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TUCSON, Ariz., and AUSTIN, Texas – November 2, 2016 – The Clinical Data Interchange Standards Consortium (CDISC), Critical Path Institute (C-Path), and TransCelerate BioPharma, Inc. (TransCelerate), announce the open availability of a CDISC Therapeutic Area (TA) Standard for Kidney Transplantation. The Kidney Transplant v1.0 standard is focused on studies of therapeutic interventions to prevent rejection of transplanted kidneys in adult recipients.

Chronic kidney disease (CKD) includes conditions that damage kidneys and decrease their ability to maintain health. Twenty-six million American adults have CKD and millions of others are at increased risk. When kidneys fail, there are three treatment choices: hemodialysis, peritoneal dialysis, and kidney transplantation. According to the National Kidney Foundation, over 2 million people worldwide currently receive treatment with dialysis or a kidney transplant to stay alive.

This Therapeutic Area User Guide – Kidney Transplant (TAUG-KT) focuses on the key assessments and donor/recipient characteristics required to match donors with recipients, and to monitor post-transplant outcomes.

The TAUG- KT is the result of a collaborative effort among C-Path, CDISC, the US Food and Drug Administration (FDA), TransCelerate, the American Society of Nephrology (ASN), and the American Society of Transplantation (AST), as part of the Kidney Health Initiative (KHI). The mission of KHI, in partnership with the FDA and nephrology community, is "to advance scientific understanding of kidney health and patient safety implications of new and existing medical products and therapies, and to foster development of therapies for diseases that affect the kidney."

"It has been a pleasure working on this project with all the collaborators and assistance of C-Path and CDISC. This is the most comprehensive and up-to-date document in kidney transplantation. The diagrams and concept maps help distill down very complex issues in transplantation, such as the Banff criteria for

kidney allograft rejection, into something that is understandable, teachable, and useful for all involved in kidney transplantation," states Daniel Brennan, MD, FACP, Director, Transplant Nephrology at Washington University School of Medicine in St. Louis.

Kidney Transplant v1.0 represents the first CDISC standard to address a therapeutic area in the field of solid organ transplant. Kidney Transplant v1.0 is available via the CDISC website, through User Guides, and will eventually be available through the Shared Health and Research Electronic Library (SHARE), CDISC's metadata repository that facilitates electronic access to the standards and enables the reuse of common concepts across future TA standards.

With funding from FDA, the Kidney Transplant v1.0 standard was developed through the Coalition for Accelerating Standards and Therapies (CFAST).

CFAST, a joint initiative of CDISC and C-Path, was formed to accelerate clinical research and medical product development by creating and maintaining data standards, tools, and methods for conducting research in therapeutic areas important to public health, with invaluable support and advice from such organizations as the National Cancer Institute, Innovative Medicines Initiative, TransCelerate, and regulatory agencies including the FDA, Japan's Pharmaceutical and Medical Devices Agency, and the European Medicines Agency.

CDISC standards have been adopted and used in more than 90 countries, and will soon be required by regulatory authorities in the US and Japan. To date, TA Standards have been developed for over 25 different disease areas, with most being developed under the CFAST program. Use of these standards from the start of clinical research programs has proven capable of saving both time and resources. Researchers working in the area of kidney transplant are encouraged to implement these standards into their processes.

About the organizations:

C-Path (Critical Path Institute) is an independent, nonprofit organization established in 2005 with public and private philanthropic support from the Arizona community, Science Foundation Arizona, and the US Food and Drug Administration (FDA). C-Path's mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world. An international leader in forming collaborations, C-Path has established 12 global, public-private partnerships that currently include over 1,450 scientists from government and regulatory agencies, academia, patient advocacy organizations, and dozens of major pharmaceutical companies. C-Path is headquartered in Tucson, Arizona. For more information, visit www.c-path.org.

CDISC is a 501(c)(3) global nonprofit charitable organization that develops clinical research data standards to streamline research and enables connections to healthcare. The CDISC suite of standards is freely available on our website and makes it possible for data to speak the same language, empowering simple data

collection and private sharing to make the most of the valuable information offered by patients participating in research studies around the globe. Implementing CDISC standards from the start of studies enables *Smarter Research to Unlock Cures (**www.unlockcures.org**)*, saving 70-90% time in the start-up of clinical research studies and ~60% overall in terms of time and resources to conduct research. CDISC is the patient's advocate, creating therapeutic area data standards for over 25 different disease areas that advance medical product development and various types of clinical research.

CDISC membership is open to any organization interested in supporting the development and adoption of CDISC standards. To learn more about CDISC membership, please visit http://www.cdisc.org/membership.

TransCelerate BioPharma Inc. is a nonprofit organization dedicated to improving the health of people around the world by accelerating and simplifying the research and development (R&D) of innovative new therapies. The organizations' mission is to collaborate across the global biopharmaceutical R&D community to identify, prioritize, design and facilitate implementation of solutions designed to drive the efficient, effective and high quality delivery of new medicines. TransCelerate evolved from conversations at various forums for executive R&D leadership to discuss current issues facing the industry, and examine solutions for addressing agreed-upon common challenges. The founding member companies are AbbVie, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly and Company, GlaxoSmithKline, Johnson & Johnson, Pfizer, the Roche Group, and Sanofi. Additional members that have joined since the inception of TransCelerate include Allergan, Inc., Amgen, Astellas Pharma Inc., EMD Serono, Inc. (a subsidiary of Merck KGaA, Darmstadt, Germany), Merck & Co., Inc., Novo Nordisk, Shionogi & Co., Ltd. and UCB.

Membership in TransCelerate is open to pharmaceutical and biotechnology companies with Research & Development operations. Executive offices are located in Conshohocken, PA. For more information, please visit http://www.transceleratebiopharmainc.com.

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