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Austin, TX – 19 November 2014 – The Clinical Data Interchange Standards Consortium (CDISC) and TransCelerate BioPharma, Inc. are pleased to announce the availability of therapeutic area (TA) standards for diabetes and cardiovascular (CV) disease areas through the Coalition for Accelerating Standards and Therapies (CFAST), a joint initiative of CDISC and the Critical Path Institute (C-Path).

Both the diabetes and CV standards were established in an effort to make clinical research more efficient while continuing to support the scientific nature of the research. The new diabetes standardincludes the most common data needed for diabetes research, examples of clinical situations from which the data arise and the reasons these data are relevant for people with diabetes. The overall goal of this standard is to provide the metadata needed to assist in establishing a common understanding of the meaning of the data, to ensure proper use and interpretation of the data by health care users, those involved in clinical trials, and the regulators who approve the medications.

“I see the need for these guidelines on a daily basis,” said Rachael Zirkle, diabetes therapeutic area standards project manager at CFAST and an Eli Lilly and Company data scientist representative on the TransCelerate Data Standards Workstream. “Establishing universal guidelines can help to both facilitate higher quality diabetes research, and to help effectively and safely treat people with diabetes.”

The cardiovascular disease area standard focuses on Acute Coronary Syndrome (ACS) and CV endpoints, which is the occurrence of anything of interest that can be used to qualify or quantify the effectiveness and/or safety of a diagnostic or therapeutic approach for patients with ACS or CV disease. The cardiovascular standard was developed in tandem with the standard for diabetes, as the assessment of CV safety has become an important focus in the development of new anti-diabetic therapies for Type 2 diabetes, and has similar endpoint concepts and terminology.

“The CV standard is the result of extensive collaboration among representatives of FDA, the American College of Cardiology, clinical researchers and informaticians at Duke University, and CDISC,” said Dr. James Tcheng, professor of medicine at Duke Translational Medicine Institute, who assisted on the CV project. “We developed a standardized vocabulary for documenting and reporting critical cardiovascular adverse events, along with specifications for the exchange of that information between computer systems. The key use will be in reporting findings to the FDA, whether in the context of clinical trials, pharmacovigilance, or device surveillance. Ultimately, we anticipate widespread adoption of this vocabulary throughout healthcare (including routine clinical care) as a catalyst for accelerating improvements in patient management and treatment.”

“The CFAST project continues to develop an ever-increasing number of therapeutic area standards,” said Rhonda Facile, CDISC senior director of Standards Development. “This body of work, coupled with work done on CDISC foundational teams and prior therapeutic area standards, is making it possible to reuse

common standards domains and information developed across therapeutic areas. This is an anticipated and exciting development that will, over time, speed up therapeutic area standards development."

CDISC standards are freely accessible via the CDISC website. To learn more about the CDISC Diabetes and Cardiovascular Therapeutic Area Standards, please visit us at www.cdisc.org.

ABOUT CDISC

CDISC is a 501(c)(3) global non-profit charitable organization, with over 350 supporting member organizations from across the clinical research and healthcare arenas. Through the efforts of volunteers around the globe, CDISC catalyzes productive collaboration to develop industry-wide data standards enabling the harmonization of clinical data and streamlining research processes from protocol through analysis and reporting, including the use of electronic health records to facilitate the collection of high quality research data. The CDISC standards and innovations can significantly decrease the time and cost of medical research and improve quality, thus contributing to the faster development of safer and more effective medical products and a learning healthcare system. The CDISC Vision is *to inform patient care and safety through higher quality medical research.*

ABOUT TransCelerate BioPharma Inc.

TransCelerate BioPharma Inc. is a non-profit 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 organization's mission is to collaborate across the global R&D community to identify, prioritize, design and facilitate implementation of solutions designed to drive the efficient, effective and high quality delivery of medicines. TransCelerate evolved from discussions at various forums for executive R&D leadership to debate 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., Astellas Pharma Inc., Biogen Idec, Cubist Pharmaceuticals, EMD Serono, Inc. (a subsidiary of Merck KGaA, Darmstadt, Germany), Forest Research Institute (a subsidiary of Forest Laboratories, Inc.), Medgenics, Inc., Shionogi & Co., Ltd. and UCB.

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