



## **FDA Approves PERSERIS™ (risperidone) for Extended-Release Injectable Suspension for the Treatment of Schizophrenia in Adults**

***PERSERIS is the first once-monthly subcutaneous risperidone-containing long-acting injectable***

**Slough, UK and Richmond, VA, 27 July 2018** – Indivior PLC (LON: INDV) today announced that the U.S. Food and Drug Administration (FDA) has approved PERSERIS™, the first once-monthly subcutaneous risperidone-containing, long-acting injectable (LAI) for the treatment of schizophrenia in adults. Clinically relevant levels were reached after the first injection of PERSERIS without use of a loading dose or any supplemental oral risperidone.<sup>1</sup>

“Treatment adherence is a major challenge in schizophrenia due to the complexity of the disease. It is important to have additional treatment options available to physicians to help them improve their patients’ symptom severity,” said Maurizio Fava, Executive Vice Chair of the Massachusetts General Hospital (MGH) Department of Psychiatry and Indivior clinical research consultant. “The studies carried out by Indivior suggest that PERSERIS may offer patients, caregivers and physicians a new once-monthly subcutaneous medication option to treat adults with schizophrenia.”

PERSERIS contains risperidone, a well-established treatment for schizophrenia, and uses the extended-release delivery system to form a subcutaneous (under the skin) depot that provides sustained levels of risperidone over one month. **Initial peak risperidone plasma levels occur within 4 to 6 hours of dosing and are due to an initial release of the drug during the depot formation process.**<sup>1</sup>

“Schizophrenia is a devastating, chronic and often disabling mental health condition that impacts the lives of people suffering from this illness, their families and caregivers. The approval of PERSERIS brings us the opportunity to provide adult patients and their healthcare providers with an innovative treatment option that we believe will make a meaningful difference,” said Shaun Thaxter, Chief Executive Officer of Indivior. “People with schizophrenia face a complex patient journey that can be hindered by ignorance, apathy and stigma. Indivior is committed to working with stakeholders to reduce the stigma of schizophrenia and expand access to evidence-based treatment.”

The efficacy of PERSERIS was evaluated in a pivotal Phase 3 randomized, double-blind, placebo-controlled, 8-week study of 354 patients (NCT 02109562). PERSERIS efficacy was demonstrated by an improvement in the primary clinical endpoint, Positive and Negative Syndrome Scale (PANSS) total score at day 57. The improvement in Clinical Global Impression Severity of Illness (CGI-S) was also statistically significant at day 57. Clinical trials of PERSERIS were designed for the product to be initiated with neither a loading dose nor any supplemental risperidone.<sup>1</sup>

The safety of PERSERIS was evaluated in 814 adults with schizophrenia who received at least one dose of PERSERIS during clinical trials. A total of 322 patients were treated with PERSERIS for at least six months, with 234 of those treated with PERSERIS for at least 12 months. The systemic safety profile of PERSERIS was consistent with the known safety profile of oral risperidone. The most common systemic adverse reactions in the pivotal Phase 3 trial (in

≥5% of PERSERIS patients and greater than twice placebo) were increased weight, sedation/somnolence and musculoskeletal pain. The most common injection site reactions (≥5% of all patients across PERSERIS and placebo groups) were injection site pain and reddening of the skin.<sup>1</sup>

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

Photos and a multimedia gallery are available at [www.IndiviorMedia.com](http://www.IndiviorMedia.com).

## **About PERSERIS™**

### **INDICATION**

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

**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](http://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**

1. PERSERIS™ [prescribing information]. North Chesterfield, VA: Indivior Inc; 2018.

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<sup>1</sup> PERSERIS [prescribing information]. North Chesterfield, VA: Indivior Inc; 2018.