



Strekin's development candidate, STR001, obtains EU orphan drug designation for the treatment of Sudden Sensorineural Hearing Loss

Strekin AG, a clinical-stage biopharmaceutical company, announced today that the European Medicines Agency (EMA) has granted orphan drug designation for the use of STR001 in the treatment of Sudden Sensorineural Hearing Loss.

"We are very pleased to receive EMA orphan drug designation for STR001", says Dr. Alexander Bausch, CEO of Strekin. "This is an important regulatory milestone for the company, and a significant step forward in clinical development of STR001 to fulfill a critical unmet need in hearing loss, for which no approved therapy exists today."

Orphan Drug Designation is granted to drug candidates under development that have demonstrated the potential for treating life-threatening or chronically debilitating conditions, which affect fewer than 5 out of 10,000 people in the EU, and which lack effective treatments.

STR001's orphan drug designation provides Strekin with various strategic advantages throughout the entire process of development to approval. These include 10 year market exclusivity, exemptions or reductions in regulatory fees, clinical protocol assistance, and access to the centralised authorisation procedure for a single application to the EMA.

About Sudden Hearing Loss

Sudden sensorineural hearing loss (SSNHL), also known as sudden deafness, is an abrupt loss of hearing caused by damage to the sound-sensing hair cells of the inner ear. Further symptoms may include ringing in the ears (tinnitus) and dizziness (vertigo). Sudden hearing loss can be considered a medical emergency. Individuals who perceive a sudden change in their hearing are recommended to contact their health care provider without delay. Hearing loss makes daily activities most people take for granted, like having a conversation, enjoying music, and communicating effectively in the work environment, difficult or impossible.

About STR001

STR001 is Strekin's lead drug candidate. STR001 is a potent PPAR γ (peroxisome proliferator-activated receptor-gamma) agonist currently in Phase 2 clinical development for the treatment of hearing loss. STR001 effectively protects auditory hair cells of the inner ear through several mechanisms, and is anticipated to promote hair cell survival and restoration of function in the face of a damaging insult or sudden deafness event. STR001's otoprotective properties have been extensively researched in diverse preclinical models of cochlear hair cell protection and hearing loss. Top-line results of the ongoing Phase 2 clinical trial of STR001 are anticipated in the 4th quarter of 2017.



About Strekin

Strekin AG is a clinical-stage biopharmaceutical company located in Basel, Switzerland. Strekin is led by an expert team with extensive experience in successful discovery, development, and commercialization of new drugs. Strekin focuses on discovering the untapped therapeutic potential of drugs affecting cell stress-related inflammatory pathways in new indications. Strekin is privately funded by a broad base of investors. Strekin has secured funding to complete the Phase 2 study of STR001 and to launch further clinical development with the support of additional investors and partners.