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## FOR IMMEDIATE RELEASE – April 8, 2014

MindChild Medical, Inc. Announces the 1,000<sup>th</sup> Successful Non-Invasive Feat Heart Monitoring Session Utilizing the MERIDIAN Fetal Heart Monitor

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

(BusinessWire, North Andover, Massachusetts), MindChild Medical, Inc. today announced that the MERIDIAN Non-Invasive Fetal Heart Rate Monitor successfully completed it's 1,000<sup>th</sup> non-invasive fetal heart monitoring session. Five separate health care facilities utilized the MERIDAN technology to monitor fetal heart rate.

Adam Wolfberg, M.D., Chief Medical Officer for MindChild commented, "We are thrilled to have reached this milestone. Current techniques employed in fetal heart monitoring are limited by a variety of factors. MERIDIAN is intended to provide non-invasive fetal heart measurements similar to those monitored with an invasive Fetal Scalp Electrode (FSE)." Dr. Wolfberg continued, "The average age of our study population was 29.7±6.1 years (ranging from 18 to 48 years old), with Body-Mass-Index (BMI) of 33.7±7.5 (ranging from 18 to 60 BMI) and gestational week at the time of monitoring of 38.1±2.6. Our population consisted of 16.8% African American, 5% Asian, 14.3% Hispanic, and 64% White Non-Hispanic. We look forward to introducing MERIDIAN to labor and delivery units nationaly later this year."

Participants in the MERIDIAN evaluation included Sangithan Jules Moodley, MD, (Cleveland Clinic, Cleveland, OH), Timothy E. Drake, MD (Summa Akron City and St. Thomas Hospitals, Akron, OH), Julian Robinson, MD, (Newton Wellesley Hospital, Newton, MA), Michael House, MD, (Tufts New England Medical Center, Boston, MA), and James Greenberg, MD (Brigham and Women's Hospital, Boston, MA).

## **Previous Announcements**

On May 1, 2013, MindChild Medical, Inc., presented the MERIDIAN™ Non-Invasive Fetal Heart Rate Monitor at the 61st Annual Meeting for the American College of Obstetricians and Gynecologists (ACOG) in New Orleans.

On February 13, 2013, MindChild Medical, Inc., presented the MERIDIAN™ Non-Invasive Fetal Heart Rate Monitor at the 33rd Annual Meeting for the Society for Maternal Fetal Medicine (SMFM) in San Francisco, CA.

On November 5, 2012, MindChild Medical, Inc., and The University of Oxford announced a Sponsored Research Agreement for the Development of Innovative Signal Processing Software for Fetal and Maternal Monitor with the MERIDIAN™ Non-Invasive Fetal Heart Rate Monitor.



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™ 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 National Fetal Monitoring Market Survey.

On February 22, 2012, MindChild reported formation of a Clinical Advisory Board for the MERIDIAN™ 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™ 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>1</sup> of the 4,000,000<sup>2</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>3</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>4</sup>. There are an estimated 28,000 fetal monitors spread over 3,400 hospitals in the US<sup>5</sup>, representing an investment of over \$700,000,000<sup>6</sup>. MERIDIAN has been developed to provide uninterruptible fECG data while 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

<sup>&</sup>lt;sup>1</sup> "ACOG Refines Fetal Heart Rate Monitoring Guidelines", 6/22/2009 The American College of Obstetricians and Gynecologists Press Release

<sup>&</sup>lt;sup>2</sup> http://www.cdc.gov/nchs/data/nvsr/nvsr59/nvsr59\_03.pdf

<sup>&</sup>lt;sup>3</sup> Journal of Midwifery. Vol 18, No, 7: 424-428. July 2010

<sup>&</sup>lt;sup>4</sup> American Family Physician, 1992 Feb;45(2):579-82

<sup>&</sup>lt;sup>5</sup> http://www.aha.org/aha/resource-center/Statistics-and-Studies/fast-facts.html

<sup>&</sup>lt;sup>6</sup> Company estimates.



(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, previously Assistant Professor, Tufts Medical Center (currently an associate at Boston Maternal-Fetal Medicine), 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.

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