First Enrolment in the ProVIDE Clinical Study for BPH Treatment

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DUBLIN, Ireland, June 10, 2022 -- ProVerum Limited, an Irish medical device company developing a minimally invasive solution to treat benign prostatic hyperplasia (BPH) in the doctor's office, today announced the commencement of the ProVIDE pivotal clinical trial to evaluate the safety and effectiveness of the ProVee System, a nitinol expander designed to gently re-shape the enlarged prostate and alleviate the symptoms caused by BPH. The first procedure was successfully performed by Sijo Parekattil, M.D., Principle Investigator at Avant Concierge Urology, Winter Garden, Florida .

According to Dr Parekattil, "The ProVee procedure is straightforward and comfortably performed in a doctor's office." He continued, "I see many patients whose quality of life are adversely impacted by the symptoms associated with an enlarged prostate and the ProVee System represents an exciting new alternative for BPH treatment".

Steve Kaplan, M.D., Professor of Urology at the Icahn School of Medicine at Mount Sinai in New York is the Global Lead Investigator for the ProVIDE study. "The ProVee System has the potential to be an effective treatment for BPH that can be safely and reliably performed in the office setting" said Dr. Kaplan. "This international, multi-center clinical study will thoroughly evaluate the safety, efficacy and long-term durability of the ProVee device and I look forward to presenting the data from this large controlled clinical trial."

About the ProVIDE Study

The ProVIDE clinical trial is a prospective, multi-center, double-blind controlled study to evaluate the safety, performance, and effectiveness of the ProVee System in patients with lower urinary tract symptoms secondary to BPH. 225 subjects, enrolled across 18 investigational sites in the US and 4 International sites, will be randomized to either receive

the ProVee System or undergo a sham procedure. After three months, patients will be unblinded and participants who underwent the sham procedure and meet the study inclusion criteria will be eligible to receive treatment with ProVee. Primary effectiveness will be evaluated using the International Prostate Symptom Score (IPSS) and based on the change from the subject's baseline measurement to those at three and twelve months.

About ProVerum Ltd

ProVerum Ltd. is an innovative Dublin based SME, founded in 2016 and focused on the development of novel minimally invasive technologies to treat BPH. The ProVee System is an investigational device and is not approved for commercial sale. For more information, please visit www.proverummedical.com

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