Osiris and FDA Reach Agreement on Regulatory Pathway for Biosurgery Products

The Associated Press

Osiris Therapeutics [1] (NASDAQ:OSIR [2]) has announced today that it has reached agreement with the United States Food and Drug Administration (FDA) regarding the regulatory pathway for its Biosurgery products, Grafix® and Ovation®.

After discussions with the FDA, the regulatory status of Grafix is confirmed and the product will remain on the market as a wound cover for the treatment of acute and chronic wounds. For certain expanded indications for Grafix, Osiris has committed to submit a Biologics License Application (BLA). Osiris will leverage existing clinical data in the preparation of the applications, including data from Protocol 302, its multi-center, randomized controlled trial which demonstrated a 192% relative improvement in closure rate of chronic diabetic foot ulcers as compared to patients receiving conventional therapy ($p<0.0001$).

Additionally, Osiris will continue transitioning its Ovation product line over to the company's newly launched OvationOS™ formulation and has agreed to complete this transition no later than the second half of 2014.

"We are pleased with the regulatory clarity this agreement provides and are excited to take this leadership role as we work with FDA in the evolving science and regulation of regenerative medicine," said C. Randal Mills, Ph.D., President and Chief Executive Officer of Osiris. "This effort will set a new standard in transplantation and will further spotlight the clinical benefits and high quality this innovative technology offers."

The commitments in this agreement will address the recent concerns FDA raised with respect to the regulatory status of Ovation and Grafix. The company's Cartiform® product is not affected.

Source URL (retrieved on *07/28/2014 - 12:04pm*):
http://www.mdtmag.com/news/2013/10/osiris-and-fda-reach-agreement-regulatory-pathway-biosurgery-products

Links:
[1] http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.osiris.com&esheet=50732635&newsitemid=20131021005456&lan=en-US&anchor=Osiris+Therapeutics%2C+Inc.&index=1&md5=81b3413de0b33c3d0f61370af71fd910

[2] https://www.google.com/finance?q=NASDAQ:OSIR