Harmony Biosciences To Present WAKIX® (pitolisant) Efficacy and Safety Data at Upcoming 2021 American Psychiatric Association Annual Meeting

April 27, 2021

Three presentations will feature analyses from the clinical development program that characterize the efficacy and safety profile of WAKIX in adult patients with narcolepsy

PLYMOUTH MEETING, Pa., April 27, 2021 /PRNewswire/ -- Harmony Biosciences Holdings, Inc. ("the Company") (Nasdaq: HRMY), a pharmaceutical company dedicated to developing and commercializing innovative therapies for patients living with rare neurological disorders who have unmet medical needs, today announced that data from three analyses of the clinical development program for WAKIX® (pitolisant), a medication approved for the treatment of excessive daytime sleepiness or cataplexy in adults with narcolepsy, will be presented at the 2021 American Psychiatric Association (APA) Annual Meeting, to be held virtually May 1-3. Two of the three poster presentations feature analyses of efficacy and safety data from the clinical development program for WAKIX in adult patients with narcolepsy and the third is based on a post-hoc analysis that evaluated the time to onset of clinical response for WAKIX.

"Both excessive daytime sleepiness and cataplexy can have a significant impact on a person's daily functioning, which may greatly affect their social, emotional and psychological well-being," said Harmony's Chief Medical Officer, Jeffrey Dayno, M.D. "Given this, and the fact that sleep disorders are co-morbid with several different psychiatric disorders, we are pleased to share these data for WAKIX with the psychiatry and mental health professional communities for the first time."

The data to be presented by Harmony will be available from 11 a.m. to 5:30 p.m. EDT on May 1-3, and includes:

- **Efficacy and Safety of Pitolisant in the Treatment of Excessive Daytime Sleepiness in Adult Patients With Narcolepsy: A Review of Clinical Trials (Poster 4463).** *L Krahn, C Davis, J-C Schwartz, J Dayno.*
  - Analysis of results from HARMONY 1 and HARMONY 1bis, two pivotal randomized, placebo-controlled, 8-week trials that assessed the efficacy and safety of pitolisant for the treatment of excessive daytime sleepiness in adults with narcolepsy.
- **Efficacy of Pitolisant, a Selective Histamine 3 (H3)-Receptor Antagonist/Inverse Agonist, in the Treatment of Cataplexy in Patients With Narcolepsy (Poster 4460).** *M Thorpy, J-C Schwartz, C Caussé, J Dayno.*
  - A review of results from HARMONY 1, HARMONY 1bis, HARMONY CTP and HARMONY 3 Phase 3 clinical trials, which assessed safety and efficacy of pitolisant for the treatment of cataplexy in adults with narcolepsy.
- **Time Course of Improvement in Excessive Daytime Sleepiness and Cataplexy During Treatment with Pitolisant in Patients with Narcolepsy (Poster 4469).** *C Davis, J Dayno, B Vaughn, Y Dauvilliers, J-C Schwartz.*
  - Analysis evaluating the time-to-response to treatment with pitolisant for excessive daytime sleepiness and cataplexy from the HARMONY-1 and HARMONY-CTP randomized, placebo-controlled trials in adults with narcolepsy.

About WAKIX® (pitolisant) Tablets

WAKIX, a first-in-class medication, is approved by the U.S. Food and Drug Administration for the treatment of excessive daytime sleepiness or

cataplexy in adult patients with narcolepsy. WAKIX has been commercially available in the U.S. since Q4 2019. 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 (France). 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 known hypersensitivity to pitolisant or any component of the formulation and 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 of WAKIX 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 neurological disorder of sleep-wake state instability that impacts approximately 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. The company was established by Paragon Biosciences, LLC, with a vision to provide novel treatment options for people living with rare neurological disorders who have unmet medical needs. For more information on Harmony Biosciences, please visit the company's website: www.harmonybiosciences.com.

Forward Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including statements regarding our product WAKIX. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: our commercialization efforts and strategy for WAKIX; the rate and degree of market acceptance and clinical utility of WAKIX, pitolisant in additional indications, if approved, and any other product candidates we may develop or acquire, if approved; our research and development plans, including our plans to explore the therapeutic potential of pitolisant in additional indications; our ongoing and planned clinical trials; our ability to expand the scope of our license agreement with Bioprojet; the availability of favorable insurance coverage and reimbursement for WAKIX; the impact of the COVID-19 pandemic; the timing of and our ability to obtain regulatory approvals for pitolisant for other indications as well as any other product candidates; our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; our ability to identify additional products or product candidates with significant commercial potential that are consistent with our commercial objectives; our commercialization, marketing and manufacturing capabilities and strategy; significant competition in our industry; our intellectual property position; loss or retirement of key members of management; failure to successfully execute our growth strategy, including any delays in our planned future growth; our failure to maintain effective internal controls; the impact of government laws and regulations; volatility and fluctuations in the price of our common stock; and the significant costs and required management time as a result of operating as a public company; the fact that the price of Harmony's common stock may be volatile and fluctuate substantially; significant costs and required management time as a result of operating as a public company. These and other important factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 25, 2021, and our other filings with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

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