FOR UK MEDICAL AND TRADE MEDIA ONLY

Media contact:
Chandni Kerai
Phone: +44 (0) 792 020 5356
Email: CKerai@ITS.JNJ.com

BYANNLI® (6-monthly Paliperidone Palmitate; PP6M) Authorised in Great Britain for the Maintenance Treatment of Schizophrenia in Adults

BYANNLI® (6-monthly paliperidone palmitate; PP6M) is the first long-acting injectable schizophrenia treatment to be granted marketing authorisation in Great Britain with a twice-yearly dosing regimen[1,2]

The marketing authorisation is based on results from the Route 6 Study, which showed that 91.9 percent of patients treated with PP6M were relapse-free at the end of the 12-month double-blind phase[1–3]

High Wycombe, UK, 1 February 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that the Medicines and Healthcare Products Regulatory Agency (MHRA) has granted marketing authorisation in Great Britain for the long-acting atypical antipsychotic therapy BYANNLI® (6-monthly paliperidone palmitate; PP6M) for the maintenance treatment of schizophrenia in adult patients who are clinically stable on 1-monthly paliperidone palmitate (PP1M) or 3-monthly paliperidone palmitate (PP3M).[1] The authorisation makes PP6M the first twice-yearly treatment for adults living with schizophrenia to be approved by the MHRA, with the longest available dosing interval for an antipsychotic medication in Great Britain.[1–3]

"Schizophrenia is a chronic and severe brain disorder, and antipsychotic medication plays an important role in its treatment. However, many people with the illness experience relapses which are often caused by poor adherence to oral medication," said Professor David Taylor*, Director of Pharmacy and Pathology at the Maudsley Hospital. *"Long-acting injectable treatments can offer better protection against relapse and greater patient convenience compared with oral*

medication. This authorisation is a major step forward for people living with schizophrenia, providing them with the option of a treatment that needs to be administered only twice a year."

The MHRA authorisation is based on data from the Route 6 Study, a randomised, double-blind, non-inferiority Phase 3 global study designed to demonstrate that PP6M is not less effective than PP3M for the prevention of relapse in participants previously stabilised on a shorter-acting formulation of paliperidone palmitate.[1–3]

The results showed non-inferiority of PP6M compared with PP3M on the primary endpoint of time to first relapse at the end of the 12-month period. Results found that 91.9 percent of patients treated with PP6M and 94.8 percent treated with PP3M were relapse-free at 12 months.[1–3] Relapse was defined as psychiatric hospitalisation, increase in Positive and Negative Syndrome Scale (PANSS) total score, increase in individual PANSS item scores, and violent behaviour resulting in self-injury or suicidal/homicidal ideation.

"*The MHRA authorisation for PP6M marks a significant step in providing a new therapeutic solution for people with schizophrenia that will help them feel less defined by their medication,*" said Vinay Patroe, Medical Affairs Director, Janssen UK. "*At Janssen, we are focused on preventing relapse and improving real world outcomes for people living with schizophrenia, and this approval is a key milestone in our ongoing work to help change the paradigm in treating schizophrenia with long-acting treatments*."

The safety profile observed for PP6M was consistent with previous studies of PP1M and PP3M, with no new safety signals emerging.[1,2] The most common treatment emergent adverse reactions (≥5.0 percent) in the Route 6 Study's PP6M group were weight increase (8.4 percent), injection site pain (7.7 percent), headache (6.7 percent) and upper respiratory tract infection (5.0 percent). There were no unexpected serious adverse reactions.[1–3]

#ENDS#

EM-83385
February 2022

*Professor David Taylor has received consultancy honoraria from Janssen. He has not been compensated for any media work.

About Schizophrenia

Schizophrenia is a chronic and severe brain disorder affecting approximately 20 million people worldwide, and nearly 300,000 people in the UK.[4,5] The disease is characterised by distortions in thinking, perception, emotions, language, sense of self and behaviour, leading to neurological impairment, severe disability and increased mortality.[4] 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.[6] Early intervention in schizophrenia may improve patient outcomes, as more than 69 percent of people with schizophrenia do not receive appropriate care.[4]

About 6-monthly paliperidone palmitate (PP6M)

6-monthly paliperidone palmitate (PP6M) is a long-acting injectable (LAI) that works by dissolving and entering the bloodstream slowly, due to its extremely low water solubility, resulting in continuous absorption of paliperidone palmitate over a 6-month period.[1,2] This offers patients the potential for up to 6 months of symptom control and a reduction in their risk of relapse with only two doses a year.[1,2] PP6M must be administered only by a healthcare professional giving the full dose in a single injection into the gluteal muscle.[1,2] For the full prescribing information, please see the Summary of Product Characteristics.

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.

EM-83385
February 2022

Janssen-Cilag Limited is a Janssen Pharmaceutical Company of Johnson & Johnson. Learn more at www.janssen.com/uk. Follow us at www.twitter.com/JanssenUK.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding BYANNLI® (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 Pharmaceutica NV and/or 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 behaviour 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 January 3, 2021, 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.

EM-83385
February 2022

References

[1] BYANNLI® (6-monthly paliperidone palmitate; PP6M). Summary of Product Characteristics. Great Britain. January 2022.
[2] BYANNLI® (6-monthly paliperidone palmitate; PP6M). Summary of Product Characteristics. EU. November 2021.
[3] Najarian D, et al. A randomized, double-blind, multicenter, noninferiority study comparing paliperidone palmitate 6-month versus the 3-month long-acting injectable in patients with schizophrenia. *International Journal of Neuropsychopharmacology*. 2021.
[4] World Health Organization. Schizophrenia. Available at: https://www.who.int/news-room/fact-sheets/detail/schizophrenia. Accessed February 2022.
[5] National Audit of Schizophrenia. Report of the second round of the National Audit of Schizophrenia (NAS2) 2014. Available at: https://eput.nhs.uk/about-us/reports-accounts/report-for-national-audit-of-schizophrenia-2/. Accessed February 2022.
[6] Higashi K, et al. Medication adherence in schizophrenia: factors influencing adherence and consequences of nonadherence, a systematic literature review. *Ther Adv Psychopharmacol*. 2013; 3(4):200–218.

EM-83385
February 2022