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EMBRYO VIABILITY STUDIES SUPPORT UTILITY OF NOVEL, METABOLOMIC PROFILING TECHNOLOGY

Molecular Biometrics presents scientific evidence supporting accuracy of its biospectroscopy-based metabolomics platform at major international conference.

BARCELONA, SPAIN, AND CHESTER, NJ, JULY 7, 2008 – Molecular Biometrics, LLC, a privately-held metabolomics company developing novel clinical tools for applications in personalized medicine to more accurately characterize biologic function in health and disease, presented data from four new studies evaluating the benefits of metabolomic profiling to determine embryo viability and enhance *in vitro* fertilization (IVF) outcomes. These study findings, presented this week at the 24th annual Meeting of the European Society for Human Reproduction and Embryology (ESHRE), include perspectives in evaluating oocytes (eggs), embryos and blastocysts (late stage embryos) to determine embryo viability using the company's novel, proprietary technology.

“As embryos develop they undergo specific metabolic changes and produce biological signals or “biomarkers” that are absorbed into the culture media that nourishes these cells,” said James T. Posillico, PhD, President and Chief Executive Officer, Molecular Biometrics. “Using highly sensitive metabolomic technology, we can accurately and non-invasively measure these signals in the culture media, creating a ‘fingerprint’ or biomarker profile to help determine embryo viability. We believe this technology may hold significant potential to more accurately estimate reproductive potential of individual embryos, thereby increasing IVF success rates.”

“We are grateful to the researchers and IVF clinics worldwide who are participating in this important clinical research,” Posillico added. “We have initiated additional studies to further validate this technology and to explore altogether new applications in IVF.”

Metabolomic Viability Scores and Implantation Rates

Currently, visual assessment of embryo morphology alone is used to determine reproductive potential of embryos for implantation in an IVF procedure. In a multi-center study, “*A viability index determined by non-invasive metabolomic profiling of embryo culture media correlates with ART outcome,*” researchers determined that a ‘viability index’ generated using Molecular Biometrics’ metabolomic technology to assess the chemical composition of the culture media surrounding an embryo can discriminate among embryos of the same morphology.

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This indicates that the metabolism of the embryo – and therefore, its reproductive potential – does not necessarily correlate with morphology.

The company's metabolomics technology was used to determine a viability score for embryos of different morphology grades that did or did not result in pregnancy after single embryo transfer. Viability scores obtained by metabolomic profiling correlated with pregnancy outcomes in a manner that was significantly greater than that achieved by morphology.

Oocyte Profiling Predicts Embryo Viability

In a second study, *“Metabolomic profile of human oocyte is predictive to embryo development and viability,”* researchers demonstrated that metabolomic profiling from spent culture media of an oocyte is able to predict embryo development at Day 3 and 5, and may also predict overall embryo viability. Just three hours of individual oocyte culture proved sufficient to produce metabolomic ‘fingerprints’ that could predict embryo development and viability.

“These data are very promising, and demonstrate that metabolomic profiling may prove to be a useful methodology for rapid, non-invasive oocyte and embryo assessment,” added Denny Sakkas, PhD, Associate Professor, Department of OB/GYN and Reproductive Sciences at the Yale University School of Medicine, Director, Assisted Reproductive Treatment Laboratories, Yale Fertility Center, and Chief Scientific Officer, Molecular Biometrics. “The application of this novel metabolomic technology may favorably impact IVF outcomes by improving procedures to more accurately predict embryo viability and reproductive potential. Having the ability to reliably select viable embryos will allow infertility specialists to reduce the number of embryos transferred in IVF and thus decrease the incidence of multiple gestations.”

Embryo and Blastocyst Profiling

Two other presentations – *“Metabolic modifications of culture medium by human embryos; correlations with embryonic characteristics and outcome in single embryo transfers,”* and *“Non-invasive metabolic profiling of day 5 spent culture media aids in the prediction of blastocyst viability”* – further highlighted the potential applications of Molecular Biometrics' proprietary metabolomic technology. The first study demonstrated that embryos that implant following transfer alter their culture media differently from embryos that failed to implant. These differences were readily detectable using the company's metabolomics platform. Viability scores, generated based on these metabolomic differences, were significantly more accurate than currently-used morphological measures in identifying viable embryos capable of implantation. The second study determined that metabolomic profiling of blastocysts can also be used to assess viability of these advanced stage embryos as well.

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Metabolomics at Molecular Biometrics

Metabolomics is a complex scientific process that identifies and measures individual signals from many small molecular compounds produced by cellular metabolism which, when evaluated as a whole, represent unique biomarkers of biologic function in health and disease.

Molecular Biometrics uses near infrared (NIR) biospectroscopy in its metabolomic applications. NIR is a robust platform that rapidly measures the vibrational energy produced by small molecule functional groups, creating a profile of molecules that are descriptive of cellular function and viability.

The spectral signatures are further analyzed by proprietary bioinformatics and chemometrics that result in the creation of a novel “metabolomic profile” or “fingerprint” that can be used to systematically distinguish between the often subtle differences that separate normal physiology from the onset or progression of disease, or an individual’s response to therapeutic intervention. Metabolomics is commonly used in pharmaceutical research, molecular diagnostics and food and agrichemical industries.

About Molecular Biometrics

Molecular Biometrics, LLC, is applying novel metabolomic technologies to develop accurate, non-invasive clinical tools for use in personalized medicine to evaluate normal biologic function in health and in disease, and for drug discovery and development. The company’s proprietary technology is being applied in reproductive health and IVF, neurodegenerative disease (e.g., Alzheimer’s disease and Parkinson’s disease), maternal fetal medicine, pulmonary metabolism and edema, and lactate metabolism. Molecular Biometrics is headquartered in Chester, NJ, with research and development facilities in New Haven, CT, and Montreal, Quebec. For more information, please visit www.molecularbiometrics.com.

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