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Austin, TX – 15 January 2015 – The Clinical Data Interchange Standards Consortium (CDISC), Critical Path Institute (C-Path) and TransCelerate BioPharma Inc. ("TransCelerate") announced today that version 1.0 of the CDISC Influenza Therapeutic Area User Guide (TAUG) and version 1.0 of the CDISC QT Studies TAUG are now available for implementers on the CDISC website. CDISC standards facilitate clinical research from end-to-end, from protocol and data collection through analysis and reporting, and have been shown to significantly decrease the time and cost of medical research while improving quality.

These user guides were developed through the Coalition for Accelerating Standards and Therapies (CFAST), a joint initiative of CDISC and the Critical Path Institute (C-Path) with partners including TransCelerate, the U.S. Food and Drug Administration (FDA) and the National Institute of Health's (NIH) National Cancer Institute – Enterprise Vocabulary Services (NCI-EVS), and with participation and input from many other organizations. An aim of the CFAST effort is to support the goals of the FDA's Therapeutic Area Standards (TAS) Initiative Project Plan. Both the influenza and QT studies standards were established in an effort to make clinical research more efficient while continuing to support the scientific nature of the research.

Concerns about the possibility of pandemic spread of novel influenza strains have led to increased interest in influenza drug development, and seasonal influenza remains a major public health concern. The new influenza standard includes the most common data elements needed for influenza research, examples of clinical situations from which the data arise and the reasons these data are relevant for people with influenza. 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.

The QT Studies standard focuses on the most common research concepts relevant for QT interval or heart rate corrected QT interval studies (a measure of time between the start of the Q wave and end of the T wave in a heart's electrical cycle), and the necessary metadata to represent such data consistent with CDISC standards, including the Study Data Tabulation Model (SDTM) and the Analysis Data Model (ADaM). "These standards represent a major improvement for sharing data from clinical drug safety studies. I look forward to the next phase of this effort to develop the standards for EKG data collection beyond thorough QT studies as this field continues to evolve," said Klaus Romero, MD, MS, FCP, C-Path Director of Clinical Pharmacology.

"The goal of the CFAST initiative with the Influenza and QT Studies TAUGs, like the CDISC Therapeutic Area Standards that have come before them, has been to identify a core set of clinical therapeutic area concepts and endpoints for these two areas and translate them into CDISC standards to improve semantic

understanding, support data sharing and facilitate faster and better quality submissions to global regulatory agencies," stated Rhonda Facile, CDISC Senior Director of Standards Development. "The resulting improvement in the drug development process is of direct benefit to patients that are in the greatest need for faster, safer and more effective medical products and therapies."

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. For more information, please visit the CDISC website.

About C-PATH

The Critical Path Institute (C-Path) is an independent, non-profit organization established in 2005 with public and private philanthropic support from the Arizona community, Science Foundation Arizona, and the U.S. 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 seven global, public-private partnerships that currently include over 1,000 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.

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 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 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 Actavis, Allergan, Inc., Astellas Pharma Inc., Biogen Idec, Cubist Pharmaceuticals, EMD Serono, Inc. (a subsidiary of Merck KGaA, Darmstadt, Germany), Medgenics, Inc., Merck & Co., Inc., Shionogi & Co., Ltd. and UCB.

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

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