HLS Therapeutics Inc.

HLS Therapeutics Announces Health Canada Approval of PERSERIS® for the Treatment of Schizophrenia

- ***first once-monthly risperidone long-acting injectable used in the treatment of schizophrenia***
- ***once-monthly dosing may help improve treatment compliance***
- ***PERSERIS is a first-line treatment option for schizophrenia and is commercially complementary to Clozaril®, which is for treatment resistant schizophrenia***

TORONTO, Nov. 17, 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 Health Canada has approved the use of PERSERIS® (risperidone for extended-release injectable suspension), 90 mg and 120 mg subcutaneous injection, a novel long-acting injectable of risperidone, for the treatment of schizophrenia in adults. HLS has in-licensed the exclusive rights to PERSERIS for the Canadian market from Indivior PLC (LON: INDV).

Risperidone is a well-established treatment for schizophrenia, and PERSERIS delivers its active ingredient, risperidone, in an extended-release delivery system with no loading doses or oral supplementation recommended. Sustained therapeutic levels of risperidone are released over a one-month period from a single injection.

"We are pleased with Health Canada's approval of PERSERIS, which we believe has the potential to become a broadly used therapy for patients with schizophrenia," said Gilbert Godin, CEO of HLS. "As a long-acting once-per-month injectable version of risperidone, PERSERIS may help enhance treatment compliance when compared to other daily treatment options[1]. This opportunity will also allow us to directly leverage our existing commercial infrastructure, relationships and reach in the Canadian psychiatric market while delivering a new, clinically meaningful therapeutic option for patients with schizophrenia."

About PERSERIS
PERSERIS is approved by Health Canada and the FDA and is the first once-monthly subcutaneous risperidone-containing long-acting injectable indicated for the treatment of schizophrenia in adults. The PERSERIS approvals were 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.[2] 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, constipation, sedation/somnolence pain in extremity, back pain, akathisia, anxiety 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.[2]

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, please visit: www.hlstherapeutics.com

ABOUT INDIVIOR PLC
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 700 individuals globally and its portfolio of products is available in over 40 countries worldwide. Visit www.indivior.com to learn more.

REFERENCES

1: Remington G, Addington D, Honer W, Ismail Z, Raedler T, Teehan M. Guidelines for the Pharmacotherapy of Schizophrenia in Adults. Can J Psychiatry. 2017 Sep;62(9):604-616. doi: 10.1177/0706743717720448. Epub 2017 Jul 13. PMID: 28703015; PMCID: PMC5593252.
2: PERSERIS, Product Monograph HLS Therapeutics Inc, Nov 2020

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 March 18, 2020 and Management's Discussion and Analysis dated November 4, 2020, both of which have 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.

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