Dendreon

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Manufacturing Facilities Footprint & Capacity:

Dendreon was the first company to receive FDA approval and bring the cell therapy from the laboratory to the solid tumor market. During that process Dendreon built the first cellular manufacturing facilities in the world. Its first commercial manufacturing facility isin Morris Plain, NJ and is currently utilized to produce Carvykti®, a BCMA-directed CAR-T product. - Dendreon now operates two commercial-scale cGMP facilities, one in Seal Beach, CA and the other in Union City, GA, each measuring 170,000 ft² (~15,800 m²). Together, they have produced and delivered more than 120,000 doses of cell therapy products to over 40,000 patients since approval. Each facility has six cleanroom suites with a unit size of 1,200 ft² (~111 m²). Each suite contains 6 workstations with dedicated incubation areas that are designed to optimize workflow and enhance productivity. The suites are operated in a closed, segregated, and modular manner, ensuring a controlled manufacturing environment. Each suite is equipped with its own dedicated air, gas, and water supplies. Dendreon's facilities have been recognized as an industry leader and have hosted more than five on-site manufacturing-related trainings organized by the US FDA. - Dendreon|Excellerate Center (DEC) is expected to be Dendreon's technology-driven service platform. It embodies over 14 years of experience in commercial manufacturing, clinical and regulatory excellence, and patient operation systems. It also integrates a consortium of innovative technology platforms enabling Dendreon to deliver high quality products and services that meet the evolving needs of the industry. It leverages four suites at the Seal Beach facility to provide production services from IND filing to various clinical and commercial productions. The Seal Beach site also has 20,000 ft² (~1,858 m²) of space reserved for further expansion, ensuring Dendreon can scale operations as demand grows and new opportunities arise.

Modalities / Tech Platforms Supported:

Dendritic cells, iPSC-NK, Macrophage, neurons, progenitor cells, TCR-T, CAR-T, T-regular cells, TILs

Process & Analytical Development Capabilities:

DEC has dedicated teams for cell therapy, Analytical Process, and Quality Development. These teams have an average tenure of 13 years and over 20 years of proprietary expertise in CMC development. The Process Development team specializes in every

phase of development, with a focus on optimization, robust characterization, and scalability. Our expertise includes scaling up and transitioning from open to closed processes, utilizing cell processing systems such as CliniMACS Plus, Prodigy, LOVO, Grex, Xuri, and bioreactors. We have extensive experience in both autologous and allogenic processes, ensuring efficient and reproducible workflows within a cGMP manufacturing environment. The team can effectively refine manufacturing protocols, reducing variability and enhancing consistency which is essential for successful scale-up to clinical and commercial production. Our Analytical Development team supports method development and method qualification, as well as method comparability and transfer activities. The team takes a systematic approach to development and optimization to produce methods that are sensitive, specific, and robust. The team works in lockstep with the QC Department to ensure all methods developed are suitable and accessible in the QC-environment.

GMP Manufacturing Capabilities:

DEC provides end-to-end manufacturing capabilities throughout the entire product lifecycle. Current cGMP suites have been designed with multi-product capability and flexibility to support both development and commercial production needs. These suites (4 modules, ~1,200 ft² (~111 m²) each, with 6 workstations, each ~90 ft² (~8 m²)) can be used for both autologous and allogeneic cell therapies of different cell types. Dendreon has equipment to perform a wide array of CGT processes. From standard equipment for open aseptic manufacturing and cell culture (biological safety cabinets, centrifuges, incubators) to closed cell processing via Prodigy, Lovo, Xuri, G-Rex, etc. Dendreon glass stir tank reactors up to 15 liter in the development labs and has expertise with single use reactors such as Xuri, PBS and G-Rex, etc.

Analytical Capabilities:

Cell therapy potency assays are a complex and challenging step in the development process. However, Dendreon has already accumulated extensive knowledge and experience in pioneering cell therapies through the commercialization journey of ProvengeTM (which has only an 18-hour shelf life). Our market-driven mindset and insights from clinical, regulatory and payers allow us to provide more hands-on guidance to projects from industry perspective during development. We are committed to supporting the development of cell-based products that truly meet market needs. Dendreon's Quality Control (QC) department provides a wide array of analytical and Microbiological services to support tech transfer, method qualification, in-process final product release testing and comprehensive environmental monitoring (EM) to support aseptic cell therapy manufacturing. Additionally, concurrent stability program management and testing is supported in-house. Dendreon has a range of analytical

equipment to support both compendial and product-specific testing. The QC laboratory offers analytical capabilities that include but not limited to a wide range of flow cytometry-based methods, ddPCR, cell culture, cell count/viability, sterility, endotoxin and various cell-based assays. In addition to in-house services, Dendreon also offers oversight and support for extended characterization, utilizing our qualified outsourced partners.

Track Record:

K562 is the most widely used cell-based APC. It has been used as a feeder cell in T-cell or iPSC-derived cell lines to enhance targeted cell proliferation. Over the past four years, DEC team has accumulated large amount of experience related to this cell line, including but not limited to technology transfer, process development and assay establishment. We have completed a master cell bank and the team has been actively in supporting IND submissions, pilot, engineering, and qualification operations of clinical studies. We also conducted six successful clinical runs in our GMP manufacturing facility. - iPSCs provide a stable platform for genetic modification. However, scaling up and making NK cells from iPSCs can be more challenging. To date, our team has gained in-depth experience with iPSC-based platforms in process and analytical development, especially, the valuable hands-on experience in developing production runs from pilot to cGMP levels to support IND and clinical studies. The practice spread across both G-rex and bioreactor systems. - At the same time, the "Experts Alliance" also enables us to potentially integrate next-generation iPSC engineering and programming platforms, enabling feeder-free and efficient differentiation and expansion of target cell clones. - DEC's advisory arm also provides guidance and support during the upstream cell biology developments. We collaborate with a range of cutting-edge technologies to help optimize the cell clone for TCR-T and CAR-T cells in IND-enabling to early clinical stage programs. Such Early-entry partnerships can potentially increase the chance of success, expedite the development efficiency to achieve the desired product profile. - Provenge is a commercial stage autologous dendritic cell therapy. Dendreon has produced and delivered more than 120,000 doses of cell therapy products to over 40,000 patients. So far, our average manufacturing and delivery success rate has reached 99.8% in the past 3 years.

Value Proposition:

DEC is not a service provider in the traditional sense, but an end-to-end effort combining potentially diversified biological R&D technologies with vertically integrated commercial capabilities to create an ecosystem with a unique value chain, providing real solutions to partners. The Expert AllianceTM, a part of DEC, is a collaborative platform that aims to integrate top innovations such as target selection, genetic design & validation, viral and non-viral vector development, and automation engineering, providing broad knowledge & expertise in cell programming, biological optimization, and

industrialization. Under the guidance of our experts, partners will be able to advance potential products in a targeted manner based on expected product profile, integrating the best resources for an optimal match between development and value. In an increasingly tight financial market for cell and gene therapies, achieving cost efficiencies is critical. DEC has a flexible pricing model that enables partners to accelerate development and capital utilization while reducing risk of failure and maximizing ROI for investors. Finally, our well-established sales force averages 10+ years in immuno-oncology and 25+ years in cell therapy reimbursement/government pricing and patient advocacy. Our RAM, CAM and MSL footprint covers all US territories with strong connections to KOL and NCCN leaders in the field. By leveraging this experience, DEC can provide market-oriented guidance in early strategic planning, as well as partnership in commercialization. Our mission is to provide real solutions and guidance to overcome bottlenecks in the community and bring more cell therapies to the market.