Sapheon Submits First Module of PMA Application for VenaSeal Sapheon Closure System

The Associated Press

Sapheon Inc. announced today that it submitted the first module of the pre-market approval (PMA) application for the VenaSeal® Sapheon Closure System to the U.S. Food and Drug Administration (FDA). The submission places Sapheon on track for timely FDA review and expected product launch in the first half of 2015. VenaSeal is a minimally invasive, single use kit intended for the treatment of venous reflux (varicose veins) disease. The device is currently under clinical investigation in a 1:1 randomized pivotal study (the VeClose Study) to determine its safety and effectiveness compared to radio frequency thermal ablation.

“VenaSeal represents a novel approach to the treatment of venous reflux disease,” said Monte Madsen, Vice President, Clinical Affairs for Sapheon. “It is designed to eliminate the need for tumescent anesthesia by using our proprietary medical adhesive to close the great saphenous vein instead of heat to burn and destroy the vein.” The VeClose Study is authorized under an investigational device exemption (IDE) approved by the FDA in December 2012. Clinical investigators at 10 sites in the U.S. have treated 242 patients in the study. In addition to the VeClose Study, Sapheon is sponsoring two other VenaSeal studies: a 70-patient European post-market evaluation at seven sites within Germany, the UK, The Netherlands and Denmark that completed enrollment in September 2012; and a 38-patient feasibility study conducted in the Dominican Republic that completed enrollment in July 2011. The clinical data collected in these studies will be used to support the PMA application as well as to support product reimbursement activities in markets outside the United States.

The VenaSeal Sapheon Closure System received CE Mark approval in September 2011. Since that time, VenaSeal has been used to treat over 1,000 veins in patients in Europe and Hong Kong without tumescent anesthesia or the need for post-procedure compression hose therapy.

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