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AUSTIN, Texas, June 30, 2026 (GLOBE NEWSWIRE) -- FocalTherics™ (Nasdaq: FOCL) (the "Company"), the global leader in robotic focal therapy, today announced the launch of the first European commercial endometriosis Focal One® Program and treatment of initial patients at Toulouse University Hospital in Toulouse, France. The hospital launched their endometriosis Focal One program following the acquisition of the system with the intention of utilizing it for treating both deep infiltrating endometriosis and prostate cancer. This launch is part of FocalTherics' broader expanded launch strategy, with more than 10 hospitals in the Company's active clinical training pathway across Europe, the United Kingdom, and Latin America.

The Focal One procedures at Toulouse University Hospital were performed by Professor Elodie Chantalat, Head of the Department of Gynecology. Professor Gil Dubernard, Head of the Gynecologic and Obstetric Department at Croix-Rousse University Hospital in Lyon, who pioneered the use of Focal One for treating deep infiltrating endometriosis, served as proctor for these initial procedures.

Approximately 38 million women worldwide suffer from deep infiltrating endometriosis, a severe form of the disease that invades organs surrounding the uterus.<sup>1</sup> It is characterized by chronic pelvic pain, painful bowel symptoms, and significant impairment in quality of life. Treatment has historically been limited to complex surgery associated with potential morbidity and lengthy recovery periods. Research indicates that 91% of women with the condition would prefer a non-surgical alternative that minimizes associated complications and underscores the unmet need that the Focal One Robotic HIFU system is positioned to address.<sup>2</sup>

Focal One Robotic HIFU utilizes imaging and high-intensity focused ultrasound technology to precisely target and ablate endometriosis lesions on the bowel and rectum without incisions or surgery. The treatment is performed under real-time image guidance and is designed to minimize impact on surrounding healthy structures.

"Launching the Endometriosis Focal One Program at Toulouse University Hospital and treating the first patients represents an important milestone in expanding access to this organ-sparing, function-preserving treatment option for women suffering from deep infiltrating endometriosis," said Ryan Rhodes, Chief Executive Officer of FocalTherics. "We believe Focal One Robotic HIFU has the potential to transform the treatment paradigm for this debilitating disease by reducing the morbidity commonly associated with conventional surgical approaches."

Professor Elodie Chantalat commented, "The ability to offer patients a minimally invasive treatment option for deep infiltrating endometriosis represents an important clinical advancement. We are pleased to be among the first centers to provide this therapy and look forward to expanding access for appropriate patients."

FocalTherics will continue to work directly with endometriosis specialists and thought leaders to launch additional Endometriosis Focal One programs at hospitals across Europe, the United Kingdom and Latin America. Focal One Robotic HIFU received CE Mark in March 2025 for the treatment of posterior deep infiltrating endometriosis and is commercially available in CE Mark countries and other select markets.

#### **About FocalTherics**

A recognized global leader in robotic focal therapy, FocalTherics develops, manufactures, and markets minimally invasive medical devices worldwide to treat various conditions using proprietary focused ultrasound technology. The Company's flagship platform, Focal One Robotic HIFU, combines advanced imaging, real-time treatment planning, robotic precision, and HIFU technology to deliver personalized focal therapy designed to optimize clinical outcomes while preserving quality of life. FocalTherics is committed to expanding the clinical adoption of its patented focused ultrasound-based robotic therapy platforms through continued innovation, clinical evidence generation, physician education, and global market development initiatives. For more information about FocalTherics, visit [FocalTherics.com](https://www.focaltherics.com).

#### **Forward-Looking Statements**

In addition to historical information, this press release contains forward-looking statements within the meaning of applicable federal securities laws, including Section 27A of the U.S. Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the U.S. Securities Exchange Act of 1934, as amended (the "Exchange Act"), which may be identified by words such as "believe," "can," "contemplate," "could," "plan," "intend," "is designed to," "may," "might," "potential," "objective," "target," "project," "predict,"

"forecast," "ambition," "guideline," "should," "will," "estimate," "expect" and "anticipate," or the negative of these and similar expressions, which reflect our views about future events and financial performance. Such statements are based on management's current expectations and are subject to a number of risks and uncertainties, including matters not yet known to us or not currently considered material by us, and there can be no assurance that anticipated events will occur or that the objectives set out will actually be achieved. Important factors that could cause actual results to differ materially from the results anticipated in the forward-looking statements include, among others, the clinical status and market acceptance of our HIFU devices; that CE Mark certification in Europe does not guarantee clinical adoption, procedure volumes, or revenue, and that commercial uptake depends on physician training, reimbursement, and other factors outside the Company's control; risks associated with the intended discontinuation of the Company's ESWL and Distribution operating segments, including that the discontinuation may take longer or cost more than expected, may result in disputes with customers, distributors, employees or other counterparties, and may not produce the strategic benefits anticipated; as well as risks associated with the current worldwide inflationary environment, the uncertain worldwide economic, political and financial environment, geopolitical instability, climate change and pandemics, or other public health crises, and their related impact on our business operations.

Other factors that may cause such a difference may also include, but are not limited to, those described in the Company's filings with the Securities and Exchange Commission and in particular, in the sections "Cautionary Statement on Forward-Looking Information" and "Risk Factors" in the Company's Annual Report on Form 10-K.

Forward-looking statements speak only as of the date they are made. Other than as required by law, we do not undertake any obligation to update them in light of new information or future developments. These forward-looking statements are based upon information, assumptions and estimates available to us as of the date of this press release, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete.

<sup>1</sup>Company Data on File

<sup>2</sup>Vercellini P, et al. Surgery versus hormonal therapy for deep endometriosis: hormonal treatment is ineffective or not tolerated in ~30% of women. *Minerva Ginecol*, 2016; PMID 27544308.

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