HLS Therapeutics Inc.

HLS Therapeutics Files New Drug Submission for PERSERIS® in Canada

If approved by Health Canada, PERSERIS would become the first once-monthly risperidone long-acting injectable used in the treatment of schizophrenia

TORONTO, Jan. 23, 2020 /CNW/ - HLS Therapeutics Inc. ("HLS" or the "Company") (TSX:HLS), a specialty pharmaceutical company focusing on central nervous system and cardiovascular markets, announces that its New Drug Submission ("NDS") for PERSERIS®, a novel long-acting injectable risperidone product for the treatment of schizophrenia was accepted for review by Health Canada on January 23, 2020. HLS is seeking approval for PERSERIS with an indication for the treatment of schizophrenia in adults.

HLS has in-licensed the exclusive rights to PERSERIS for the Canadian market from Indivior PLC. PERSERIS is not approved in Canada.

"Schizophrenia is a critical and fragile disease state where the treatment requirements are immense and complex. As a result, treatment adherence is a significant challenge," said Greg Gubitz, CEO of HLS Therapeutics. "We want to leverage our experience and our presence in this therapeutic area to provide practitioners with new and innovative treatments to help patients with schizophrenia. PERSERIS, if approved, with its unique sub-cutaneous long-acting injectable delivery formulation, could bring another treatment option to patients and practitioners. Furthermore, it is complementary to our CNS business, which includes CLOZARIL® for treatment resistant schizophrenia, and CSAN® Pronto™ a point of care testing device for measuring white blood cells."

Risperidone is a well-established treatment for schizophrenia and PERSERIS uses a sub-cutaneous extended-release delivery system that forms a depot providing sustained therapeutic levels of risperidone over a one-month period from a single injection.

About PERSERIS

PERSERIS is approved by the FDA and is the first once-monthly subcutaneous risperidone-containing long-acting injectable indicated for the treatment of schizophrenia in adults. The PERSERIS approval by the FDA 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 HLS THERAPEUTICS INC.

Formed in 2015, HLS is a specialty pharmaceutical company focused on the acquisition and commercialization of late stage development, commercial stage promoted and established branded pharmaceutical products in the North American markets. HLS's focus is on products targeting the central nervous system and cardiovascular therapeutic areas. HLS's management team is composed of seasoned pharmaceutical executives with a strong track record of success in these therapeutic areas and at managing products in each of these lifecycle stages. For more information visit: www.hlstherapeutics.com

FORWARD LOOKING INFORMATION

This release includes forward-looking statements regarding HLS and its business. Such statements are based on the current expectations and views of future events of HLS's management. In some cases the forward-looking statements can be identified by words or phrases such as "may", "will", "expect", "plan", "anticipate", "intend", "potential", "estimate", "believe" or the negative of these terms, or other similar expressions intended to identify forward-looking statements, including, among others, statements with respect to HLS's pursuit of additional product and pipeline opportunities in certain therapeutic markets, statements regarding growth opportunities and expectations regarding financial performance. The forward-looking events and circumstances discussed in this release may not occur and could differ materially as a result of known and unknown risk factors and uncertainties affecting HLS, including risks relating to the specialty pharmaceutical industry, risks related to the regulatory approval process, economic factors and many other factors beyond the control of HLS.

Forward-looking statements and information by their nature are based on assumptions and involve known and unknown risks, uncertainties and other factors which may cause HLS's actual results, performance or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statement or information. Accordingly, readers should not place undue reliance on any forward-looking statements or information. A discussion of the material risks and assumptions associated with this release can be found in the Company's Annual Information Form dated April 1, 2019, which has been filed on SEDAR and can be accessed at www.sedar.com. Accordingly, readers should not place undue reliance on any forward-looking statements or information. Except as required by applicable securities laws, forward-looking statements speak only as of the date on which they are made and HLS undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise.

ABOUT INDIVIOR

Indivior is a global pharmaceutical company working to help change patients' lives by developing medicines to treat addiction and serious mental illnesses. Indivior's vision is that all patients around the world will have access to evidence-based treatment for the chronic conditions and co-occurring disorders of addiction. 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 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. 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.

REFERENCES

[1]https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210655s000lbl.pdf

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