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News Release

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Janssen Submits Marketing Authorisation Extension to the European Medicines Agency to Register Paliperidone Palmitate 6-Monthly (PP6M) for Treatment of Schizophrenia in Adults

If approved, PP6M will be the first long-acting injectable schizophrenia treatment with a twice-yearly dosing regimen

BEERSE, BELGIUM, December 4, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson submitted a Marketing Authorisation Extension Application to the European Medicines Agency (EMA) to register paliperidone palmitate 6-monthly (PP6M) for the maintenance treatment of schizophrenia in adult patients who are clinically stable on paliperidone palmitate 1-monthly (PP1M)[1] or 3-monthly (PP3M)[2] injectable products. If approved, this long-acting injectable will provide adults living with schizophrenia a twice-yearly dosing regimen, the longest dosing interval available for an antipsychotic medication in the European Economic Area.[3]

"Janssen's roots in neuroscience began with research and development of novel therapeutic options for schizophrenia, and this filing builds on that 60-year commitment," said Bill Martin, Global Therapeutic Area Head, Neuroscience, Janssen Research & Development, LLC. "We designed this unique dosing regimen so people

with schizophrenia and their healthcare team can focus less on medication intervals and more on other aspects of their treatment plan, such as psychosocial interventions. We look forward to working with the European Medicines Agency to add a 6-month formulation to our family of paliperidone palmitate products."

The extension application is based on the Route 6 Study, a randomised, double-blind, non-inferiority Phase 3 global study that enrolled 702 adults living with schizophrenia from 20 countries, including Bulgaria, Czech Republic, France, Hungary, Italy, Poland and Spain.[4] Of these individuals, 81.3 percent completed the 12-month double-blind phase without a relapse event.[5] Data showed non-inferior efficacy of PP6M compared to PP3M on the primary endpoint of time to relapse at the end of the 12-month period in both intent-to-treat and per-protocol analysis sets.[5] The safety profile observed for PP6M was consistent with previous studies of PP1M and PP3M with no new safety signals emerging.[5] The most common treatment emergent adverse events in the study's PP6M group were weight increase (8.4 percent), injection site pain (7.7 percent), headache (6.7 percent) and upper respiratory infection (5.0 percent).[5] There were no unexpected serious adverse reactions.[5]

"Antipsychotic medication plays an important role in schizophrenia symptom control; however, non-adherence to prescribed medicines has been recognised as a problem worldwide," said Mathai Mammen, Global Head of Janssen Research & Development, Johnson & Johnson. "Addressing this challenging aspect of treatment has been the catalyst for our research and development of long-acting injectable medications for people living with schizophrenia."

PP6M is intended to be used only after patients have been stabilised on a shorter acting formulation of paliperidone palmitate such as XEPLION®[1] (PP1M) or TREVICTA®[2] (PP3M), with the goal of administering fewer injections.

#ENDS#

About the Route 6 Trial

The Route 6 Study was a randomised, double-blind, non-inferiority global Phase 3 study of 702 adults with schizophrenia, designed to demonstrate that injection of PP6M is not less effective than PP3M for the prevention of relapse in participants previously stabilised on corresponding doses of PP1M (100 or 150 mg dose) or PP3M (350 or 525 mg dose).[4]

The study consisted of mainly three phases: a screening phase (up to 28 days), a maintenance phase (of one or three months), and a double-blind phase (of 12 months). The maintenance phase was used to stabilise patients on PP1M or PP3M prior to the double-blind phase. Study evaluations included efficacy, pharmacokinetics, pharmacodynamics, and safety. The study's duration varied from approximately 13 months to 19 months.[4]

About Long-Acting Injectables

Long-acting injectables (LAIs) allow for the slow release of a drug into the blood and have been on the market for more than 50 years.[6] LAI antipsychotics offer a number of advantages compared with oral medication, including not having to remember to take drugs daily, improved patient outcomes, improved patient and physician satisfaction, and lower relapse rates.[7]

About Schizophrenia

Schizophrenia is a chronic and severe brain disorder affecting approximately 20 million people worldwide[8] and an estimated 3.7 million people in the EU.[9] The disease is characterised by distortions in thinking, perception, emotions, language, sense of self and behavior leading to neurological impairment, severe disability and increased mortality.[7]

Antipsychotic medication is recognised as an essential component in the treatment of schizophrenia, and adherence to medication plays a critical role in preventing symptoms and relapses.[10] However, nearly 75 percent of patients with schizophrenia

experience a relapse, often driven by non-adherence to prescribed medication.[11] Early intervention in schizophrenia may improve patient outcomes as more than 69 percent of people with schizophrenia do not receive appropriate care.[8]

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com/emea.

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Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding 6-monthly paliperidone palmitate (PP6M). The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialise, actual results could vary materially from the expectations and projections of Janssen-Cilag International NV, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays;

competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2019, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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References

[1] Xeplion SmPC 2018. Available at: https://www.ema.europa.eu/en/documents/product-information/xeplion-epar-product-information_en.pdf (last accessed November 2020).
[2] Trevicta SmPC 2019. Available at: https://www.ema.europa.eu/en/documents/product-information/trevicta-epar-product-information_en.pdf (last accessed November 2020).
[3] Berwaerts J et al. Efficacy and safety of the 3-month formulation of paliperidone palmitate vs placebo for relapse prevention of schizophrenia: a randomized clinical trial. *JAMA Psych.* 2015; 72(8):830–9.
[4] European Clinical Trials Register. Available at: https://www.clinicaltrialsregister.eu/ctr-search/trial/2017-001941-28/ES (last accessed November 2020).
[5] Data on file. RF-148071
[6] National Alliance on Mental Illness. Long-Acting Injectables. Available at: https://www.nami.org/Learn-More/Treatment/Mental-Health-Medications/Long-Acting-Injectables (last accessed November 2020).
[7] Brissos S, et al. The role of long-acting injectable antipsychotics in schizophrenia: a critical appraisal. *Ther Adv Pyschopharmacol*. 2014 Oct; 4(5):198–219.
[8] World Health Organization. Schizophrenia. Available at: https://www.who.int/news-room/fact-sheets/detail/schizophrenia (last accessed November 2020).
[9] Athanasopoulou C, et al. An analysis of online health information on schizophrenia or related conditions: a cross-sectional survey. *BMC Med Inform Decis Mak.* 2013; 13:98.

[10] Higashi K, et al. Medication adherence in schizophrenia: factors influencing adherence and consequences of nonadherence, a systemic literature review. *Ther Adv Psychopharmacol*. 2013 Aug; 3(4):200–18.
[11] Weiden PJ, et al. Partial compliance and risk of rehospitalization among California Medicaid patients with schizophrenia*. Psychiatr Serv*. 2004 Aug; 55(8):886–91.