Harmony Biosciences Announces Initiation of First-In-Human Study With Potential Best-In-Class Orexin 2 Receptor Agonist (BP1.15205) for Central Disorders of Hypersomnolence

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BP1.15205 is a differentiated chemical scaffold, demonstrating high potency and selectivity in preclinical studies with a favorable safety profile and the potential for once-daily dosing

Topline clinical data expected in 2026

PLYMOUTH MEETING, Pa.--(BUSINESS WIRE)--Nov. 19, 2025-- Harmony Biosciences Holdings, Inc. (Nasdaq: HRMY) today announced dosing of the first participant in a Phase 1 clinical trial of BP1.15205, an investigational, potentially best-in-class, orexin 2 receptor (OX2R) agonist being developed for the treatment of narcolepsy, idiopathic hypersomnia and other central disorders of hypersomnolence. The Phase 1 clinical trial will assess the safety, tolerability, pharmacokinetics and pharmacodynamics of BP1.15205 after single and multiple ascending doses in healthy volunteers and sleep-deprived healthy subjects. Topline data are expected in 2026.

“We are very excited to advance BP1.15205 into clinical development based on its compelling preclinical risk-benefit profile,” said Kumar Budur, MD, MS, Chief Medical and Scientific Officer at Harmony Biosciences. “Based on the potency data for BP1.15205, it has the potential to enable very low, once-daily dosing, which may translate into a favorable risk-benefit profile for patients with central disorders of hypersomnolence.”

Earlier this year, Harmony Biosciences presented comprehensive preclinical safety and efficacy data for BP1.15205 at SLEEP 2025 and at the World Sleep Congress. Functional receptor studies confirmed that the asset is a highly potent and selective OX2R agonist with no observed off-target effects. The preclinical data revealed no adverse events of interest, supporting a favorable safety and tolerability profile.

“The advancement of our orexin program is an important expansion of our sleep-wake franchise, especially in a market where polypharmacy is the norm,” Dr. Budur added. “We believe orexin agonists will complement our pitolisant-based assets, allowing Harmony to offer additional treatment options that address the complex, individualized needs of patients with narcolepsy and other hypersomnolence disorders.”

The Phase 1 clinical trial is being conducted by Bioprojet Pharma in the European Union. Bioprojet originally licensed BP1.15205 from Teijin Pharma. Harmony Biosciences has an exclusive licensing agreement with Bioprojet to develop, manufacture and commercialize BP1.15205 in the United States and Latin American territories.

About Narcolepsy

Narcolepsy is a rare, chronic, debilitating neurological disease of sleep-wake state instability that impacts approximately 170,000 Americans and is primarily characterized by excessive daytime sleepiness (EDS) and cataplexy – its two cardinal symptoms – along with other manifestations of REM sleep dysregulation (hallucinations and sleep paralysis), 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/orexin, a neuropeptide in the brain that supports sleep-wake state stability. This disease 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 Idiopathic Hypersomnia

Idiopathic Hypersomnia (IH) is a rare and chronic neurological disease that is characterized by excessive daytime sleepiness (EDS) despite sufficient or even long sleep time. EDS in IH cannot be alleviated by naps, longer sleep or more efficient sleep. People living with IH experience significant EDS along with the symptoms of sleep inertia (prolonged difficulty waking up from sleep) and 'brain fog' (impaired cognition, attention, and alertness). The cause of IH is unknown, but it is likely due to alterations in areas of the brain that stabilize states of sleep and wakefulness. IH is one of the central disorders of hypersomnolence and, like narcolepsy, is a debilitating sleep disorder that can result in significant disruption in daily functioning.

About Harmony Biosciences

Harmony Biosciences is a pharmaceutical company dedicated to developing and commercializing innovative therapies for patients

with rare neurological diseases who have unmet medical needs. Driven by novel science, visionary thinking, and a commitment to those who feel overlooked, Harmony Biosciences is nurturing a future full of therapeutic possibilities that may enable patients with rare neurological diseases to truly thrive. Established by Paragon Biosciences, LLC, in 2017 and headquartered in Plymouth Meeting, Pa., we believe that when empathy and innovation meet, a better future can begin; a vision evident in the therapeutic innovations we advance, the culture we cultivate, and the community programs we foster. For more information, please visit www.harmonybiosciences.com.

Forward-Looking Statements

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 full year 2025 net product revenue, expectations for the growth and value of WAKIX, plans to submit an sNDA for pitolisant in idiopathic hypersomnia; our future results of operations and financial position, business strategy, products, prospective products, product approvals, the plans and objectives of management for future operations and future results of anticipated products. 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 pitolisant in additional indications, if approved, and any other product candidates we may develop or acquire, if approved, including ZYN002 and EPX-100; 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 agreements with Bioprojet Société Civile de Recherche ("Bioprojet"); the availability of favorable insurance coverage and reimbursement for WAKIX; 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 additional financing needs; our ability to identify, acquire and integrate 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; 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; statements related to our intended share repurchases and repurchase timeframe; and macroeconomic effects and changes in market conditions, including the impact of tariffs, inflation and the risk of recession. 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 February 25, 2025, 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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