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# Societal CDMO Selected To Provide Tech Transfer And Manufacturing Services To Support Clinical Development Of An Oral Solid Dose Product In Europe

## Agreement Highlights Momentum in Onshoring of Contract Manufacturing Projects to U.S. from Sites Around the World

SAN DIEGO and GAINESVILLE, Ga., July 20, 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 that it has been selected to provide CDMO services to support the ongoing clinical development of a novel drug candidate in Europe. The compound is an oral solid dose anti-viral therapy product approved for the prevention and treatment of human immunodeficiency virus (HIV) in select countries in Europe and Societal's work is focused on supporting the expansion of the product's indications.

Under terms of the new agreement, Societal CDMO will execute appropriate technology transfer activities, followed by cGMP manufacture of clinical trial material to support the initiation and execution of Phase 2 studies of the drug candidate. This work will include production, packaging and labeling of both the active compound and matching placebo for the study.

"This is a key new agreement for Societal CDMO as it is a clear demonstration of the company's ability to capitalize on the increasing interest of drug developers in the onshoring and reshoring of contract manufacturing activities to the U.S. from other regions around the globe. We are proud to be trusted by our partner to execute the tech transfer, manufacturing and packaging services that will be necessary for the initiation of its planned Phase 2 study in Europe," said David Enloe, chief executive officer of Societal CDMO. "We continue to be pleased with our progress in leveraging our end-to-end CDMO service offerings to grow our business and expand our client base."

### 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](http://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, 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](http://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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