

HLS Therapeutics Comments on Rule Enacted by Quebec Health Minister Christian Dubé and the Absence of an Exception for New Refractory Schizophrenic Patients

DORVAL, QC, April 1, 2021 /CNW Telbec/ - HLS Therapeutics Inc. regrets the adoption of a new regulation, published yesterday in the Gazette officielle du Québec, which limits access to a support program for new patients suffering from refractory schizophrenia, and urgently requests a meeting with the Quebec Minister of Health and Social Services Christian Dubé.

This regulation will impact access of new patients to the risk management program called CSAN (CLOZARIL® Support and Assistance Network), a care portal and patient registry required by Health Canada for patients prescribed CLOZARIL® (clozapine), a treatment of last resort prescribed by psychiatrists to treat patients with refractory schizophrenia who do not respond to other treatments.

For nearly five years, HLS has enabled new patients to have access to CSAN and to CLOZARIL by covering the difference in cost between its medication and the amount reimbursed by RAMQ. By removing the cost difference, physicians were able to choose the support system best suited to the needs of their patients, without any financial impact.

The published regulation was meant to define the exceptions to the application of Article 80.2 of Law 92, which prohibits the reimbursement of all, or part of a drug covered by the Quebec general drug insurance plan. However, **although patients currently on treatment will continue to be able to benefit from access to CSAN/CLOZARIL®**, the government has chosen not to allow for an exception for future patients. Thus, deprived of financial assistance from CSAN, new patients will not have access to CSAN unless they pay the difference between the price of CLOZARIL® and the cost reimbursed by the RAMQ, a near impossible requirement given the often-precarious circumstances of this patient population. This regulation will create two classes of patients, an injustice that could be easily avoided.

"The law stipulates that the Minister of Health can make an exception on humanitarian grounds which would permit the continuation of financial support from HLS to all new eligible patients and thus allow them to choose CSAN, without any financial impact to the government of Quebec, taxpayers or the Régie d'assurance maladie du Québec (RAMQ)," said Mr. Gilbert Godin, CEO of HLS Therapeutics Inc. "It is a question of compassion and social responsibility. Patients suffering from refractory schizophrenia are among the most disadvantaged in Quebec society. Given its stated commitment to mental health, the government's position doesn't make sense, especially since no explanation has been provided."

A REAL EXCEPTION

To ensure patient safety, the use of CLOZARIL® (clozapine) is well regulated by Health Canada, which among other things, requires each manufacturer to keep a register and put in place a monitoring program of hematological parameters. Such Health Canada directives are important but very uncommon as only 13 medications in Canada are required to have this type of risk management program. Of these 13 products, only clozapine will be affected by section 80.2 of Law 92. It is therefore clearly an exceptional situation. Since 2016, many healthcare professionals, patients and associations have been asking government for an exception for clozapine. Recently, almost one hundred of these specialists urgently requested an exception but to no avail.

"This decision is very regrettable. It will also deprive French-speaking psychiatrists and nurses' access to Quebec-based expert consultants in their own language, to the detriment of the health of their new patients," said Dr. Jean C Grégoire, cardiologist at the Montreal Heart Institute and expert consultant to CSAN. "Even though all manufacturers of clozapine are required to comply with the risk management rules dictated by Health Canada, there are differences in the scope and usefulness of the complementary services that these programs offer. The majority of mental health specialists in Quebec, whether psychiatrists or nurse clinicians, consider that CSAN and its unique offering can have a significant impact on the health and safety of their patients. For example, the range of services offered by CSAN helps manage the risks of hematological, cardiovascular, metabolic, and neurological side effects by providing a 24-hour consultation service. Paradoxically, it is in new patients that the risk of relapse, neutropenia and the burden of adherence to mandatory diagnostic tests are greatest, with 39 blood tests required during the first year of treatment."

A SOLUTION WITHIN REACH OF THE QUEBEC MINISTER OF HEALTH

We recommend that the Minister of Health grant an exception to the regulations for the few drugs subject to a risk management program prescribed by Health Canada. This real and very limited exception would only concern clozapine and would not set a precedent that could be used by other manufacturers. Specifically, the exception would allow new patients to benefit from HLS's financial assistance program that pays for the

difference between the cost of its product and the amount paid by RAMQ.

This exception would ensure continued freedom of choice and access to support services from all manufacturers including CSAN at no additional cost for RAMQ or patients. In Quebec, clozapine is subject to the Lowest Price rule. For almost five years now, HLS has paid the difference between its product and the RAMQ price for new patients thus ensuring that these new patients have access to its product and services at no additional cost.

"We would like to discuss our solution directly with Minister Dubé. Clozapine is the treatment of last resort for these most precarious, vulnerable and disadvantaged patients, and extreme precautions are required due to the potential risks and side effects associated with the use of clozapine. Given the human tragedy and disproportionate costs to society that are associated with either avoidance or failure of schizophrenia treatment, there are many reasons that justify ensuring that this entire patient population and their caregivers can access the treatment of their choice," added Mr. Godin.

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

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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 17, 2021 and Management's Discussion and Analysis dated March 17, 2021, 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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