Tengion Announces FDA Orphan-Drug Designation for Neo-Urinary Conduit

Bio-Medicine.Org

EAST NORRITON, Pa., June 9, 2011 /PRNewswire/ -- Tengion, Inc. (Nasdaq: TNGN [1]) today announced that the U.S. Food and Drug Administration (FDA) has granted orphan-drug designation to the Company's Neo-Urinary Conduit™, for treatment of bladder dysfunction requiring incontinent urinary diversion.

"This designation is another important step in advancing the development of our Neo-Urinary Conduit, our lead clinical product candidate, currently being studied in patients with bladder cancer," said Sunita Sheth, M.D., Chief Medical Officer of Tengion.

Orphan drug designation entitles Tengion to seven years of U.S. marketing exclusivity for the Neo-Urinary Conduit if and when it receives regulatory approval, as well as additional incentives in the form of tax credits for clinical research expenses and a waiver of the FDA's application user fee. Orphan-drug status is granted by the FDA to promote the development of new therapies for medical conditions affecting fewer than 200,000 individuals in the United States.

About Tengion

Tengion, a clinical-stage biotechnology company, has pioneered the Organ Regeneration Platform™ that enables the Company to create proprietary product candidates that are intended to harness the intrinsic regenerative pathways of the body to produce a range of native-like organs and tissues. Tengion's product candidates seek to eliminate the need to utilize other tissues of the body for a purpose to which they are poorly suited, procure donor organs or administer anti-rejection medications. An initial clinical trial is ongoing for the Company's lead product candidate, the Neo-Urinary Conduit, an autologous implant that is intended to catalyze regeneration of native-like bladder tissue for bladder cancer patients requiring a urinary diversion following bladder removal. The Company's lead preclinic
'/>"/>

SOURCE [2]

Source URL (retrieved on *08/29/2014 - 6:12am*):
http://www.mdtmag.com/news/2011/06/tengion-announces-fda-orphan-drug-designation-neo-urinary-conduit?qt-video_of_the_day=0

Links:

[1] http://studio-5.financialcontent.com/prnews?Page=Quote&Ticker=TNGN
[2] http://www.bio-medicine.org/medicine-technology-1/Tengion-Announces-FDA-Orphan-Drug-Designation-for-Neo-Urinary-Conduit-18009-1/