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### FOR IMMEDIATE RELEASE

## MindChild Medical, Inc., and The University of Oxford Announces a Sponsored Research Agreement for the Development of Innovative Signal Processing Software for Fetal and Maternal Monitor with the MERIDIAN<sup>™</sup> Non-Invasive Fetal Heart Rate Monitor<sup>1</sup>

# MERIDIAN Provides Continuous Non-Invasive Fetal Heart Rate Readings Using Surface Electrodes That Detect Fetal ECG (fECG)

(BusinessWire, North Andover, Massachusetts), MindChild Medical, Inc., and The University of Oxford today announced the signing of a Sponsored Research Agreement for the development of innovative signal processing algorithms for use with the MERIDIAN<sup>™</sup> non-invasive fetal heart monitor. MindChild previously announced clearance for its Pre-Marketing Notification (510(k)) from the US Food and Drug Administration (FDA) for the MERIDIAN<sup>™</sup> non-invasive fetal heart monitor. MindChild anticipates entering the US market with MERIDIAN now that it has received the FDA clearance. Additional pre-market regulatory filings are anticipated during 2013.

The Sponsored Research Agreement will be managed by Gari Clifford, PhD<sup>2</sup>. Dr. Clifford is a member of the faculty at the University of Oxford in the Department of Engineering Science where Dr. Clifford is a University Lecturer and runs the Intelligent Patient Monitoring Group at the Institute of Biomedical Engineering (IBME), University of Oxford. Dr. Clifford is also the Director of the Centre for Doctoral Training in Healthcare Innovation, a major UK government funded centre for teaching translational biomedical engineering. Previously, Dr. Clifford held the position of Principal Research Scientist in the Laboratory for Computational Physiology at the Harvard-MIT Division of Health Sciences. Dr. Clifford received his PhD in Neural Networks and Biomedical Engineering from Oxford University.

Dr. Clifford commented, "I have spent the majority of my academic career developing innovative signal processing approaches which lend themselves to fetal and maternal monitoring. Having participated in the development of the MERIDIAN software design, I am gratified to continue the evolution of this import clinical technology under the auspices of Oxford." Dr. Clifford continued, "The Sponsored Research Agreement will enable my group to continue the collaboration between industry and academia, which began at MIT. I look forward to advancing the capabilities of MERIDIAN technology following the recent FDA pre-market clearance."

"We are thrilled to have initiated this important collaboration with Oxford", stated Bill Edelman, CEO. He continued, "MERIDIAN is the first in a series of non-invasive fetal monitor technologies developed by MindChild that are intended to provide the healthcare community enhanced monitoring capabilities for both fetal heart rate and fetal ECG. We anticipate

<sup>&</sup>lt;sup>1</sup> MERIDIAN received Pre-Marketing Notification (510(k)) from the US Food and Drug Administration (FDA) on September 25, 2012

<sup>&</sup>lt;sup>2</sup> Dr Clifford is also Chief Technology Officer and co-founder of Mindchild



significant clinical interest for this innovative technology in the markets where MERIDIAN will be cleared for commercial distribution."

#### **Previous Announcements**

On September 25, 2012, MindChild announced clearance of a 510(k) Pre-Marketing Notification with the US Food and Drug Administration (FDA) for the MERIDIAN<sup>™</sup> Non-Invasive Fetal Heart Rate Monitor

On June 18, 2012, MindChild announced the appointment Thomas Garite, M.D. to the Clinical Advisory Board for the MERIDIAN Line of Non-Invasive Fetal Heart Rate Monitors.

On June 11, 2012, MindChild announced Results of the National Fetal Monitoring Market Survey.

On February 22, 2012, MindChild reported formation of a Clinical Advisory Board for the MERIDIAN<sup>™</sup> Line of Non-Invasive Fetal Heart Rate Monitors.

On February 6, 2012, MindChild reported filing of a 510(k) Pre-Marketing Notification Application with the US Food and Drug Administration for the MERIDIAN<sup>™</sup> Line of Non-Invasive Fetal Heart Rate Monitors.

