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Ra Medical Systems Announces Enrollment of First Patient in Pivotal Atherectomy Clinical Study

CARLSBAD, Calif.--(BUSINESS WIRE)-- Ra Medical Systems, Inc. (NYSE: RMED), a medical device company focused on commercializing excimer laser systems to treat vascular and dermatological diseases, announces enrollment of the first patient in its pivotal study to evaluate the safety and effectiveness of the DABRA excimer laser system for use as an atherectomy device for the treatment of peripheral vascular stenoses.

“My extensive experience with DABRA in treating infrainguinal vascular occlusions gives me confidence in the safety and efficacy of the device,” said Athar Ansari, MD, FACC, Director of the California Heart & Vascular Clinic in El Centro, Calif. and the study chairman. “We are thrilled to be the first center to begin enrollment in the atherectomy study, which represents an important next step in expanding the DABRA indications for use.”

“We are committed to the successful commercialization of DABRA and we believe that initiating patient enrollment in this study is a significant step forward in achieving this goal,” said Andrew Jackson, Ra Medical Systems CFO and Interim CEO. “Furthermore, we have built a team of experienced, motivated and enthusiastic physician partners and employees to execute on this goal and we look forward to providing updates on our progress.”

Ra Medical received investigational device exemption (IDE) approval for the study from the FDA in January 2020. This multicenter, open-label pivotal atherectomy clinical study will enroll up to 100 patients with symptoms of PAD (Rutherford Class 2-4). 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, before any adjunctive treatment. Major adverse events at 30 days and incidence of primary target lesion revascularization (TLR) at six months will be the safety and clinical success endpoints.

About DABRA

DABRA is Ra Medical’s minimally invasive excimer laser system used by physicians as a tool in the endovascular treatment of vascular blockages resulting from lower extremity vascular disease, a form of PAD, both above and below the knee. DABRA reduces all plaque types into their fundamental chemistry, such as proteins, lipids and other chemical compounds, eliminating blockages by essentially dissolving them without generating potentially harmful particulates. DABRA employs photoablation, or the removal of arterial tissue by using photons to clear blockages by breaking the bonds of the obstructing plaque.

About Ra Medical Systems

Ra Medical Systems commercializes excimer lasers and catheters for the treatment of vascular and dermatological diseases. In May 2017, the DABRA excimer laser system received FDA 510(k) clearance in the U.S. 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. 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, and the successful commercialization of DABRA. 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, 2018 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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