FOR IMMEDIATE RELEASE

Oricula Therapeutics Secures $2M National Institutes of Health Grant to Further Develop Medicine to Preserve Hearing

Grant Supports Steps Towards Investigational New Drug Filing and Clinical Trials

SEATTLE, Wash. (February 2, 2016) – Oricula Therapeutics, LLC, a biotech company uniquely positioned to introduce medicines to preserve hearing and balance, announced that it has received a Phase 2 Grant of $2.06 million through the Small Business Innovation Research (SBIR) Program by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health. The award supports completion of the preclinical workup for their lead clinical compound (ORC-13661) and submission of an FDA Investigational New Drug (IND) application to support subsequent clinical trials. If successful, Oricula’s product will be the first medicine to be FDA-approved to protect the inner ear from permanent hearing loss caused by aminoglycoside antibiotics.

Oricula Therapeutics has focused its research on protecting the sound-sensing hair cells needed for hearing from damage caused by aminoglycosides, an effective but currently underused class of antibiotics. Prior to receiving this funding, Oricula Therapeutics had shown that ORC-13661 provides 100 percent hearing protection for rats co-administered a 10-day course of the aminoglycoside, amikacin. Further, histological examination of the cochlear epithelium from these animals shows no evidence of hair cell death. ORC-13661 is not mutagenic and does not interfere with the in vitro bactericidal potency of aminoglycosides against such bacteria strains as E.coli, P. aeruginosa, and M.tuberculosis. In addition, early rodent toxicology studies demonstrated that it is very well tolerated with a wide therapeutic index. The new SBIR funding will enable GLP-safety and toxicology testing required to file the IND and initiate Phase 1 human testing. According to Oricula CEO Malcolm Gleser, MD, PhD, “Now that the preclinical workup is assured, I’m spending much of my time designing the ideal first-in-human proof-of-concept clinical trials for our lead compound.”

While aminoglycosides are effective for the treatment of a variety of serious infectious diseases, including septicemia and multiple drug resistant tuberculosis, as many as 20 percent of patients treated with these antibiotics develop measurable, irreversible hearing loss or even deafness. Oricula Therapeutics’ goal to provide an adjunct therapy that effectively protects hearing and reduces or eliminates this safety concern would open the door to broader worldwide use of this highly effective, inexpensive class of antibiotics.

About Oricula Therapeutics

Privately held Oricula Therapeutics, LLC, headquartered in Seattle, Wash., is one of the first biotech companies focused on introducing medications to preserve hearing and balance from the damaging effects of medications and aging. Founded in 2013, Oricula is commercializing research conducted...
at the University of Washington and holds exclusive license to the resulting intellectual property. This uniquely positions Oricula to introduce the first FDA-approved medication to prevent hearing loss for patients undergoing aminoglycoside antibiotic treatment by protecting the sound-sensing hair cells in the inner ear that are necessary for hearing. By reducing or eliminating the debilitating side effect of permanent hearing loss, Oricula plans to open the door to wider worldwide use of these inexpensive yet effective antibiotics in the treatment of life-threatening bacterial infections. Oricula's first product has received funding to support progress toward FDA Initial New Drug (IND) filing. For more information, visit ORICULARX.COM.

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