



Indivior Announces Launch of PERSERIS™ (risperidone) for the Treatment of Schizophrenia in Adults

PERSERIS is the only subcutaneous risperidone-containing long-acting injectable available in the United States

Slough, UK and Richmond, VA, 27 February 2019 – Indivior PLC (LON: INDV) today announced the launch of once-monthly PERSERIS™ (risperidone) for extended-release injectable suspension in the United States. PERSERIS is approved by the U.S. Food and Drug Administration for the treatment of schizophrenia in adults. PERSERIS delivers its active ingredient, risperidone, in an extended-release delivery system with no loading doses or oral supplementation recommended.¹

Schizophrenia is a chronic and severe mental disorder that requires ongoing treatment to manage symptoms.² People with schizophrenia are often unable to perceive their illness, which is a key reason they stop taking their medication.^{3,4,5} Long-acting injectable antipsychotics, including PERSERIS, provide patients with steady-state plasma concentrations of active drug that remain within a therapeutic range for an extended period.⁶

“Schizophrenia is a complex disease and part of the complexity is that a patient may not recognize that they are ill and therefore not see the need to take medicine,” said Anne Andorn, MD, Chief Medical Officer at Indivior. “PERSERIS is a once-monthly injection of a commonly prescribed medication known to reduce symptoms of schizophrenia and does not depend on the patient taking additional oral medication. Reducing the symptoms of schizophrenia is very important to help reduce the abnormal behaviors that can lead to the stigma of this disease.”

PERSERIS uses an extended-release delivery system to form a depot under the skin following abdominal subcutaneous administration by a healthcare provider. Risperidone is released on initial depot formulation followed by sustained release from the depot over an entire month. Initial peak levels of risperidone occur in four to six hours of dosing.¹ Before starting PERSERIS, physicians should establish tolerability with oral risperidone in patients who have never taken it before. Patients on stable doses of oral risperidone lower than 3 mg or higher than 4 mg a day may not be candidates for PERSERIS.

“With the launch of PERSERIS, Indivior continues to focus on delivering innovative treatments that address patient needs,” said Shaun Thaxter, Chief Executive Officer of Indivior. “PERSERIS helps treatment initiation while also eliminating the need for daily antipsychotic medication dosing.”

Indivior is committed to helping ensure our products are affordable to patients. A PERSERIS copay assistance program will be available to eligible patients. Eligible patients may pay as little as \$5 each month. The INSUPPORT Copay Assistance Program is valid only for patients with private insurance who are prescribed PERSERIS for on-label use. Patients with government insurance (government insurance includes, but is not limited to, Medicare, Medicaid, Medigap, VA, DoD, TRICARE, CHAMPVA, or any other federally or state-funded, government-assisted program) are not eligible for the Copay Assistance Program. Other restrictions may apply. Visit www.INSUPPORT.com for full terms and conditions and more information.

PERSERIS is available for healthcare providers to acquire through wholesalers, specialty distributors and pharmacies in an open network approach. For more information, visit www.PERSERIS.com.

The full prescribing information, including **BOXED WARNING**, for PERSERIS can be found [here](#).

Photos and a multimedia gallery are available at www.IndiviorMedia.com.

About PERSERIS Clinical Trial Results

The FDA approval of PERSERIS was based on a pivotal Phase 3 study in patients aged 18 to 55 years with acute exacerbations of schizophrenia (NCT 02109562). The primary efficacy endpoint measure was change in Positive and Negative Syndrome Scale (PANSS) total score at eight weeks. Both PERSERIS 90 mg and 120 mg doses demonstrated a statistically significant improvement compared with placebo from baseline to end of study.

The systemic safety profile of PERSERIS is consistent with the known safety profile of oral risperidone.¹ The most common systemic adverse reactions in the pivotal Phase 3 trial (in ≥5 percent of PERSERIS patients and greater than twice placebo) were increased weight, sedation/somnolence and musculoskeletal pain. The most common injection site reactions (≥5 percent of all patients across PERSERIS and placebo groups) were injection site pain and reddening of the skin.¹

About PERSERIS™

INDICATION

PERSERIS™ (risperidone) is indicated for the treatment of schizophrenia in adults.

HIGHLIGHTED SAFETY INFORMATION

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

See full prescribing information for complete boxed warning.

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.

PERSERIS is not approved for use in patients with dementia-related psychosis.

