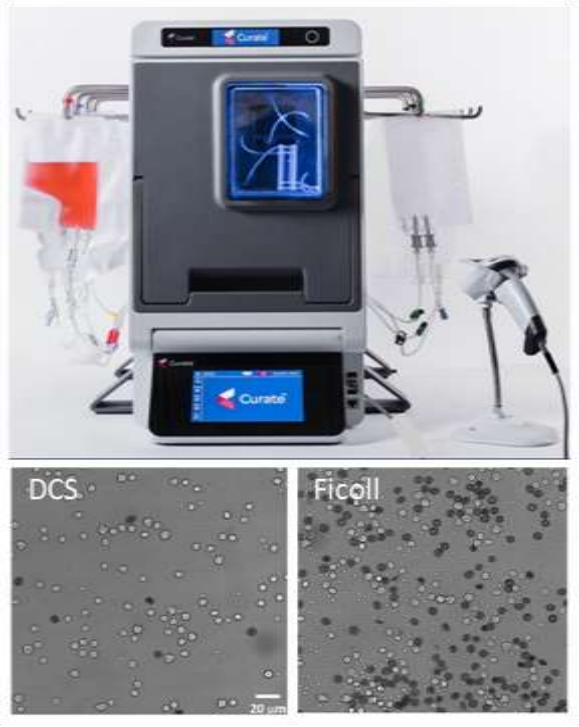

Figure 1 – Curate System, Example Leukopack split and processed by DCS vs. Ficoll (Sepax)

DCS processing also delivers >3 log wash-out efficiencies without pelleting the cells – further simplifying workflows. Finally, the system is also capable of concentrating Leukocytes to $200x10^6$/mL guideline limits as part of the same process.

Capable of processing samples at 400mL/hour, the Curate® system reduces the time to expansion ready cells by ~6-fold vs. centrifugal methods (Bowles, et al. Cytotherapy 2018;20(5):S109.)

In summary, the Curate cell processing system should enable a significant breakthrough in the CAR-T cell manufacturing process by recovering more, cleaner and healthier T cells, while also simplifying processing workflows by reducing the number of steps as well as hands-on time.