

13therapeutics Completes Pre-IND Meeting with the FDA

PORTLAND, OR--13therapeutics, Inc., a bio-pharmaceutical company that develops peptides to treat a variety of inflammatory and auto-immune system diseases, announced today that the Company has completed a Type B pre-investigational new drug (Pre-IND) meeting with the U.S. Food and Drug Administration (FDA) to determine the clinical and regulatory pathway to advance its anti-inflammatory peptide, P13, for topical treatment of Acute Otitis Media (AOM) and Otitis Media with Effusion (OME).

AOM is the most frequent diagnosis in children with over 21 million cases each year in the U.S. and annual costs of over \$5 billion. AOM results in inflammation and fluid retention within the middle ear and Eustachian tube which can lead to hearing loss, delayed speech and language development, recurrent infections, and costly ear tubes. AOM is the most common indication for which an antibiotic is prescribed to children, but antibiotics have been shown to have limited therapeutic value, antibiotic resistant bacteria are a major public health concern, and antibiotics do not impact fluid retention in the middle ear.

“There is a major unmet medical need for a clinical therapeutic for AOM and OME that reduces middle ear inflammation and fluid and associated hearing impairment and sequelae, including learning impairment,” said Tom Bruggere, CEO of 13therapeutics. “In pre-clinical models of AOM and OME, P13 has been demonstrated to be an effective inhibitor of middle ear inflammation, to significantly reduce middle ear fluid retention, and to reduce hearing impairment.”

"We are very pleased with the outcome of our Pre-IND interaction with the FDA," commented Dr. Steven Hefeneider, President and CSO of 13therapeutics. "The FDA was very supportive of our efforts to advance a topical (ear drop) treatment for AOM and OME. As a result of the feedback we received on our Pre-IND package, we believe we have clear visibility for the required pathway to complete our toxicity testing for P13."

Founded in 2008, Portland, Oregon-based 13therapeutics has produced a portfolio of peptides with demonstrated immune-regulatory activity and with varying mechanisms of action. Many of the company's peptides are capable of multiple methods of delivery, have shown serum stability, and have other desired features of clinical therapeutics. The management team and research scientists of 13therapeutics are veterans of bioscience, research and technology. Website: www.13therapeutics.com.

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