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CRITICAL PATH INSTITUTE ANNOUNCES EXPANSION OF REGULATORY SCIENCE CONSORTIUM FOR TUBERCULOSIS

Collaboration and innovation to tackle TB combination drug development challenges

Tucson, Arizona, April 29, 2011 – Critical Path Institute (C-Path) is proud to announce that the Regulatory Science Consortium, an arm of the Critical Path to TB Drug Regimens (CPTR), has added ten new member organizations that include over 100 participants in five workgroups.

The CPTR Regulatory Science Consortium focuses on establishing consensus on preferred standards, methods, and tools for developing new TB drug regimens, and obtaining official acceptance from international regulatory authorities. New members announced today are: AstraZeneca, Celgene, Cepheid, GlaxoSmithKline, Otsuka, Pfizer, sanofi-aventis, Treatment Action Group, Tibotec, and Vertex.

Co-founded by C-Path, the Bill and Melinda Gates Foundation, and the TB Alliance and launched in March 2010, CPTR is a public/private initiative that aims to tackle the major challenges facing TB drug development to dramatically reduce the time needed to develop impactful, new tuberculosis (TB) drug regimens. Although TB is often thought of as a disease of the past, 1.7 million people still die from it each year. Current treatments are nearly 50 years old with unacceptably long regimens and significant adverse effects and drug interactions. In addition, drug resistance is increasing, and the process for developing new drug regimens is unacceptably long.

U.S. Food and Drug Administration (FDA) Commissioner, Dr. Margaret Hamburg, helped launch CPTR last March. At that time, she committed to support CPTR and develop a guidance for industry that would address the needs of combination drug development. In December 2010 the FDA's [Guidance for Industry - Codevelopment of Two or More Unmarketed Investigational Drugs for Use in Combination](#) was released.

"The FDA's new guidance, along with the Regulatory Science Consortium's efforts to establish novel approaches to develop significantly more effective new tools, will make the pathway for new TB drug regimens much clearer," said Dr. Mel Spigelman, President and CEO of the TB Alliance. "We applaud the commitments of the FDA and regulators in Europe who are providing their support and guidance in developing innovative testing methods," said Dr. Raymond Woosley, President and CEO of C-Path.

About Critical Path Institute (C-Path): An independent, non-profit organization established in 2005 with public and private philanthropic support from the Southern Arizona community, Science Foundation Arizona (SFAz), and the U.S. Food and Drug Administration (FDA), C-Path is committed to transformational improvement of the drug development process. An international leader in forming collaborations around this mission, C-Path has

established first-of-its-kind global partnerships that currently include over 1,000 scientists from government regulatory agencies, academia, patient advocacy organizations, and thirty major pharmaceutical companies. C-Path is headquartered in Tucson, Arizona, with offices in Phoenix, Arizona, and Rockville, Maryland. For more information, visit www.c-path.org.

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