Incept BioSystems Completes First Human Clinical Trial of the SMART Start™ Embryo Culture System and Submits 510(k) Application to the FDA

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ANN ARBOR, Mich., Oct. 12 /PRNewswire/ -- Incept BioSystems, Inc. ("Incept"), a privately-held biomedical device company using patented, microfluidic technology developed at the University of Michigan, announced today the completion of the first U.S. human clinical trial of its proprietary, SMART Start™ Embryo Culture System, and the recent submission of a 510(k) application to the U.S. Food & Drug Administration ("FDA"). A decision as to market clearance for the device is expected from the FDA sometime in 2011.

As compared with the current in vitro fertilization ("IVF") practice of culturing embryos in a static environment (i.e. a microdrop in a culture dish), Incept's SMART Start Embryo Culture System is a device that enables a continuous, refreshable culture microenvironment while using industry-standard IVF culture medium.

The objective of the clinical trial, for patients undergoing IVF, was to assess the impact on a) morphological embryo development (structural characteristics), and b) embryo survival rates, when embryos are subjected to a refreshable culture microenvironment. A total of 496 embryos from 36 couples who were diagnosed with infertility, and were planning to undergo IVF and embryo transfer, were enrolled in the prospective, randomized performance study, which took place at four investigational sites. Data from the study (P=0.0145) showed that Incept's SMART Start Embryo Culture System met the primary endpoint and was non-inferior to the conventional static dish culture, based on the number of embryos that reached the 8-cell stage at 72 hours of culture.

Commenting on today's news, Christopher Bleck, President and Chief Executive Officer of Incept, noted, "We are pleased with the trial results, which confirmed the safety of the SMART Start Embryo Culture System. This is the first time that any microfluidic technology has been used successfully to help treat infertility patients and is, therefore,
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