



Early Detection, Better Outcomes

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## **Guided Therapeutics Reports Update on FDA Review of LuViva™ Advanced Cervical Scan PMA Application**

### *Panel review of technology no longer planned for FDA decision*

NORCROSS, GA (November 2, 2011) – -- [Guided Therapeutics, Inc.](#) (OTCBB & OTCQB: GTHP) today announced the U.S. Food and Drug Administration (FDA) has informed the company that the agency is not planning a panel review to render a decision on the Premarket Approval (PMA) application of the LuViva™ Advanced Cervical Scan.

The FDA acknowledged that it had previously stated that there would be a panel review, but, in a conference call with the company, said that after further review of the PMA application a review by an outside panel of experts was not needed. According to the FDA, this decision does not affect the likelihood of approval or disapproval and the PMA review is continuing. The reasons given by FDA for not requiring a panel meeting were: that the agency staff believed they understood LuViva's technology, that they understood the clinical application and had reviewed similar devices in the past.

“While this new position from FDA is not an indication of the likelihood of approval or disapproval of the LuViva application, we believe that it could shorten the time frame for a final decision by the agency, based on our previous expectations,” said Mark L. Faupel, Ph.D., CEO and President of Guided Therapeutics, Inc. “We will continue to work with FDA on the premarket approval process and, while we await a decision, we are preparing for any further FDA requirements, such as manufacturing or other facility audits or inspections.”

“Concurrently, our team is preparing the documentation for the CE Mark application and we look forward to meeting with our new international distributors and European doctors, all leaders in the field of women's health, at the upcoming 2011 Medica Trade Fair in Germany later this month,” said Dr. Faupel.

Based on FDA guidelines, the company expects a decision from FDA by January 20, 2012. While the panel meeting is no longer planned, if there is a panel review at a future date, Guided Therapeutics believes it will be prepared to present the technology.

### **About LuViva**

LuViva scans the cervix with light to identify cancer and pre-cancer painlessly and non-invasively. Unlike Pap or HPV tests, 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 in a referred population which has undergone

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initial screening and is called back for follow up - called a colposcopy examination - which in many cases involves taking a biopsy of the cervix.

### **About Guided Therapeutics**

Guided Therapeutics, Inc. (OTCBB & 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 Opto to develop a non-invasive test for Barrett's esophagus using the technology platform. For more information, visit: [www.guidedinc.com](http://www.guidedinc.com).

*The LuViva Advanced Cervical Scan and Barrett's Esophagus technology are investigational devices and are limited by federal (U.S.) law to investigational use.*

*The LuViva mark, LuViva and wave logo are trademarks owned by Guided Therapeutics, Inc.*

“Safe Harbor” Statement under the Private Securities Litigation Reform Act of 1995. 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: 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, 2010, and subsequent quarterly reports.

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