Guided Therapeutics and FDA Agree on Plan for LuViva® Advanced Cervical Scan PMA

The Associated Press

NORCROSS, Ga.--(BUSINESS WIRE)--Jul 25, 2012--Guided Therapeutics, Inc. (OTCBB: GTHP) (OTCQB: GTHP) today announced that it met with the Food and Drug Administration (FDA) on July 20, 2012. The company believes the meeting was very positive and plans to work with FDA to finalize the path forward to gain premarket approval (PMA) for the LuViva ® Advanced Cervical Scan, a non-invasive device used to detect cervical disease that leads to cancer, instantly and at the point of care.

The preliminary plan calls for the company to file a PMA amendment using existing clinical data to address the agency's questions stemming from its January 20, 2012 "not approvable" letter. The company maintained at the meeting with the FDA that the new data analysis to be included in the amended PMA demonstrates the clinical benefit of LuViva in light of new cervical cancer screening guidelines adopted earlier this year.

"We are pleased with both the tenor and substance of the meeting with FDA and believe we have a good plan to move the PMA process forward through what we hope will be a quick review and approval for LuViva," said Mark L. Faupel, Ph.D., President and CEO of Guided Therapeutics. "We believe that once approved, LuViva will have a very positive impact on the U.S. healthcare system by improving the standard of care for the early detection of cervical disease, and providing women and doctors the first test with instant results." LuViva has been under FDA PMA review since September 23, 2010. The company received a "not approvable" letter for the product on January 20, 2012. In May, 2012 the company requested a meeting with the agency, and suggested a path for possible approval to which the FDA was receptive. After a PMA amendment is submitted, the FDA has 180 days during which it can respond.

In addition to the recently announced CE Mark, LuViva has marketing approval from Health Canada. Guided Therapeutics was awarded ISO 13485 certification in January, 2011. The company continues to anticipate a launch in international markets later in 2012.

About LuViva ® Advanced Cervical Scan LuViva is a technologically advanced diagnostic device that scans the cervix with light and uses spectroscopy to measure how light interacts with the cervical tissue. Spectroscopy identifies chemical and structural indicators of precancer that may be below the surface of the cervix or misdiagnosed as benign. This technique is called biophotonics. Unlike Pap, HPV tests or biopsies, LuViva does not require laboratory analysis or a tissue sample, and is designed to provide results immediately, which eliminates costly, painful and unnecessary testing. LuViva is designed for use with women who have undergone

initial screening and are called back for follow up with a colposcopy examination, which in many cases involves taking a biopsy of the cervix. The device is used in conjunction with the LuViva ® Cervical Guide single-use patient interface and calibration disposable.

About Guided Therapeutics Guided Therapeutics, Inc. (OTCBB: GTHP) (OTCQB: GTHP) is developing a rapid and painless testing platform for the early detection of disease based on its patented biophotonic technology that utilizes light to detect disease at the cellular level. The Company's first planned product is the LuViva ® Advanced Cervical Scan, a non-invasive device used to detect cervical disease instantly and at the point of care. In a multi-center clinical trial, with women at risk for cervical disease, the technology was able to detect cervical cancer up to two years earlier than conventional modalities, according to published reports. Guided Therapeutics has also entered into a partnership with Konica Minolta to develop a non-invasive test for Barrett's Esophagus using the technology platform. For more information, visit: www.guidedinc [1] .com.

The Guided Therapeutics LuViva ® Advanced Cervical Scan is an investigational device and is limited by federal law to investigational use. LuViva, the wave logo and "Early detection, better outcomes" are registered trademarks owned by Guided Therapeutics, Inc. Forward-Looking Statements Disclaimer: A number of the matters and subject areas discussed in this news release that are not historical or current facts deal with potential future circumstances and developments. The discussion of such matters and subject areas is qualified by the inherent risks and uncertainties surrounding future expectations generally and also may materially differ from Guided Therapeutics' actual future experience involving any of or more of such matters and subject areas. Such risks and uncertainties include those related to the exchange offer, as described in the Offer to Exchange, as well as those related to: the early stage of products in development, the uncertainty of market acceptance of products, the uncertainty of development or effectiveness of distribution channels, the intense competition in the medical device industry, the uncertainty of capital to develop products, the uncertainty of regulatory approval of products, dependence on licensed intellectual property, as well as those that are more fully described from time to time under the heading "Risk Factors" in Guided Therapeutics' reports filed with the SEC, including Guided Therapeutics' Annual Report on Form 10-K for the fiscal year ended December 31, 2011, and subsequent quarterly reports.

CONTACT: Investors: Cameron Associates Alison Ziegler, 212-554-5469 or Guided Therapeutics Bill Wells, 770-242-8723 Ext. 241 KEYWORD: UNITED STATES NORTH AMERICA GEORGIA INDUSTRY KEYWORD: HEALTH MEDICAL DEVICES FDA SOURCE: Guided Therapeutics, Inc. Copyright Business Wire 2012 PUB: 07/25/2012 08:05 AM/DISC: 07/25/2012 08:05 AM
http://www.businesswire.com/news/home/20120725005226/ [2]

Source URL (retrieved on *05/22/2013 - 8:09am*):
http://www.mdtmag.com/news/2012/07/guided-therapeutics-and-fda-agree-plan-

luviva%C2%AE-advanced-cervical-scan-pma

Links:
[1] http://www.guidedinc
[2] http://www.businesswire.com/news/home/20120725005226/