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MindChild Medical, Inc. Announces 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

MERIDIAN is intended to Provide Continuous Non-Invasive Fetal Heart Rate Readings Equivalent to the Gold Standard Fetal Scalp Electrode

(PRNewsWire, North Andover, Massachusetts), MindChild Medical, Inc. today announced that it has successfully completed filing of a Pre-Marketing Notification Application (510(k)) with the US Food and Drug Administration (FDA) for its MERIDIAN non-invasive fetal heart monitor. MindChild expects feedback from the FDA during the next quarter and anticipates entering the US market with MERIDIAN following FDA pre-market clearance. Additional pre-market regulatory filings are anticipated during 2012.

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%[1] of the 4,100,000[2] 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[3]. 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[4]. There are an estimated 28,000 fetal monitors spread over 3,400 hospitals in the US[5], representing an investment of over $700,000,000[6]. MERIDIAN has been developed to provide uninterruptible fECG data while addressing the deficiencies in both Doppler and FSE via innovative non-invasive monitoring technology.

“We are excited to have reached this milestone”, 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

[1] "ACOG Refines Fetal Heart Rate Monitoring Guidelines", 6/22/2009 The American College of Obstetricians and Gynecologists Press Release
[2] http://www.cdc.gov/nchs/data/nvsr/nvsr59/nvsr59_03.pdf
[3] Journal of Midwifery. Vol 18, No, 7: 424-428. July 2010
[4] American Family Physician, 1992 Feb;45(2):579-82
[5] http://www.aha.org/aha/resource-center/Statistics-and-Studies/fast-facts.html
[6] Company estimates.

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capabilities for both heart rate and fECG. We anticipate significant clinical interest for this innovative technology in the markets where MERIDIAN will be cleared for commercial distribution."

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.