#### About the MERIDIAN Non-Invasive Fetal Heart Rate Monitor

MERIDIAN is a fetal monitor that non-invasively measures and displays fetal heart rate (FHR). MERIDIAN acquires and displays the FHR tracing from abdominal surface electrodes that detect the fetal ECG signal (fECG). MERIDIAN may also be used to measure and display fetal heart rate using direct ECG (DECG) with a Fetal Scalp Electrode (FSE). MERIDIAN is designed for women who are at term (> 36 completed weeks), in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen. MERIDIAN is intended for use by healthcare professionals in a clinical setting.

#### About the Fetal Heart Monitoring Market

Over 85%<sup>3</sup> of the 4,000,000<sup>4</sup> live births occurring in the US during 2011 required fetal monitoring during labor and delivery. Current non-invasive Doppler, employing ultrasound to detect FHR is subject to loss of fetal heart rate due to maternal/fetal movement<sup>5</sup>. Fetal Scalp Electrodes (FSE) that connect directly to the fetus during the later stages of labor and delivery are associated with increased risk of maternal/fetal infection<sup>6</sup>. There are an estimated 28,000 fetal monitors spread over 3,400 hospitals in the US<sup>7</sup>, representing an investment of over \$700,000,000<sup>8</sup>. MERIDIAN has been developed to provide uninterruptible fECG data while

<sup>&</sup>lt;sup>3</sup> "ACOG Refines Fetal Heart Rate Monitoring Guidelines", 6/22/2009 The American College of Obstetricians and Gynecologists Press Release

<sup>&</sup>lt;sup>4</sup> http://www.cdc.gov/nchs/data/nvsr/nvsr59/nvsr59\_03.pdf

<sup>&</sup>lt;sup>5</sup> Journal of Midwifery. Vol 18, No, 7: 424-428. July 2010

<sup>&</sup>lt;sup>6</sup> American Family Physician, 1992 Feb;45(2):579-82

<sup>&</sup>lt;sup>7</sup> http://www.aha.org/aha/resource-center/Statistics-and-Studies/fast-facts.html

<sup>&</sup>lt;sup>8</sup> Company estimates.



addressing the deficiencies in both Doppler and FSE via innovative non-invasive monitoring technology.

### About MindChild Medical, Inc.

MindChild Medical, Inc., is a privately funded medical device company founded in 2008. MindChild's principal technology platform, the MERIDIAN non-invasive fetal electrocardiograph (fECG) monitor, is designed to report fetal heart rate data equivalent to the gold standard fetal scalp electrode in addition to novel ECG metrics intended to provide obstetricians a deeper understanding of fetal/maternal health and management.

MindChild was co-founded by Adam Wolfberg, MD, Assistant Professor, Tufts Medical Center, Gari Clifford, PhD, previously Principal Research Scientist at Harvard-MIT Division of Health and Science Technology (currently on the faculty at the University of Oxford in the Department of Engineering Science), James Robertson, President and CEO, and Jay Ward, Executive Vice President, both of E-TROLZ, Inc. MindChild has exclusively licensed intellectual property from the Massachusetts Institute of Technology, Tufts Medical Center and E-TROLZ, Inc., a Massachusetts technology company that develops and commercializes breakthrough physiologic monitoring platforms for a wide variety of applications. For more information, please visit www.mindchild.com.

#### About the Institute of Biomedical Engineering (IBME), University of Oxford

The Institute of Biomedical Engineering (IBME) is a research institute of the Department of Engineering Science located on the University's medical campus in Headington adjacent to the Churchill Hospital (about a mile from the City centre). Opened in April 2008, the IBME offers a world-class venue for engineers and clinicians to work together on addressing unmet needs in the prevention, early diagnosis and treatment of major diseases. The Institute's core mission is to develop novel medical devices, technology and systems capable of delivering substantial healthcare benefit. Research at the IBME covers patient monitoring, heart disease, stroke, cancer, organ transplantation, regenerative medicine, management of chronic disease, orthopedic engineering and drug delivery systems. More information about the Institute and its research programs may be found at http://www.ibme.ox.ac.uk.

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