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FOR IMMEDIATE RELEASE

CFAST Launches Two New CDISC Therapeutic Area Standards

CFAST Develops Processes to Accelerate Understanding of Alzheimer's disease and Asthma

Austin, TX – 28 January 2014 – 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 Asthma Therapeutic Area (TA) User Guide (UG) and version 2.0 of the Alzheimer's TAUG are now available for implementers on the [CDISC website](#). These user guides and the new standards development process through which they were formed are expected to further accelerate the development of additional TA standards. This is expected to streamline the process of developing new therapies for patients.

The release of these two standards marks the first time that TA standards have been fully developed through the CFAST partnership using the enhanced CDISC standards development process. CFAST is a joint initiative of CDISC and C-Path, with partners such as 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](#).

Version 2.0 of the Alzheimer's TAUG provides guidance on the implementation of the Study Data Tabulation Model (SDTM) to represent Alzheimer's data in regulatory submissions. This User Guide describes the most common research concepts relevant to studies of Alzheimer's disease and mild cognitive impairment, and gives guidance on the necessary metadata to represent in a way that is consistent with CDISC standards. The goal of this project was to expand upon v1.0, including a broader set of concepts for Alzheimer's clinical trials and research, using the Alzheimer's Disease Neuroimaging Initiative (ADNI) as the primary source of input. Substantive additions from version 1.0 include 10 new clinical scales of cognition/function, cerebrospinal fluid (CSF) biomarkers sample handling and processing, and imaging biomarkers including volumetric MRI, amyloid PET imaging and FDG-PET imaging.

"This project would not have been possible without the generous support of and the many contributions by clinicians, scientists, C-Path and CDISC members, staff and volunteers. This team worked closely with subject matter experts to enhance the AD data standard which is now being used to develop new tools to analyze aggregated data and better understand Alzheimer's disease progression," said Martha Brumfield, C-Path President and CEO.

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It is anticipated that the process followed for the Asthma standard will serve as a model for the development of many more TA standards through the CFAST initiative. The Asthma TA data standard specifically includes variables being collected in clinical research studies in support of therapies for asthma in adults.

“The development of the first data standard created entirely within the CFAST initiative is a landmark achievement,” stated Diane Wold, Director of Data Standards at GlaxoSmithKline, member of TransCelerate and CDISC Clinical Data Standards teams and CFAST Asthma team member. “We are looking forward to applying what we learned during the Asthma project to future TA standards development projects.”

ABOUT CDISC

CDISC is a 501(c)(3) global non-profit charitable organization, with over 300 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

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 improve human health and well-being by developing new technologies and methods to accelerate the development and review of medical products. An international leader in forming collaborations, C-Path has established global, public-private partnerships that currently include 1,000+ scientists from government regulatory agencies, academia, patient advocacy organizations, and dozens of major pharmaceutical companies. For more information, please visit the [C-Path website](#).

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 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 & Development operations. Executive offices are located in Philadelphia, PA. For more information, please visit <http://www.transceleratebiopharmainc.com>.