Guided Therapeutics Submits PMA Amendment to FDA for LuViva® Advanced Cervical Scan

The Associated Press

NORCROSS, Ga.--(BUSINESS WIRE)--Nov 13, 2012--Guided Therapeutics, Inc., (OTCBB: GTHP) (OTCQB: GTHP), today announced that it has submitted its premarket approval (PMA) Amendment 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 amendment is in response to a “not approvable” letter received by the company in January and includes additional data analysis requested by the U.S. Food and Drug Administration (FDA).

"We are pleased to move the FDA review process forward with the filing of the amended PMA for LuViva,” said Mark L. Faupel, Ph.D., President and CEO of Guided Therapeutics. “We have worked with the agency over the last several months to provide responses to the key questions in the PMA amendment and are hopeful this filing will ultimately lead to approval for the product. 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, providing women and doctors with the first test with instant results and detecting cervical disease at an earlier stage, when it can be better treated.” 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 July, 2012 the company met with the agency and agreed to file a PMA amendment to address the agency’s questions stemming from the “not approvable” letter. With the PMA amendment now formally submitted, the FDA has 180 days during which it can respond.

LuViva currently has marketing approval from Health Canada and received its first CE Mark, an ISO 60601 Edition 2 Notification, in July. The company is in the process of testing the LuViva system for compliance with the Edition 3 CE Mark requirements, which the company expects to achieve near the end of this year. Guided Therapeutics was awarded ISO 13485 certification in January, 2011.

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 the early detection of esophageal cancer using the technology platform. For more information, visit: www.guidedinc.com [1].

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 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 ONCOLOGY FDA SOURCE: Guided Therapeutics, Inc. Copyright Business Wire 2012 PUB: 11/13/2012 04:02 PM/DISC: 11/13/2012 04:02 PM
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Links:

[1] http://www.guidedinc.com
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