For Immediate Release

FDA Clears Oricula Therapeutics Investigational New Drug Application for Clinical Trials
ORC-13661 Could be the First Medicine Approved Specifically to Prevent Hearing Loss of Patients Using Certain Antibiotics

SEATTLE, Wash. (February 5, 2018) – ORICULA THERAPEUTICS, LLC, a biotech company introducing medications to preserve hearing and balance, announced FDA permission to begin volunteer human testing for safety, tolerability, and pharmacokinetics of their novel, new medicine, ORC-13661. In animal studies, ORC-13661 provided highly significant protection of hearing in rats exposed to high doses of aminoglycoside antibiotics, a common cause of human hearing loss. If the same benefits hold true in clinical trials, ORC-13661 may be the first FDA-approved medicine to prevent hearing loss for patients undergoing aminoglycoside treatment.

Oricula Therapeutics CEO Malcolm Gleser, MD, Ph.D., elaborated, “Patients with cystic fibrosis, immune suppression, endocarditis, non-TB Mycobacteria, multiple drug-resistant TB as well as premature newborn infants are all candidate for aminoglycoside treatment and could benefit.” The compound works by protecting the sound-sensing hair cells in the inner ear that are necessary for hearing. Gleser added, “By reducing or eliminating the debilitating side effect of permanent hearing loss, Oricula sees expanded worldwide use of these inexpensive, highly effective antibiotics for treating life-threatening bacterial infections.”

Oricula is commercializing research conducted at the University of Washington and the Fred Hutchinson Cancer Research Center and holds an exclusive license to the resulting intellectual property. Edwin Rubel, Oricula co-founder and University of Washington Chaired Professor of Hearing Sciences said, “This research began in 2001 as a collaboration with Oricula co-founder David Raible, Professor of Biological Structure at the UW School of Medicine, to advance our understanding of the injury and death of receptor cells in the inner ear. Since these modest beginnings, we established a great, diverse team to accelerate development. We are now on the precipice of having an important, life-changing impact on the ability of people to communicate. I am enormously excited about the opportunity to begin clinical trials.”

Funding for the preclinical development was obtained through grants from the National Institutes of Health, including a $2.1 million grant from National Institute Of Allergy And Infectious Diseases.

About Oricula Therapeutics
Founded in 2013, privately held Oricula Therapeutics, LLC, headquartered in Seattle, Wash., is one of the first biotech companies introducing medications to preserve hearing and balance from the damaging effects of medications and aging. Oricula is commercializing research conducted at the University of Washington and the Fred Hutchinson Cancer Research Center and holds an exclusive license to the resulting intellectual property. This uniquely positions Oricula to introduce the first FDA-approved medication designed specifically to prevent hearing loss for patients undergoing aminoglycoside antibiotic treatment and expand the worldwide use of these inexpensive yet effective antibiotics to
treat life-threatening bacterial infections. Oricula’s first product has received FDA Initial New Drug (IND) approval to proceed with human trials. For more information, visit ORICULARX.COM.

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