HARMONY BIOSCIENCES ANNOUNCES FILE ACCEPTANCE OF ITS NEW DRUG APPLICATION FOR PITOLISANT

FDA GRANTS PRIORITY REVIEW OF THE PITOLISANT NDA

PLYMOUTH MEETING, PA, February 12, 2019 — Harmony Biosciences, LLC (Harmony) announced today that the U.S. Food and Drug Administration (FDA) has accepted for filing the New Drug Application (NDA) for its investigational product, pitolisant, and has granted Priority Review for this NDA. Pitolisant is a first-in-class molecule with a novel mechanism of action; it is a potent and highly selective histamine 3 (H_3) receptor antagonist/inverse agonist for the potential treatment of excessive daytime sleepiness (EDS) and/or cataplexy in adult patients with narcolepsy. A Priority Review designation by the FDA indicates that, if approved, pitolisant would provide a significant improvement in the safety or effectiveness of the treatment of EDS and/or cataplexy in adult patients with narcolepsy when compared to existing treatments. Harmony's goal is to obtain FDA approval to market pitolisant in the U.S. in 2019.

"The impact of narcolepsy can be significant, and severely disruptive to everyday life for up to 200,000 Americans living with this disorder," said John C. Jacobs, President and CEO at Harmony. "This is an important step for patients and for our company, whose mission is to develop novel treatment options for people living with rare and orphan diseases."

"Pitolisant offers a novel approach to the treatment of both EDS and cataplexy in patients with narcolepsy, for which there have been no new treatment options in over 15 years," said Jeffrey M. Dayno, M.D., Chief Medical Officer at Harmony. "We look forward to working with the FDA during its review of the pitolisant NDA with our hope of being able to offer this new treatment option to help address an important unmet medical need for people living with narcolepsy."

The NDA submission is based on results from the clinical development program in narcolepsy which included over 300 patients, some of whom were treated for up to five years. It also included safety data in over 1500 patients across multiple patient populations.

About Pitolisant

Pitolisant is an investigational medication in the U.S. that is not approved by the FDA. It was granted orphan designation for the treatment of narcolepsy, Fast Track designation for the treatment of excessive daytime sleepiness (EDS) and cataplexy in patients with narcolepsy, and Breakthrough Therapy designation for the treatment of cataplexy in patients with narcolepsy. Pitolisant, a first-in-class medication, is a potent and highly selective histamine 3 (H_3) receptor antagonist/inverse agonist; it enhances the activity of histaminergic neurons in the brain that function to improve a patient's

wakefulness and inhibit attacks of cataplexy. It was designed and developed by Bioprojet who has marketed the product in Europe since its approval by the European Medicines Agency in 2016. Harmony's goal is to obtain FDA approval to market this new medication in the U.S. in 2019. If approved, pitolisant would represent the first new therapy in the U.S. in over 15 years for the treatment of both EDS and cataplexy in adult patients with narcolepsy.

About Narcolepsy

Narcolepsy is a rare, chronic, debilitating neurologic disorder of sleep-wake state instability that impacts up to 200,000 Americans and is primarily characterized by EDS, cataplexy, and other manifestations of REM sleep dysregulation, which intrude into wakefulness. In most patients, it is caused by the loss of hypocretin, a neuropeptide in the brain that supports sleep-wake state stability. This disorder affects men and women equally with typical symptom onset in adolescence or young adulthood; however, it can take up to a decade to be properly diagnosed. Narcolepsy can cause significant burden for patients and their families, affecting their ability to perform routine tasks, limit achievement at school and work, impact social relationships and cause impairment in overall quality of life.

About Cataplexy

Cataplexy is one of several symptoms of narcolepsy that represent elements of REM sleep state intruding into wakefulness, characterized by sudden temporary loss of muscle tone. Cataplexy can be subtle, such as drooping of eyelids, or severe, such as knee buckling or total body collapse. Often times, symptoms of cataplexy may go unrecognized because of the subtle nature of the symptoms in some patients, variability of how cataplexy is expressed, and/or lack of patient complaints or physician recognition of the symptoms as manifestations of cataplexy. This symptom of narcolepsy can often cause significant impact on a person's ability to carry out normal daily functions. Up to two-thirds of all patients with narcolepsy have cataplexy (known as Type 1 narcolepsy); cataplexy is one of the most debilitating symptoms of this chronic, rare neurologic disorder.

Harmony Biosciences, LLC

Harmony Biosciences, LLC, is a private biopharmaceutical company headquartered in Plymouth Meeting, PA. The company was established in October 2017 with a vision to provide novel treatment options for people living with rare and orphan diseases with an emphasis on central nervous system disorders, starting with patients living with narcolepsy. Harmony is committed to advancing the understanding of narcolepsy and providing information and resources to individuals who live with, and healthcare professionals who treat, patients with this disorder. For more information on Harmony Biosciences, visit **www.harmonybiosciences.com**.

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