



Indivior Enters into Exclusive License Agreement with HLS Therapeutics for PERSERIS™ (risperidone) in Canada

Slough, UK and Richmond, VA, May 9, 2019 - Indivior PLC (LON: INDV) (“Indivior” or the “Group”) today announced that it has entered into a definitive license agreement with HLS Therapeutics Inc. (TSX: HLS) (“HLS”) for exclusive commercialization rights to PERSERIS™ (risperidone) in Canada.

HLS is a specialty pharmaceutical company focused on acquiring and commercializing late-stage products for the Canadian market. Commercially, if approved, PERSERIS™ would be complementary to HLS’ product Clozaril® (clozapine), an atypical antipsychotic which, in Canada, is indicated for the management of the symptoms of treatment-resistant schizophrenia (“TRS”). HLS employs a unique branded platform called the Clozaril® Support and Assistance Network (“CSAN®”) that includes value-added treatment provider and patient services to support Clozaril®. PERSERIS, if approved, could benefit from the CSAN® offerings.

Shaun Thaxter, Chief Executive Officer of Indivior, said, “We understand the challenges of patients living with schizophrenia and are pleased that PERSERIS may become available to Canadian patients through HLS. HLS has an experienced clinical and regulatory team with a strong track record of commercialization success in Canada, as well as a specialized team dedicated to psychiatry. In addition, there are significant synergies between PERSERIS, HLS’ product Clozaril and HLS’ unique CSAN platform. Given these advantages, we are confident that HLS is the right partner for Indivior and we look forward to the potential growth we see for PERSERIS in Canada with HLS.”

Under the terms of the agreement, Indivior has granted an exclusive license to HLS to file and commercialize PERSERIS in Canada. In addition, Indivior will provide technical assistance to file the Canadian dossier and will enter into a supply agreement to furnish finished goods to HLS for sale in the territory.

Indivior will receive \$1 million upon signing of the definitive agreement and a near-term payment of \$4 million contingent upon achieving certain regulatory and pre-commercial milestones. Upon commercialization in the territory, Indivior is also eligible to receive escalating double-digit royalties based on annual net sales.

About PERSERIS

IN CANADA, PERSERIS IS AN INVESTIGATIONAL PRODUCT THAT HAS NOT UNDERGONE REVIEW BY HEALTH CANADA

Once-monthly PERSERIS (risperidone) for extended-release injectable suspension has been approved by the US FDA for the treatment of schizophrenia in adults.

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 endeavour, 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 800 individuals globally and its portfolio of products is available in over 40 countries worldwide. Visit www.indivior.com to learn more.

Contact:

Jason Thompson
804-402-7123
Vice President, Investor Relations
jason.thompson@indivior.com

[PERSERIS™ \(risperidone\) for extended-release injectable suspension](#)

INDICATION AND HIGHLIGHTED SAFETY INFORMATION

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).

For more information about PERSERIS, the full Prescribing Information including BOXED WARNING, and Medication Guide visit www.perseis.com.

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