HLS Therapeutics Inc.

HLS Therapeutics to Become Distributor of the Saladax MyCare™ Psychiatry Line including the Insite Point-of-Care Device and Antipsychotic Reagents

- **The MyCare Insite is a point-of-care (POC) device that uses just a single drop of blood to measure the most commonly used antipsychotic drugs in patients' blood**
- **The MyCare Psychiatry Clozapine Assay Test Kit has been granted Market Authorization by the U.S FDA; no such product exists in the Canadian market today**
- **Tests for 5 additional POC antipsychotics are in the final stages of development**
- **Device is complementary to the Company's CNS/Psychiatry business**

TORONTO, June 1, 2020 /CNW/ - HLS Therapeutics Inc. ("HLS" or the "Company") (TSX:HLS), a specialty pharmaceutical company focusing on central nervous system ("CNS") and cardiovascular markets, announces that it has become the exclusive Canadian distributor for the MyCare™ Insite point-of-care device and its related line of diagnostic tests from Saladax Biomedical, Inc. ("Saladax") of Bethlehem, Pennsylvania.

The MyCare Insite is a point-of-care device that is intended to measure the blood levels of the most common antipsychotic drugs, clozapine, risperidone, quetiapine, aripiprazole, olanzapine and paliperidone. Similar to a blood glucose test, MyCare Insite is easy to use and requires only a single drop of blood taken by a finger stick to measure patient drug levels, providing results in just minutes. Tests to achieve such results today are often clinically impractical, complex, and costly in terms of time and money. MyCare Insite for clozapine has been launched in Europe and Saladax will file MyCare Insite for clozapine testing with Health Canada this year and expects to file tests for additional drug products thereafter.

"Measuring and monitoring clozapine levels and hematological parameters is considered an important step towards optimizing therapy for patients who are taking that medication[1]," said Dr. Gary Remington, MD, PhD, FRCPC, Professor, Faculty of Medicine, University of Toronto. "Point-of-care devices have consistently been shown to improve patient outcomes while also reducing healthcare costs[2,3]. Using a point-of-care device to measure blood levels for common psychotic drugs could provide information to help determine if a patient is taking their medication, if optimal drug concentrations are being achieved and ultimately whether the proper therapy is being pursued."

"MyCare Insite reflects our commitment to bringing highly valuable clinical tools to practitioners in the CNS space to help them make informed decisions and enhance their level of patient care," said Greg Gubitz, CEO of HLS. "No point-of-care test to measure clozapine or other broadly used anti-psychotic levels is on the market today. We believe that if approved, the MyCare Insite device could serve to support practitioners contending with a range of schizophrenic and bi-polar conditions and who prescribe six of the most common antipsychotic drugs for their patients."

It is estimated that schizophrenia affects 1% of the population, or approximately 300,000 Canadians. Schizophrenia interferes with a person's ability to think clearly, manage emotions, make decisions and relate to others[4]. The causes and the course of the illness is unique for each patient, making the diagnosis of its causes difficult. Research has linked schizophrenia to a multitude of possible causes, including aspects of brain chemistry and structure, as well as environmental causes. No single, simple course of schizophrenia treatment exists. Patients suffering with schizophrenia face various challenges in the health care system, providing them with a means to simplify and optimize the treatment process could enhance their lives and those of their families.

Similarly, the MyCare Products may be used in bi-polar disorder patients to measure the blood concentrations of indicated drug products such as risperidone, aripiprazole, quetiapine, and olanzapine once those individual tests are approved. Bi-polar disorder affects up to 2.6%[5] of the population, or approximately 910,000 Canadians.

Knowing if patients have optimal blood levels provides immediate insight for treatment discussions. MyCare can help provide greater clarity to improve treatment decisions, identify the causes of treatment failure (i.e. adherence, drug resistance, drug-drug interactions and drug metabolism) and may help distinguish medication non-response from lack of adherence. This information may help physicians establish the right medication at the right dose more quickly than relying on patient self-report.

In addition to the exclusive distribution rights of the MyCare Insite point-of-care technology, HLS will have non-exclusive distribution rights to the full MyCare Psychiatry line of tests that can be processed on major analyzers used in large Laboratory systems. Saladax recently received FDA authorization to market the clozapine test to US laboratories.

HLS anticipates that Saladax will receive its response from Health Canada in the second half of 2020. Should the medical device license be granted, HLS will incorporate MyCare Insite into its CNS/Psychiatry division and will be the exclusive supplier of MyCare Tests in Canada.

To learn more about MyCare Insite, please visit: https://mycaretests.com/psychiatry/insite.

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.

ABOUT SALADAX BIOMEDICAL, INC.
Founded in 2004, Saladax Biomedical, Inc. is a privately held company headquartered at Ben Franklin TechVentures® located in Bethlehem, PA.

Saladax develops rapid blood tests for point-of-care and for laboratory analysers for use in psychiatry and oncology. The Saladax MyCare Psychiatry line provides drug level tests of the most commonly prescribed antipsychotics. This line of reagents is protected by an extensive intellectual property portfolio that covers the use of rapid testing for antipsychotics drugs. Saladax believes that truly personalized medicine can only exist when the right drug is taken at the right dose. Saladax's diagnostic reagent kits are distributed worldwide and are under development for use in the United States. Saladax is ISO 13485:2016 certified. For more information, visit MyCareTests.com.

REFERENCES

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3. Price CP, Kricka LJ, Kricka LJ. Improving healthcare accessibility through point-of-care technologies. Clin Chem. 2007;53:1665–1675. doi:10.1373/clinchem.2006.084707
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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, 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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