FDA Grants Prostate IDE Approval for NanoKnife System

AngioDynamics

AngioDynamics (Nasdaq:ANGO [1]) has announced the U.S. Food & Drug Administration (FDA) has granted Investigational Device Exemption (IDE) approval to conduct a clinical study of the NanoKnife System for the ablation of focal prostate cancer.

The Company is moving forward with institutional review board (IRB) submissions and anticipates commencing patient enrollment in the Company's fiscal 2014 second quarter, which ends November 30, 2013.

"The time is right to expand the NanoKnife System's evidence base in prostate," said Rick Stark, Senior Vice President of AngioDynamics' Oncology/Surgery Business. "Patients want less invasive procedures, and as imaging technology improves, the urology field is echoing the call by demanding options for focal ablation. With institutions like the University of Miami agreeing to participate in a study upon IRB approval, we are positioned to achieve high-quality insight into the potential for this technology."

Separately, AngioDynamics has established a partnership with the Clinical Research Office of the Endourological Society (CROES) and is pursuing a study to establish evidence for the NanoKnife System's position within the treatment armamentarium for low-intermediate localized prostate cancer. The study, "Multicenter Randomized Two-Arm Intervention Study Evaluating Irreversible Electroporation for the Ablation of Localized Unilateral Prostate Cancer," will involve six European centers and 200 patients.

"AngioDynamics has made a long term investment in the opportunity the NanoKnife System offers to physicians and their patients," said Joseph M. DeVivo, AngioDynamics President and Chief Executive Officer. "The place for this therapy is opening up as we pursue high quality evidence, and we look forward to sharing further details during our fourth quarter fiscal year 2013 earnings report and conference call."

Links:
[1] https://www.google.com/finance?q=NASDAQ:ANGO