WAKIX® (PITOLISANT) DATA FROM HARMONY BIOSCIENCES INCLUDED ON AMERICAN ACADEMY OF NEUROLOGY SCIENCE HIGHLIGHTS VIRTUAL PLATFORM

June 2, 2020 12:00 PM EDT

PLYMOUTH MEETING, PA, June 2, 2020 —Harmony Biosciences, LLC ("Harmony"), a private pharmaceutical company dedicated to developing and commercializing novel treatment options for people living with rare diseases, announced today that it uploaded two posters with data on the efficacy and safety of WAKIX® (pitolisant) to the American Academy of Neurology (AAN) Science Highlights virtual platform. The abstracts of these posters are also included in an online supplement of the journal *Neurology* in the "Sleep Medicine: Focus on Therapies 2" poster session.

"We are pleased to have an opportunity to share these important data via this innovative approach with the broader neurology community," said Harmony's Chief Medical Officer, Jeffrey Dayno, M.D. "These data on the efficacy and safety of WAKIX strengthen the body of scientific evidence that supports WAKIX as a potential treatment option for adult patients living with narcolepsy."

The data posted by Harmony on AAN's Science Highlights virtual platform include:

- **Efficacy of Pitolisant in Patients with High Burden of Narcolepsy Symptoms.** *Davis, L Krahn, B Vaughn, M Thorpy.*
    - Results from a post-hoc analysis evaluating the efficacy of pitolisant in patients with a high burden of narcolepsy symptoms. Data were pooled from two randomized, placebo-controlled, seven- and eight-week studies of pitolisant in adults with narcolepsy.
- **Safety and Tolerability of Pitolisant in the Treatment of Adult Patients With Narcolepsy: An Open-Label Expanded Access Program in the United States.** *E Bauer, C Davis, A Patroneva, J Dayno, M Thorpy.*
    - Results from the final data analysis of the Pitolisant Expanded Access Clinical Evaluation (PEACE) Program, which provided adult patients in the U.S. living with narcolepsy access to treatment with pitolisant before its approval by the U.S. Food and Drug Administration (FDA).

About WAKIX (pitolisant) Tablets
WAKIX is a first-in-class medication approved by the U.S. Food and Drug Administration in August 2019 for the treatment of excessive daytime sleepiness in adult patients with narcolepsy. It was granted orphan drug designation for the treatment of narcolepsy in 2010. WAKIX is a selective histamine 3 (H_3) receptor antagonist/inverse agonist. The mechanism of action of WAKIX is unclear; however, its efficacy could be mediated through its activity at H_3 receptors, thereby increasing the synthesis and release of histamine, a wake promoting neurotransmitter. WAKIX was designed and developed by Bioprojet Societe Civile de Recherche (Bioprojet), who has marketed the product in Europe since its approval by the European Medicines Agency in 2016. Harmony has an exclusive license from Bioprojet to develop, manufacture and commercialize pitolisant in the United States.

Important Safety Information
WAKIX is contraindicated in patients with severe hepatic impairment. WAKIX is extensively metabolized by the liver and there is a significant increase in WAKIX exposure in patients with moderate impairment.

WAKIX prolongs the QT interval; avoid use of WAKIX in patients with known QT prolongation or in combination with other drugs known to prolong the QT interval. Avoid use in patients with a history of cardiac arrhythmias, as well as other circumstances that may increase the risk of the occurrence of torsade de pointes or sudden death, including symptomatic bradycardia, hypokalemia or hypomagnesemia, and the presence of congenital prolongation of the QT interval.

The risk of QT prolongation may be greater in patients with hepatic or renal impairment due to higher concentrations of pitolisant; monitor these patients for increased QTc. Dosage modification is recommended in patients with moderate hepatic impairment and moderate or severe renal impairment. WAKIX is not recommended in patients with end-stage renal disease (ESRD).

In the placebo-controlled clinical trials conducted in patients with narcolepsy with or without cataplexy, the most common adverse reactions (≥5% and twice placebo) for WAKIX were insomnia (6%), nausea (6%), and anxiety (5%). Other adverse reactions that occurred at ≥2% and more frequently than in patients treated with placebo included headache, upper respiratory infection, musculoskeletal pain, heart rate increased, hallucinations, irritability, abdominal pain, sleep disturbance, decreased appetite,

cataplexy, dry mouth, and rash.

Please see the Full Prescribing Information for WAKIX for more information.

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 excessive daytime sleepiness (EDS) and cataplexy – its two cardinal symptoms – along with other manifestations of REM sleep dysregulation, which intrude into wakefulness. EDS is the inability to stay awake and alert during the day and is the symptom that is present in all people living with narcolepsy. In most patients, narcolepsy 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.

About Harmony Biosciences, LLC
Harmony Biosciences, LLC is a private pharmaceutical company headquartered in Plymouth Meeting, PA. The company was established in October 2017 by Paragon Biosciences, LLC www.paragonbiosci.com 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. For more information on Harmony Biosciences, visit www.harmonybiosciences.com.

Harmony Biosciences, LLC Media Contact:
Nancy Leone
215-891-6046
nleone@harmonybiosciences.com