HLS Therapeutics Inc.

HLS Therapeutics Licenses and Files 'Athelas One' Point-of-Care Device

- ***From a single drop of blood from the tip of a finger, the point-of-care technology generates white blood cell counts and neutrophils numbers in minutes***
- ***When approved in Canada, the Athelas One technology could help lower the most commonly cited barrier for using clozapine among those who could benefit from it***
- ***Upon its approval, the technology will become part of the Clozaril Support and Assistance Network (CSAN®) and made available to Canadian Institutions and HCPs under the name CSAN® Pronto™***

TORONTO, March 14, 2019 /CNW/ - HLS Therapeutics Inc. ("HLS" or the "Company") (TSX: HLS), a specialty pharmaceutical company focused on central nervous system and cardiovascular markets, announces that it has in-licensed the exclusive Canadian rights for the *Athelas One* device. The *Athelas One* is an FDA-cleared capillary point-of-care medical device that is designed to help enhance and simplify the mandatory safety blood monitoring process for patients that are prescribed CLOZARIL® (clozapine), the only class of medication approved for Treatment Resistant Schizophrenia ("TRS"). HLS has the exclusive rights to the device in the field of schizophrenia.

Following its filing in January, the device was accepted for review by Health Canada on March 13th. Conditional on its approval in Canada, HLS will introduce the device as part of the current Clozaril Support and Assistance Network (CSAN®) under the name, "CSAN® Pronto™".

It is estimated that schizophrenia affects 1% of the population, or approximately 370,000 Canadians, and 25-30% of patients with schizophrenia (approximately 111,000) meet the criteria for TRS.[1,2] TRS patients are those that are suffering with schizophrenia and are found to be non-responsive to, or intolerant of, conventional antipsychotic medications. For these patients, the only treatment that is approved and recommended by Canadian Psychiatric Association guidelines is clozapine.[2,3] Clozapine has been commercially available in Canada since 1991; and is on the World Health Organization Model List of Essential Medicines for treating TRS.[4] However, clozapine is underutilized in Canada when compared to some industrialized countries where it is prescribed at rates up to three times greater.[5] Patients suffering with schizophrenia face various challenges in the health care system, providing them with a means to simplify the treatment process could enhance their lives and those of their families.

Because of the significant risk of agranulocytosis (a significant, decrease in white blood cell counts), a potentially life-threating adverse event associated with clozapine, patients must agree to routine blood monitoring, which can present challenges to patients.[3] Blood monitoring is one of the most widely cited barriers to the use of clozapine.[1] In the first year of treatment, a minimum of 39 intravenous blood draws are required to monitor patients, with 12 or more intravenous blood draws required in each year thereafter that the patient remains on the medication.[3] Traditionally such blood monitoring required patients to undergo venous blood sampling at a laboratory and results would be available a day or two later.

"The mandatory blood testing regimen is an important factor in the under-utilization of Clozapine," said Dr Gary Remington, Chief, Schizophrenia Division, Centre for Addiction and Mental Health (CAMH) and Professor of Psychiatry, University of Toronto.

CSAN Pronto is designed to streamline blood testing for both patients and healthcare practitioners by enabling patients to have their blood monitoring work done right in their health care provider's office and to receive test results during their visit. CSAN Pronto uses imaging technology and artificial intelligence to quantitatively determine white blood cell and Neutrophil counts from a single-drop of blood, obtained from a "finger-stick" blood test. Results are communicated in minutes and will be securely uploaded to a patient's CSAN profile becoming simultaneously available to everyone on the patient's healthcare team. Based on the interpretation and documentation of results in the registry, patients can access their medication from their pharmacist. A point-of-care finger-stick blood test has the potential to reduce two important barriers to clozapine use, which are a patient's non-adherence to blood work and the burden of the blood work regimen on the patient.

"CSAN Pronto may help reduce the burden associated with the blood draw regimen for clozapine patients, generating laboratory-accurate blood work in just minutes right there in the doctor's office, hospital or other treatment center," said Greg Gubitz CEO of HLS Therapeutics. "CSAN Pronto reflects HLS's strategy of focusing on patient and physician needs. By providing a less invasive safety monitoring environment for blood work, we think CSAN Pronto has potential benefits for TRS patients and the practitioners who treat them, which ultimately could be conducive to creating better access to a proven treatment."

HLS anticipates a response from Health Canada within 90 days of the filing and if approved, the point-of-care device is scheduled for introduction to the CSAN suite of services later this year under the name CSAN Pronto. Athelas has responsibility for supplying the devices and test strips to HLS and for performing the blood monitoring services that will be incorporated into the CSAN suite of services. Athelas will earn performance-based fees and commercial milestones contingent on commercial success.

ABOUT CLOZARIL® (clozapine)
Clozaril® is approved in Canada for the management of symptoms of treatment-resistant schizophrenia in adults over 18 years old.

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. CLOZARIL, CSAN and CSAN Patient Care Portal + Design are all registered trademarks of Novartis AG

ABOUT Athelas One
Athelas One was cleared by the FDA on November 5, 2018. On February 1st, 2019 HLS filed with Health Canada for approval to use Athelas One in Canada.

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 October 26, 2018, 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.

References

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3. HLS Therapeutics, Clozaril Product Monograph. January 2019
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