Guided Therapeutics Notified of CE Mark Approval for LuViva® Advanced Cervical Scan

The Associated Press

NORCROSS, Ga.--(BUSINESS WIRE)--Jul 18, 2012--Guided Therapeutics, Inc. (OTCBB: GTHP) (OTCQB: GTHP) today announced that it has received notification that CE Mark approval has been granted for 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 CE Mark is required to sell products in the 27 nations that comprise the European Union (EU). There are about 146 million women who are targeted by existing or planned cervical cancer screening programs in EU member states, according to the European Cancer Observatory.

“The notification of CE Mark for LuViva is a significant milestone for the company and allows us to begin our European launch later this year, as planned,” said Mark L. Faupel, Ph.D., president and CEO of Guided Therapeutics. “We believe that together with our distributors, we have a tremendous opportunity to improve the detection of cervical disease, reduce false positives and unnecessary biopsies, and provide significant savings to healthcare systems throughout Europe.” “Notification of the CE Mark and previously announced Health Canada approval for LuViva further validates the product and our ability to manufacture to the highest standards. We expect the CE Mark award will generate more demand for the product and open opportunities in markets outside the EU as well. In addition to the more than 20 countries already covered by distribution agreements, we plan to expand our network to additional countries in Europe, Latin America and Asia and having the CE Mark should accelerate those efforts,” Dr. Faupel added.

Today's CE Mark notification is the first of two expected for LuViva. A second CE Mark application is expected to be filed later this year to comply with updated European medical device standards and to include design improvements. The company also must continue to pass annual ISO audits of its quality system in order to maintain the CE Mark on its products. The company has passed two consecutive ISO audits, the last being in January of 2012.

In addition to the CE Mark, LuViva has marketing approval from Health Canada and remains under U.S. Food and Drug Administration premarket approval review. Guided Therapeutics was awarded ISO 13485 certification in January, 2011.

The study used to support LuViva’s CE Mark application was the multi-center U.S. pivotal trial, in which 1,607 women at risk for developing cervical disease were evaluated. In this patient population, LuViva was able to detect cervical cancer up to two years earlier than the Pap test, human papillomavirus (HPV) test, colposcopy and biopsy. LuViva detected 86.3 percent of the cervical disease cases that had

been missed by Pap, HPV tests and biopsy. LuViva would have reduced the number of unnecessary biopsies by about 40 percent. LuViva is initially intended as a follow-up test after a positive Pap result.

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.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 EUROPE NORTH AMERICA GEORGIA INDUSTRY KEYWORD: WOMEN HEALTH CLINICAL TRIALS MEDICAL DEVICES ONCOLOGY CONSUMER SOURCE: Guided Therapeutics, Inc. Copyright Business Wire 2012 PUB: 07/18/2012 08:05 /DISC: 07/18/2012 08:05 http://www.businesswire.com/news/home/20120718005191/

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