HARMONY BIOSCIENCES TO PRESENT NEW DATA FOR WAKIX® (PITOLISANT) AT SLEEP 2020 ANNUAL MEETING

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Four poster presentations will feature clinically relevant efficacy and safety data analyses for WAKIX in adult patients with narcolepsy

PLYMOUTH MEETING, PA, and CHICAGO, IL, August 24, 2020 —Harmony Biosciences Holdings, Inc. ("Harmony") (Nasdaq: HRMY), a pharmaceutical company dedicated to developing and commercializing innovative therapies for patients living with rare neurological disorders who have unmet medical needs, announced today it will present new data on the safety and efficacy of WAKIX® (pitolisant), including four poster presentations at the upcoming 34th Annual Meeting of the Associated Professional Sleep Societies (APSS), known as "SLEEP 2020." The meeting is being held virtually from August 27-30. Abstracts of the WAKIX data will also be published in the journal SLEEP as an online supplement.

The data include a final analysis of the Pitolisant Expanded Access Clinical Evaluation Program (PEACE), two post-hoc analyses on clinically relevant outcomes from the Phase 3 clinical trials, and analyses that further characterize the cardiac safety profile of WAKIX from the clinical development program.

"We continue to analyze the extensive database from the clinical development program for WAKIX and are pleased to have the opportunity to highlight new analyses that demonstrate clinically relevant outcomes for WAKIX in the treatment of adult patients with narcolepsy," said Harmony's Chief Medical Officer, Jeffrey Dayno, M.D. "These analyses add to the growing body of scientific evidence supporting WAKIX and validate our commitment to continuing to provide patients and their healthcare providers with important information about this treatment option."

The data being presented by Harmony include:

- Safety and Tolerability of Pitolisant in the Treatment of Adult Patients With Narcolepsy: Final Analysis of An Open-Label, Expanded Access Program in the United States (Poster 0766) E Bauer, C Davis, A Patroneva, J Dayno, M Thorpy.
    - Results from a final 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).
- Time Course of Improvement in Excessive Daytime Sleepiness and Cataplexy During Treatment with Pitolisant in Patients with Narcolepsy (Poster 0768) A Roy, C Davis, B Vaughn, J Dayno, Y Dauvilliers, J-C Schwartz.
    - Analysis evaluating the time-to-response of pitolisant for both excessive daytime sleepiness and cataplexy from three randomized, placebo-controlled studies in adult patients with narcolepsy.
- Efficacy of Pitolisant in Patients with High Burden of Narcolepsy Symptoms (Poster 0762) C Davis, U Kallweit, L Krahn, B Vaughn, M Thorpy.
    - Results from a post-hoc analysis evaluating the efficacy of pitolisant in patients who had a high burden of the main narcolepsy symptoms of excessive daytime sleepiness and cataplexy at baseline. Data were pooled from two randomized, placebo-controlled studies of pitolisant in adult patients with narcolepsy.
- Cardiac Safety Profile of Pitolisant in Patients with Narcolepsy (Poster 0744) W Winter, S Wanaski, A Patroneva, J Dayno.
    - Analysis of the cardiac safety profile of pitolisant in adults with narcolepsy from the clinical development program.

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 165,000 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
Harmony Biosciences is a pharmaceutical company headquartered in Plymouth Meeting, PA and Chicago, IL. The company was established in October 2017 by Paragon Biosciences, LLC, with a vision to provide novel treatment options for people living with rare, neurological disorders who have unmet medical needs.

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