

Press Release

Astellas and Frequency Therapeutics Enter into License Agreement for FX-322, a Regenerative Treatment Candidate for Hearing Loss

Astellas Obtains the Exclusive Rights to Develop and Commercialize FX-322 in Ex-US Markets; Frequency Retains U.S. Rights

Frequency will Receive \$80 Million Upfront from Astellas with the Potential of up to \$545 Million in Future Milestone Payments as well as Double-Digit Royalties

TOKYO and WOBURN, Mass., July 17, 2019 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., “Astellas”) and Frequency Therapeutics, Inc. (CEO: David Lucchino, “Frequency”) today announced that they have entered into an exclusive license agreement to develop and commercialize Frequency’s regenerative therapeutic candidate, FX-322, for the treatment of sensorineural hearing loss, the most common type of hearing loss. At present, there are no approved therapeutic options for sensorineural hearing loss.

Under the terms of the agreement, Astellas will be responsible for the development and commercialization of FX-322 outside of the U.S. and Frequency will be responsible for U.S. development and commercialization. The companies will be jointly responsible for conducting global clinical studies and coordinating commercial launch activities. Frequency will receive an upfront payment of \$80 million and may also receive up to an additional \$545 million based on development and commercial milestones, as well as royalties on any future product sales in the licensed territory.

Frequency recently completed a Phase 1/2 clinical study in the U.S. in which FX-322 was observed to be well-tolerated following a single intratympanic injection, with no serious adverse events. Improvements in hearing function were observed in multiple FX-322 treated patients. Frequency plans to initiate a Phase 2a study in the fourth quarter of 2019.

FX-322 is a proprietary combination of small-molecule drugs designed to restore hearing function by activating inner ear progenitor cells already present in the body to induce hair cell regeneration. Sensorineural hearing loss is the result of damage to and/or loss of sensory hair cells in the inner ear. These inner ear hair cells do not spontaneously regenerate once damaged, although progenitor cells capable of regenerating hair cells remain present in the ear in an inactive state.

The World Health Organization (WHO) estimates that there are currently more than 800 million adults with hearing loss globally. According to the U.S. National Institutes of Health, approximately 90 percent of those with hearing loss are affected by sensorineural hearing loss.

“FX-322 is a program that focuses on the mechanism of regeneration. Astellas is committed to exploring all types of partnership opportunities to turn cutting-edge

science and technological advances into VALUE for patients,” said Naoki Okamura, Representative Director Corporate Executive Vice President, Chief Strategy Officer, Astellas. “We look forward to further investigating the potential of FX-322 to improve hearing function in patients around the world.”

“Collaborating with Astellas provides us an opportunity to work with a partner that has deep, global clinical development and commercial expertise and shares our focus in pursuing novel regenerative medicines for patients with diseases where there are no therapeutic options,” said David Lucchino, Frequency’s Chief Executive Officer. “We are excited to collaborate with them to advance FX-322 for patients with sensorineural hearing loss and to further demonstrate the potential of our platform for progenitor cell activation.”

Astellas reflected the impact from this agreement in its financial forecasts of the current fiscal year ending March 31, 2020.

About Sensorineural Hearing Loss

Sensorineural hearing loss is the most common form of hearing loss, resulting from damage to the hair cells in the inner ear or problems with the nerve pathways that convert sound waves from the inner ear to the brain. Hair cells are commonly lost due to chronic noise exposure, or as a result of aging, certain viral infections or exposure to ototoxic drugs. The WHO estimates that 1.1 billion children and adults ages 12 to 35 years old are at risk for hearing loss from recreational noise exposure.

About Astellas

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. For more information, please visit our website at <https://www.astellas.com/en>

About Frequency Therapeutics

Frequency Therapeutics is a biotech company focused on developing small molecule drugs that stimulate cells in the body to reverse biological deficits and restore healthy tissue. Through the transitory activation of these cells, Frequency aims to develop therapies that can enable disease modification without the complexity of genetic engineering. Our development candidates use a proprietary combination of small-molecule drugs that induce progenitor cells to multiply and create new cells. While Frequency’s lead program targets hearing restoration, our PCA platform may have the potential to touch upon a wide breadth of therapeutic areas. For more information visit www.frequencytx.com.

Cautionary Notes (Astellas)

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management’s current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to

pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties. Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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