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# Harmony Biosciences Acquires US Rights To Pitolisant From Bioprojet; Raises \$270 Million In Equity Financing

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**FUNDING WILL ACCELERATE DEVELOPMENT AND REGISTRATION OF A NOVEL DRUG FOR ADULTS SUFFERING FROM NARCOLEPSY**

October 5, 2017—Plymouth Meeting, PA — Biopharmaceutical company Harmony Biosciences, LLC (Harmony), a member of the Paragon Biosciences (Paragon) corporate family, today announced it has acquired the exclusive US right to develop, register and market the drug pitolisant from French company Bioprojet SCR (Bioprojet). Harmony, established and guided by Paragon and its experienced team, also announced that it completed a \$270 million equity financing

to facilitate this acquisition and accelerate its ability to address unmet needs for patients with sleep and other central nervous system disorders.

Pitolisant is a selective histamine H<sub>3</sub>-receptor antagonist/inverse agonist that enhances the activity of histaminergic neurons. The drug is approved in the European Union (EU) and distributed under the tradename WAKIX<sup>®</sup> for the treatment of narcolepsy in adult patients with and without cataplexy. Currently no H<sub>3</sub>-receptor antagonist/inverse agonist has been approved by the US Food & Drug Administration (FDA).

Pitolisant has been recently approved by the European Medicines Agency (EMA) to treat adults suffering from narcolepsy, a serious, chronic disorder characterized by excessive daytime sleepiness (EDS), with or without cataplexy. Cataplexy is characterized by sudden and uncontrolled muscle weakness or paralysis. Pitolisant increases the release of the brain chemical histamine to increase a patient's wakefulness and alertness.

Harmony and the Paragon family of companies are dedicated to biomedical

innovation for patients suffering from challenging and debilitating but often ignored diseases. With Paragon's significant resources and expertise, Harmony raised over \$270 million from highly experienced equity investors including Valor Equity Partners, Fidelity Management & Research Company, HBM Healthcare Investments, Vivo Capital, venBio Partners, Novo Holdings and Nan Fung Life Sciences. This funding will enable Harmony to fulfill its mission of providing novel treatment options to patients with orphan and rare conditions, with a focus on CNS disorders.

Pitolisant was developed after decades of research by Bioprojet co-founders Dr. Jeanne-Marie Lecomte and Prof. Jean-Charles Schwartz.

“Bioprojet is proud to partner with Harmony. With our collaborative best-in-class approach, we plan to help bring much needed relief to thousands of people suffering from these debilitating diseases and to research and develop pitolisant for other unsatisfied medical conditions,” said Prof. Schwartz.

Harmony is led by CEO Bob Repella, a veteran of the pharmaceutical industry with significant experience in bringing drugs to market to treat orphan and rare disorders.

“We’re excited to research, develop and seek US approval for pitolisant, a potential first-in-class therapy to treat patients with narcolepsy,” Repella said. “In addition to working with the FDA, Harmony will be working closely with healthcare providers, advocacy organizations, and other stakeholders to help address the unmet needs of the patient community.”

Harmony and Bioprojet will continue collaborative research/development under the guidance of a joint development committee. Harmony intends to establish an expanded access program (EAP) for pitolisant in the US in early 2018 and expects to submit a new drug application (NDA) for the treatment of narcolepsy in adult patients during the first half of 2018.

Octagon Capital Group served as financial advisor to Harmony Biosciences in connection with the financing and

acquisition transactions. Bionest Partners Finance served as financial advisor to Bioprojet in connection with the acquisition transaction. Katten Muchin Rosenman LLP served as legal counsel to Harmony. McDermott Will & Emery served as legal counsel to Bioprojet.

### **About Pitolisant:**

Pitolisant is a selective histamine H<sub>3</sub>-receptor antagonist/inverse agonist which enhances the activity of histaminergic neurons. The drug was approved by the EMA in 2016 for the treatment of narcolepsy in adults with or without cataplexy but is not approved in the US. Pitolisant has an orphan designation in the EU and the US for the treatment of narcolepsy.

### **About Narcolepsy:**

Narcolepsy is a rare, chronic, debilitating neurological disorder characterized by excessive daytime sleepiness, cataplexy, a sudden loss of muscle control triggered by emotions, and hallucinations among other symptoms. Two types of narcolepsy are currently recognized according to the ICSD<sub>3</sub> diagnostic criteria, Type 1 and 2. Type 1 is associated with cataplexy and a

reduction in of hypocretin-1 levels, while Type 2 is not associated with cataplexy.

## **IMPORTANT SAFETY INFORMATION:**

In clinical trials conducted in patients with narcolepsy, the most frequent adverse drug reactions (ADRs) reported with pitolisant were insomnia (8.4%), headache (7.7%), nausea (4.8%), anxiety (2.1%), irritability (1.8%), dizziness (1.4%), depression (1.3%), tremor (1.2%), sleep disorders (1.1%), fatigue (1.1%), vomiting (1.0%), vertigo (1.0%), dyspepsia (1.0%), weight increase (0.9%), and upper abdominal pain (0.9%). Pitolisant is contraindicated in patients with severe hepatic impairment (Child-Pugh C) and in women breastfeeding their children.

**Harmony Biosciences, LLC** is a biopharmaceutical company dedicated to developing innovative therapies to help patients with unmet medical needs. Harmony is focused on providing novel treatment options to patients with orphan and rare conditions, with an emphasis on central nervous system disorders. Harmony is headquartered in Plymouth Meeting, PA and also has offices

in the Chicago, Illinois area. For more information visit:  
[www.harmonybiosciences.com](http://www.harmonybiosciences.com)

**Bioprojet SCR** is a research-based pharmaceutical company. Bioprojet is headquartered in Paris, France and its Research Center located in Rennes, France. Its activity is focused on the design, synthesis and development of novel classes of drugs for unmet medical needs. For more information visit [www.bioprojet.com](http://www.bioprojet.com)

**Paragon Biosciences, LLC** improves the lives of patients suffering from debilitating diseases by building innovative biotechnology companies that bring important medicines to the market. Paragon's portfolio companies are managed by healthcare industry leaders and biotech entrepreneurs committed to improving outcomes for patients. Paragon's leadership and management team leverage their entrepreneurial experiences, and their expertise in securing 13 FDA drug approvals, to develop and finance biotechnology companies and accelerate their advancements. Paragon Biosciences

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