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# PRESS RELEASE

CytoSolve's combination drug therapy receives IND allowance from FDA in record 11 months.

**Cambridge, November 10, 2013:** A two-drug combination developed by CytoSolve has received an exemption from IND regulations by the United States Food and Drug Administration and is cleared for Phase 2 clinical trials. The whole process took a total of 11 months from start to finish.

"This is the testament to the paradigm shifting nature of CytoSolve's approach to drug development. We developed the in silico models of pancreatic cancer, identified a drug combination that did better than the current gold standard, gemcitabine, filed and received an exemption from the FDA in a total of 11 months," said Dr. Andrew Koo, Director of Research at CytoSolve.

CytoSolve's approach is revolutionary. It is based on integrating mechanisms of molecular pathway interactions derived from actual wet lab experiments. This approach is not "big data analysis" or mathematical statistical modeling that simply provides input-output results, without providing an understanding of mechanisms, which is what biologist require to advance drug discovery and development.

"There is an increased emphasis nowadays to develop combination treatments for complex diseases such as pancreatic cancer, in the post genomic era. The current methods of drug development have proved woefully inadequate when it comes to developing combination treatment because of the complexity, time and cost involved. CytoSolve has provided a revolutionary methodology to overcome the hurdles in developing combination treatments. We were pleasantly surprised when we got a call from the FDA director's office saying that using such technologies as CytoSolve to accelerate the drug development is part of FDA director's vision for the 23<sup>rd</sup> century," said Dr. V. A. Shiva Ayyadurai, Chairman and C.E.O. of CytoSolve, Inc.

CytoSolve is headquartered in Cambridge, MA. CytoSolve's revolutionary technology for in silico mechanistic modeling is accelerating discovery and development of single and multi-combination therapeutics.