

Sound Pharmaceuticals Files Second IND with the FDA for the Prevention of Chemotherapy Induced Hearing Loss in Advanced Stage Cancer

SEATTLE, July 23 /PRNewswire/ -- Sound Pharmaceuticals (SPI) has filed an Investigational New Drug Application with the FDA for the clinical testing of a proprietary formulation of ebselen for the prevention of chemotherapy induced hearing loss or ototoxicity. The oral capsule containing ebselen, SPI-3005, will be tested in advanced stage lung cancer and head and neck cancer patients receiving platinum based chemotherapy. This marks the second development program for SPI to enter clinical testing for a hearing loss indication. Last year, SPI-1005, an oral capsule containing ebselen entered Phase II testing with the US Navy for the prevention and treatment of noise induced hearing loss.

Currently there are no FDA approved drugs for the prevention and treatment of drug induced hearing loss or ototoxicity. SPI hopes to address this unmet medical need with its first in class first in indication drug. Several different research groups have shown that chemotherapy treatment reduces glutathione peroxidase (GPx) activity in the mammalian inner ear resulting in hearing loss, tinnitus, vertigo and dizziness. GPx is the dominant catalytic antioxidant enzyme within the inner ear, and a loss of its activity results in irreparable damage to hair cells, neurons and non-sensory tissues that are critical for hearing and balance. "A dose limiting side effect of platinum based chemotherapies are their devastating ototoxicity and neurotoxicity, and SPI-3005 is designed to attenuate these side effects without inhibiting the therapeutic efficacy of platinum or taxane based chemotherapies," said VP Eric Lynch, PhD.

"Otoprotectants such as SPI-3005 have the potential to reduce and/or alleviate chemotherapy-induced ototoxicity, and clinical studies should be pursued," said Stephen Fausti, PhD, and Director of the National Center for Rehabilitative Auditory Research (NCRAR) at the Portland VA, Professor of Otolaryngology and Neurology at Oregon Health Sciences University.

Sound Pharmaceuticals, Inc., is a privately held biopharmaceutical company with a focus on developing the first drugs for hearing loss and brain injury. For more information please contact Jonathan Kil, MD, President and CEO, 206-634-2559 or <http://www.soundpharma.com>.

SOURCE Sound Pharmaceuticals