

June 8, 2022



Societal CDMO Announces Key New Customer Project Within Automated Fill/Finish and Lyophilization Unit at San Diego Facility

Japanese Biopharmaceutical Company Engages Societal for Formulation, Fill/Finish and Lyophilization Activities to Support Ongoing Clinical Development of Novel Cancer Therapeutic

SAN DIEGO and GAINESVILLE, Ga., June 08, 2022 (GLOBE NEWSWIRE) -- Societal CDMO, Inc. ("Societal CDMO"; NASD: [SCTL](#)), a contract development and manufacturing organization (CDMO) dedicated to solving complex formulation and manufacturing challenges primarily in small molecule therapeutic development, today announced a key new customer project utilizing its automated fill/finish line and lyophilization unit at the company's San Diego facility. The recently initiated project is focused on formulation development and sterile GMP manufacturing of a lyophilized novel cancer therapeutic for intravenous infusion. Societal has been contracted by an emerging Japan-based biopharmaceutical company to conduct this work in support of the company's ongoing clinical development of the compound as a potential treatment for solid tumors.

Societal's aseptic fill/finish suite features a sterile, automated vial filling system with the capability to fill up to 2,000 presterilized vials per hour at a range of volumes. The company's lyophilization offering incorporates a novel, patented approach to uniformity and instantaneously induces nucleation via pressurization and depressurization. This equipment provides the capacity for lyophilization of approximately 9,000 10 mL vials during each 3-5 day freeze-drying cycle.

"Our decision to add fill/finish and lyophilization capabilities to our suite of CDMO services was driven by the opportunity to unlock an additional revenue source for the company and further our goal of providing end-to-end CDMO services for our customers. With ongoing customer activities moving through our fill/finish and lyophilization unit, we are now directly realizing those important benefits that triggered this strategic service expansion," said David Enloe, chief executive officer of Societal CDMO. "It is important to note that we are undertaking this project on behalf of a Japan-based biopharma, which we believe is yet another example of a growing interest among ex-U.S. drug developers to conduct critical CDMO activities within the U.S. As such, we expect that having a bi-coastal base of operations in the U.S. will continue to serve as a competitive advantage for Societal."

About Societal CDMO

Societal CDMO (NASDAQ: [SCTL](#)) is a bi-coastal contract development and manufacturing

organization (CDMO) with capabilities spanning pre-Investigational New Drug (IND) development to commercial manufacturing and packaging for a wide range of therapeutic dosage forms with a primary focus in the area of small molecules. With an expertise in solving complex manufacturing problems, Societal CDMO is a leading CDMO providing therapeutic development, end-to-end regulatory support, clinical and commercial manufacturing, aseptic fill/finish, lyophilization, packaging and logistics services to the global pharmaceutical market.

In addition to our experience in handling DEA controlled substances and developing and manufacturing modified-release dosage forms, Societal CDMO has the expertise to deliver on our clients' pharmaceutical development and manufacturing projects, regardless of complexity level. We do all of this in our best-in-class facilities, which total 145,000 square feet, in Gainesville, Georgia and San Diego, California.

Societal CDMO: Bringing Science to Society. For more information about Societal CDMO's customer solutions, visit societalcdmo.com.

Forward-Looking Statements

This press release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The words "anticipate", "believe", "could", "estimate", "upcoming", "expect," "intend", "may", "plan", "predict", "project", "will" and similar terms and phrases may be used to identify forward-looking statements in this press release. Our operations involve risks and uncertainties, many of which are outside our control, and any one of which, or a combination of which, could materially affect our results of operations and whether the forward-looking statements ultimately prove to be correct. Factors that could cause the company's actual outcomes to differ materially from those expressed in or underlying these forward-looking statements include risks and uncertainties associated with the ongoing economic and social consequences of the COVID-19 pandemic, inflation and global instability, including political instability, including any adverse impact on the customer ordering patterns or inventory rebalancing or disruption in raw materials or supply chain; demand for the company's services, which depends in part on customers' research and development and the clinical plans and market success of their products; customers' changing inventory requirements and manufacturing plans; customers and prospective customers decisions to move forward with the company's manufacturing services; the average profitability, or mix, of the products the company manufactures; the company's ability to enhance existing or introduce new services in a timely manner; fluctuations in the costs, availability, and suitability of the components of the products the company manufactures, including active pharmaceutical ingredients, excipients, purchased components and raw materials, or the company's customers facing increasing or new competition. These forward-looking statements should be considered together with the risks and uncertainties that may affect our business and future results presented herein along with those risks and uncertainties discussed in our filings with the Securities and Exchange Commission at www.sec.gov. These forward-looking statements are based on information currently available to us, and we assume no obligation to update any forward-looking statements except as required by applicable law.

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Source: Societal CDMO, Inc.