FOR IMMEDIATE RELEASE

Evidera and CSS Collaborate to Develop Joint Real-world and Patient-centered Research Capabilities in Japan

WILMINGTON, N.C. (August 21, 2019) – Evidera, a business of Pharmaceutical Product Development, LLC (PPD), has entered into an exclusive collaboration agreement with Clinical Study Support, Inc. (CSS), a subsidiary of Shin Nippon Biomedical Laboratories Ltd. (SNBL), extending both organizations' capabilities to deliver more robust consulting and analytical capabilities and creating a more complete geographic customer solution for clinical, real-world and patient-centered research.

Evidera is a leading provider of evidence-based solutions to demonstrate the real-world effectiveness, safety and value of health care products, and CSS is a clinical research organization based in Nagoya, Japan, that provides post-market real-world research services, including database studies, questionnaire development and pharmacoeconomics.

Together, Evidera and CSS will leverage their combined expertise, including Japan-based multilingual experts, to provide research services to global or Japan-based clients undertaking studies that include a Japanese component. Such research services include the design and implementation of real-world studies, epidemiological studies, qualitative and quantitative patient-centered research, clinical outcome assessment development and validation, patient recruitment for prospective studies, health economics modeling, and market access and health technology assessment consulting services. The companies also are committed to the joint development of direct-to-electronic medical record (EMR) and EMR-enabled observational studies in Japan.

"Our collaboration with Evidera allows us to support larger global projects that may benefit from our knowledge and expertise in Japanese-specific settings," said Tatsuya Isomura, M.S., Ph.D., founder and chief executive officer of CSS. "Our clients will gain access to global project management and operational resources that will enable larger and more complex research programs, as well as more robust evidence of product value and safety."

Karen Kaucic, M.D., president of Evidera, said, "This collaboration will allow us to provide broader solutions for our clients as they develop evidence to support regulatory submissions and market access in Japan. We are excited to work with our CSS colleagues to tap into real-world insights from the growing Japanese market, which is already the third-largest drug market in the world, to inform and improve drug development and drug coverage decision-making at a global level."

Evidera and CSS plan to establish a joint office in Japan to facilitate collaboration and efficient project delivery. The two organizations also intend to continue to explore opportunities to expand their joint capabilities in data analytics and management, epidemiology, biostatistics, medical writing and qualitative research.

Representatives of Evidera and CSS will attend the International Society for Pharmacoepidemiology (ISPE) conference in Philadelphia Aug. 24-28 and will be available at

booth #202 to provide additional information on the collaboration and their expanded capabilities in real-world and patient-centered research.

About Evidera
Evidera, a PPD business, is a leading provider of evidence-based solutions to demonstrate the real-world effectiveness, safety and value of health care products. We help biopharmaceutical, biotechnology and medical device companies generate the evidence needed to optimize the market access and commercial potential of their products. For more information, visit www.evidera.com.

About PPD
PPD is a leading global contract research organization providing comprehensive, integrated drug development, laboratory and lifecycle management services. Our clients and partners include pharmaceutical, biotechnology, medical device, academic and government organizations. With offices in 48 countries and more than 21,000 professionals worldwide, PPD applies innovative technologies, therapeutic expertise and a firm commitment to quality to help clients and partners bend the cost and time curve of drug development and optimize value in delivering life-changing therapies to improve health. For more information, visit www.ppdi.com

About CSS
Since 2004, Clinical Study Support (CSS), Inc. has supported clinical research in real-world settings and patient-reported outcomes questionnaire development. We have strong expertise in supporting professional experts from local to global levels through English communication. For more information, visit www.jp-css.com.

About SNBL
SNBL is a Japanese global business corporation that works mainly in pre-clinical research, pharmacokinetics and analysis, and translational research. SNBL is a business partner of PPD regarding clinical research business in Japan and has jointly managed the joint venture PPD-SNBL, a clinical research service provider in Japan, since 2015. Since being founded as Japan's first contract research organization in 1957, SNBL has supported clients by committing to freeing patients from suffering by supporting drug development and improving medical technology. SNBL is a listed company on the first section of the Tokyo Stock Exchange. For more information, visit www.snbljapan.com.

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