GAINESVILLE, Fla., Dec. 5, 2012 /PRNewswire/ -- The University of Florida (UF) has started enrolling subjects in a new study testing the oral drug developed by Sound Pharmaceuticals, Inc. (SPI-1005) to prevent hearing loss caused by loud music. Loud music or noise can induce temporary and permanent auditory threshold shifts (TTS or PTS). As people age, the level of PTS grows and results in a moderate loss of speech perception and discrimination, especially in noisy environments. In this Phase-II interventional clinical trial, volunteers will listen to pre-selected music delivered using an iPod® and insert earphones providing an exposure that results in small but reliable temporary threshold shifts. Volunteers will take a placebo or SPI-1005 before and after this exposure, to assess the extent to which TTS is reduced, and/or the rate of recovery is accelerated. SPI-1005 is an oral capsule that contains ebselen, a synthetic molecule that mimics the activity of Glutathione Peroxidase (GPx), a critical enzyme in the inner ear that protects it from damage caused by loud sounds or noise. In animal studies, GPx decreases in several important auditory structures including hair cells, supporting cells, nerve and lateral wall structures such as the stria vascularis. In several preclinical studies, ebselen treatment was shown to improve the GPx levels within these structures and to reduce the TTS and PTS induced by loud noise.

"The goal of this clinical trial is to determine if SPI-1005 can prevent or reduce the TTS induced by listening to loud music," said Dr. Colleen Le Prell, PhD, Associate Professor and Lead Investigator at the UF College of Public Health and Health Professions' Department of Speech, Language, and Hearing Sciences.

Currently there are no FDA approved drugs for the prevention and treatment of sensorineural hearing loss. "The enrollment of this Ph-II study represents a significant milestone for SPI and we are excited to advance of our clinical programs to achieve proof of concept in man" said Eric Lynch, PhD, President, SPI. Details of the study can be viewed online at www.clinicaltrials.gov by searching SPI-1005.

SPI is a privately held biopharmaceutical company in Seattle with a focus on developing the first drugs for the prevention and treatment of hearing loss.

Please visit http://www.SoundPharma.com
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