Guided Therapeutics Continues to Await Update from FDA on Its PMA Application for LuViva® Advanced Cervical Scan

Business Wire

Guided Therapeutics, Inc. (OTCBB: GTHP) (OTCQB: GTHP) today commented on the status of its Pre-market Approval (PMA) application for the LuViva ® Advanced Cervical Scan. While the Company requested a phone meeting with the U.S. Food and Drug Administration (FDA) after the passing of their 180 day internal guidance and did speak with the agency, the company was informed that LuViva remains under FDA review.

“While we understand that FDA can take longer than is sometimes expected, we were pleased to learn that the FDA review is still active and we look forward to hearing back from them soon once their review is complete,” commented Mark L. Faupel, Ph.D., president and CEO of Guided Therapeutics. “While the U.S. market is important to us, we believe that the international market offers the greater opportunity for LuViva and a faster path to profitability. In order to take advantage of this opportunity, we have hired a Latin American specialist as part of our distributor management team, are working to be included in national healthcare plans, such as our recent announcement from Turkey, and continuing to add new distributors to our network. Additionally, our recent purchase orders from Turkey and other opportunities in Europe, Latin America and Southern Asia put us on track to be breakeven without the need for additional capital, if we execute on our manufacturing and sales plan.”

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.

The LuViva Advanced Cervical Scan is compliant with both Edition 2 and Edition 3 CE standards, has marketing approval from Health Canada and the Singapore Health Sciences Authority, and is under U.S. Food and Drug Administration Premarket review.

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