HLS Therapeutics Inc.

HLS Therapeutics announces Health Canada grants medical device license for White Blood Cell Point-of-Care Device to be marketed as CSAN® PRONTO™

- ***From a single drop of blood from the tip of a finger, Athelas One WBC System generates white blood cell counts and neutrophils percentages in minutes***
- ***The device could help lower the most commonly cited barrier for using Clozaril® among those who could benefit from it***
- ***HLS has the exclusive Canadian rights to the device in the field of schizophrenia under a licensing agreement with Athelas, Inc. ("Athelas")***
- ***The device 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, Oct. 17, 2019 /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 granted a medical device license for the Athelas One WBC System for use as a point-of-care device indicated for quantitative determination of white blood cells (WBC) and neutrophil percentages in capillary or venous whole blood. This medical device may help enhance and simplify the mandatory safety blood monitoring process for Treatment Resistant Schizophrenia ("TRS") patients that are prescribed Clozaril® (clozapine). HLS intends to launch the device as part of its current Clozaril Support and Assistance Network ("CSAN®") program under the name, CSAN® Pronto™.

"Clozapine has provided effective treatment for TRS patients for more than 25 years; however, the mandatory blood testing regimen, which requires 39 venous blood draws in the first year of treatment, has been cited as a key factor in the under-utilization of the medication[1]," said Greg Gubitz, CEO of HLS. "Clozapine is underutilized in Canada when compared to some industrialized countries where it is prescribed at rates up to three times greater.[2] Patients suffering with schizophrenia face various challenges in the health care system. Providing these patients with a means to simplify the safety blood monitoring process could enhance their lives and those of their families."

Mr. Gubitz added: "CSAN Pronto requires only a finger prick and a single drop of blood and generates a diagnostic result in just minutes right in the doctor's office. This compares to the traditional blood monitoring process which requires patients to undergo venous blood sampling at a laboratory with results available a day or two later. CSAN Pronto fits in very well with our Clozaril franchise and we think the device may help 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[1]."

ABOUT Clozaril (clozapine) and TRS
Clozaril is approved in Canada for the management of symptoms of treatment-resistant schizophrenia in adults over 18 years old. 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.[3,4] 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.[4,5] Clozapine has been commercially available in Canada since 1991; and is on the World Health Organization Model List of Essential Medicines for treating TRS.[6]

ABOUT Athelas One WBC System and CSAN PRONTO
Athelas One WBC System was cleared by the FDA in November 2018, and a medical device license for the Athelas One WBC System has now been granted by Health Canada.

CSAN Pronto integrates the Athelas One WBC System device in a way that 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 percentages 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 these documented results in the registry, patients can access their medication from their pharmacist.

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.

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SOURCE HLS Therapeutics Inc.

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