NEWS RELEASE

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Contact: Ronald Trahan, APR, Ronald Trahan Associates Inc., +1 (508) 816-6730, rtrahan@ronaldtrahan.com

Eximo Medical Receives FDA Clearance for *B-Laser™ Atherectomy System* to Treat Peripheral Artery Disease (Including ISR)

REHOVOT, Israel, Oct. 8, 2018—**Eximo Medical Ltd.** announced today it has received **510(k) clearance** from the **U. S. Food & Drug Administration (FDA)** for its **B-Laser™ Atherectomy System** for Peripheral Artery Disease (PAD). B-Laser™ is a transformative 355nm wavelength laser technology designed to address unmet clinical needs for treating multiple vascular indications. The specific indication cleared by the FDA is: "The B-Laser Atherectomy System is intended for use in the treatment, including atherectomy, of infrainguinal stenoses and occlusion, including in-stent restenosis (ISR)."

"This clearance represents a significant milestone for Eximo, as we can now offer the B-Laser™ Atherectomy System for PAD in the US. This is the first solid state, short pulse, 355nm laser system cleared in the U.S. for vascular interventions. Based on its technical characteristics, pre-clinical and clinical results and feedback that we have received from physicians, it seems that this laser system provides significant advantages over traditional 308nm excimer laser systems in terms of safety, efficacy, cost and ease of use" said **Yoel Zabar**, CEO of Eximo Medical. "We also plan to leverage our B-Laser™ platform technology to develop additional devices to address significant unmet needs in other vascular indications including lead extraction (for which we have completed a proof of concept), CAD, thrombectomy and Venous Disease. Additionally, we are developing an add-on photo-acoustic monitoring tool and a disruptive medical device for interventional gastrointestinal procedures."

Clinical evaluation of the B-Laser™ device in the intended population was performed in a prospective, single-arm, multi-center, open-label, non-randomized pilot clinical study in 50 subjects in Europe, as well as in a pivotal, prospective, single-arm, multi-center, open-label, non-randomized IDE clinical study in 97 subjects in the U.S. and Europe.

In the pilot clinical study, the results presented 100% success in crossing the target with no device-related perioperative clinically significant adverse events and no complications requiring intervention. There were no major adverse events (MAE) at one month and six months post procedure, and only two cases (4.3%) of TLRs among 46 subjects that completed the 1-year post-procedure follow-up. In the pivotal study, the safety and efficacy primary endpoints were achieved with high margins and the 6-months data was consistent with the pilot study results.

"I used the B-Laser™ in challenging procedures during the pivotal study and found the device easy to set up and use, and a valuable addition to our treatment portfolio," said the national PI, **Dr. John Rundback**, Interventional Radiologist and Director of the Interventional Institute at Holy Name Medical Center, Teaneck, NJ. "The enrollment in both US and Europe was quick (6.5 months), and the study results up to six months, have been very impressive despite treating diverse lesions including calcium, thrombus, and restenosis including ISR, both above and below the knee".

"After working with EXIMO and watching their unique technology mature over several years, it is exciting to see their B-Laser™ system achieve such positive results in a rigorous clinical trial, and to obtain FDA 510(k) clearance as a result. This user-friendly, compact and versatile therapeutic system, with indications for essentially all lesion subsets below the inguinal ligament, represents a significant advance and provides a new tool to help optimize results for our patients. I look forward to the development of many other applications for this unique laser system, which appears to have a superb safety and efficacy profile." said the SAB member, **Dr. Kenneth Rosenfield**, Section Head for Vascular Medicine and Intervention at Massachusetts General Hospital.

"I have been extremely impressed with the results with the B-Laser™ Atherectomy System demonstrated in the clinical trials. The excellent safety profile combined with extremely low need for repeat procedures make this a very promising alternative for our patients with complex vascular disease", said the SAB member **Dr. John Laird**, Medical Director of the Adventist Heart and Vascular Institute.

About Eximo Medical Ltd.

Eximo Medical is an Israeli startup company with a novel hybrid technology for superior tissue resection in various vascular and gastrointestinal endoluminal applications. B-Laser™, Eximo's proprietary single-use catheter, combines the best of the leading technology solutions: optical fibers that deliver short laser pulses, aspiration, and other innovative solutions.

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