CONTRAINDICATIONS

PERSERIS should not be administered to patients with known hypersensitivity to risperidone, paliperidone, or other components of PERSERIS.

WARNINGS AND PRECAUTIONS

Cerebrovascular Adverse Reactions, Including Stroke in Elderly Patients with Dementia-Related Psychosis: Increased risk of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack), including fatalities. PERSERIS is not approved for use in patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS): Manage with immediate discontinuation and close monitoring.

Tardive Dyskinesia: Discontinue treatment if clinically appropriate.

Metabolic Changes: Monitor for hyperglycemia, dyslipidemia and weight gain.

Hyperprolactinemia: Prolactin elevations occur and persist during chronic administration. Long-standing hyperprolactinemia, when associated with hypogonadism, may lead to decreased bone density in females and males.

Orthostatic Hypotension: Monitor heart rate and blood pressure and warn patients with known cardiovascular disease or cerebrovascular disease, and risk of dehydration or syncope.

Leukopenia, Neutropenia, and Agranulocytosis: Perform complete blood counts (CBC) in patients with a history of a clinically significant low white blood cell count (WBC) or history of leukopenia or neutropenia. Consider discontinuing PERSERIS if a clinically significant decline in WBC occurs in absence of other causative factors.

Potential for Cognitive and Motor Impairment: Use caution when operating machinery.

Seizures: Use caution in patients with a history of seizures or with conditions that lower the seizure threshold.

ADVERSE REACTIONS

The most common adverse reactions in clinical trials ($\geq 5\%$ and greater than twice placebo) were increased weight, sedation/somnolence and musculoskeletal pain. The most common injection site reactions ($\geq 5\%$) were injection site pain and erythema (reddening of the skin).

About Indivior

Indivior is a global specialty pharmaceutical company with a 20-year legacy of leadership in patient advocacy and health policy while providing education on evidence-based treatment models that have revolutionized modern addiction treatment. The name is the fusion of the words individual and endeavor, and the tagline “Focus on you” makes the Company’s commitment clear. Indivior is dedicated to transforming addiction from a global human crisis to a recognized and treated chronic disease. Building on its global portfolio of opioid dependence treatments, Indivior has a strong pipeline of product candidates designed to both expand on its heritage in this category and address other chronic conditions and co-occurring disorders of addiction, including alcohol use disorder and schizophrenia. Headquartered in the United States in Richmond, VA, Indivior employs more than 900 individuals globally and its portfolio of products is available in over 40 countries worldwide. Visit www.indivior.com to learn more.

Forward-Looking Statements

This press release contains certain statements that are forward-looking, and which should be considered, amongst other statutory provisions, in light of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. By their nature, forward-looking statements involve risk and uncertainty as they relate to events or circumstances that may or may not occur in the future. Actual results may differ materially from those expressed or implied

in such statements because they relate to future events. Forward-looking statements include, among other things, statements regarding the Indivior Group's financial guidance for 2018 and its medium- and long-term growth outlook, its operational goals, its product development pipeline and statements regarding ongoing litigation.

Various factors may cause differences between Indivior's expectations and actual results, including: factors affecting sales of Indivior Group's products; the outcome of research and development activities; decisions by regulatory authorities regarding the Indivior Group's drug applications; the speed with which regulatory authorizations, pricing approvals and product launches may be achieved; the outcome of post-approval clinical trials; competitive developments; difficulties or delays in manufacturing; the impact of existing and future legislation and regulatory provisions on product exclusivity; trends toward managed care and healthcare cost containment; legislation or regulatory action affecting pharmaceutical product pricing, reimbursement or access; claims and concerns that may arise regarding the safety or efficacy of the Indivior Group's products and product candidates; risks related to legal proceedings, including the ongoing investigative and antitrust litigation matters; the Indivior Group's ability to protect its patents and other intellectual property; the outcome of patent infringement litigation relating to Indivior Group's products, including the ongoing ANDA lawsuits; changes in governmental laws and regulations; issues related to the outsourcing of certain operational and staff functions to third parties; uncertainties related to general economic, political, business, industry, regulatory and market conditions; and the impact of acquisitions, divestitures, restructurings, internal reorganizations, product recalls and withdrawals and other unusual items.

This press release does not constitute an offer to sell, or the solicitation of an offer to subscribe for or otherwise acquire or dispose of shares in the Company to any person in any jurisdiction to whom it is unlawful to make such offer or solicitation.

References

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