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CLINXUS JOINS INTERNATIONAL CRITICAL PATH INSTITUTE CONSORTIUM

*Consortium of leading pharmaceutical companies aims to improve and speed up
FDA development process for life-saving drugs*

Grand Rapids, MI (January 9, 2008) – ClinXus, a Grand Rapids-based, life-sciences alliance, recently became the first non-profit organization to join the Critical Path Institute’s Predictive Safety Testing Consortium (PSTC).

Critical Path Institute supports the U.S. Food and Drug Administration (FDA) with collaborative research and education programs that enable the safe acceleration of medical product development. The PSTC brings pharmaceutical companies together to share and validate each other’s safety testing methods under advisement of the FDA and its equivalent in Europe, the European Medicines Agency (EMA).

“The PSTC has been described as a model for modernizing the development of medicinal products,” said ClinXus Board President Craig P. Webb, Ph.D., Van Andel Institute scientific investigator and director of translational medicine. “It allows pharmaceutical companies and partners to share knowledge and resources to bring life-saving drugs to the FDA more quickly and safely.”

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The FDA launched the Critical Path Initiative in March 2004, to identify medical product development problems and opportunities for improvement. The study identified the process for preclinical and clinical testing of drugs as a major contributor to delays in drug development. Critical Path Institute was established in 2005 as an independent nonprofit research and education institute to facilitate collaboration between scientists in government, industry and academia.

In March 2006, Department of Health and Human Services Secretary Mike Leavitt, announced the formation of the PSTC involving scientists from the FDA, Critical Path Institute and several of the United States' largest pharmaceutical companies to share internally developed laboratory methods to predict the safety of new treatments before they are tested in humans.

The initial PSTC members include Bristol-Myers Squibb Company, GlaxoSmithKline, Johnson & Johnson Pharmaceutical Research & Development, LLC, Merck and Co., Inc., Novartis Pharmaceutical Corporation, Pfizer, Inc., Roche Palo Alto, LLC, and Schering Plough Research Institute. Since that time, the PSTC has added seven additional pharmaceutical industry members and invited EMEA to serve in an advisory role similar to that of the FDA.

William Mattes, Ph. D., director of the PSTC noted, "The PSTC has made rapid progress since its inception last year and this is a testimony to the commitment and willingness of the member companies to share their testing methods and data. We have already found a number of improved tests for drug safety that can be used in the early stages of drug development. ClinXus will greatly facilitate the next phase that includes clinical evaluation of these new tests."

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ClinXus, a life-sciences alliance dedicated to introducing molecular biomarkers into the clinical trial process, a fundamental component of personalized medicine, becomes the first non-profit organization to join the consortium. ClinXus was formed in July 2006, with the assistance of a \$1.5 million grant from the Michigan 21st Century Jobs Fund in addition to funding and in-kind donations from each of the six member institutions. The alliance uses the expertise and services of each member institution to provide a single point of contact for clinical research clients, as well as patients and physicians that participate in clinical studies. Its focus is to develop innovative clinical trials that are primarily biomarker driven, involving new medicines, devices and diagnostics in all stages of testing. ClinXus' members include Van Andel Institute (VAI), Spectrum Health, Saint Mary's Health Care, Jasper Clinical Research & Development, Grand Valley State University (GVSU) and Grand Valley Medical Specialists.

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ClinXus was formed in July, 2006 to establish innovative clinical trial designs that are primarily biomarker driven and to increase access to clinical research and emerging technologies provided by member organizations, enhancing patient care and establishing West Michigan as a national destination for innovative clinical research. The alliance's six founding members include Grand Valley Medical Specialists, Grand Valley State University, Jasper Clinical Research & Development, Saint Mary's Health Care, Spectrum Health and Van Andel Institute.