April 20, 2021

Ra Medical Systems Provides Enrollment Update for its Pivotal Atherectomy Clinical Trial

42 total subjects enrolled as of April 19, 2021

12 subjects enrolled since mid-March

CARLSBAD, Calif.--(BUSINESS WIRE)-- Ra Medical Systems, Inc. (NYSE American: RMED), a medical device company focused on commercializing excimer laser systems to treat vascular and dermatological diseases, announces an increase in enrollment in its pivotal clinical trial to evaluate the safety and effectiveness of the DABRA excimer laser system as an atherectomy device for the treatment of peripheral arterial disease (PAD). A total of 42 subjects have been enrolled as of April 19, 2021.

“We are encouraged by recent progress in our atherectomy trial with 12 subjects enrolled since our last update in mid-March,” said Will McGuire, Ra Medical Systems CEO. “Five clinical sites are cleared for enrollment in this study with two additional sites currently in various stages of the qualification process.”

The DABRA excimer laser system received U.S. FDA 510(k) clearance in May 2017 for crossing chronic total occlusions, or CTOs, in patients with symptomatic infrainguinal lower extremity vascular disease with an intended use for ablating a channel in occlusive peripheral vascular disease. The FDA defines atherectomy to include a prespecified improvement in luminal patency. Third-party research estimates the value of the combined CTO and atherectomy markets in the U.S. at approximately $900 million for 2021, with atherectomy representing more than $750 million.

The open-label pivotal atherectomy clinical trial can enroll up to 100 subjects with symptoms of PAD (Rutherford Class 2-5) at up to 10 sites. Outcome measures include safety, acute technical success and clinical success. The trial’s primary efficacy endpoint is the mean reduction in percent diameter stenosis in each patient’s primary lesion as measured by angiography immediately following treatment with DABRA and before any adjunctive treatment. The trial’s safety and clinical success endpoints are major adverse events at 30 days post-procedure and incidence of primary target lesion revascularization at six months post-procedure.

About Ra Medical Systems

Ra Medical Systems commercializes excimer lasers and catheters for the treatment of vascular and dermatological diseases. The Pharos excimer laser system is FDA-cleared and is used as a tool in the treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma.

DABRA and Pharos are both based on Ra Medical's core excimer laser technology platform and deploy similar mechanisms of action. Ra Medical manufactures DABRA and Pharos excimer lasers and catheters in a 32,000-square-foot facility located in Carlsbad, Calif. The vertically integrated facility is ISO 13485 certified and is licensed by the State of California to manufacture sterile, single-use catheters in controlled environments.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements generally relate to future events or Ra Medical's future financial or operating performance. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these words or other similar terms or expressions that concern Ra Medical's future expectations, strategy, plans or intentions. Forward-looking statements in this press release include, but are not limited to, statements regarding the timing and potential outcome of the DABRA atherectomy clinical study. Ra Medical's expectations and beliefs regarding these matters may not materialize, and actual results in future periods are subject to risks and uncertainties that could cause actual results to differ materially from those projected or implied by such forward-looking statements. The potential risks and uncertainties which contribute to the uncertain nature of these statements include, among others, challenges inherent in developing, manufacturing, launching, marketing, and selling new products; risks associated with acceptance of DABRA and Pharos and procedures performed using such devices by physicians, payors, and other third parties; development and acceptance of new products or product enhancements; clinical and statistical verification of the benefits achieved via the use of Ra Medical's products; the results from our clinical trials, which may not support intended indications or may require Ra Medical to conduct additional clinical trials or modify ongoing clinical trials; challenges related to commencement, patient enrollment, completion, an analysis of clinical trials; Ra Medical's ability to manage operating expenses; Ra Medical's ability to effectively manage inventory; Ra Medical's ability to recruit and retain management and key personnel; Ra Medical's need to comply with complex and evolving laws and regulations; intense and increasing competition and consolidation in Ra Medical's industry; the impact of rapid technological change; costs and adverse results in any ongoing or future legal proceedings; adverse outcome of regulatory inspections; and the other risks and uncertainties described in Ra Medical's news releases and filings with the Securities and Exchange Commission. Information on these and additional risks, uncertainties, and other information affecting Ra Medical's business and operating results is contained in Ra Medical's Annual Report on Form 10-K for the year ended December 31, 2020 and in its other filings with the Securities and Exchange Commission. The forward-looking statements in this press release are based on information available to Ra Medical as of the date hereof, and Ra Medical disclaims any obligation to update any forward-looking statements, except as required by law.

Ra Medical investors and others should note that we announce material information to the public about the company through a variety of means, including our website (www.ramed.com), our investor relations website (https://ir.ramed.com/), press releases, SEC filings, and public conference calls in order to achieve broad, non-exclusionary distribution of information to the public and to comply with our disclosure obligations under

Regulation FD. We encourage our investors and others to monitor and review the information we make public in these locations as such information could be deemed to be material information. Please note that this list may be updated from time to time.

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