HLS Therapeutics Inc.

HLS Therapeutics Announces Update on Health Canada Filings for MyCare and Trinomia

- ***Health Canada approves MyCare Psychiatry Lab Assays for use in diagnostic lab settings to measure blood levels in patients prescribed six of the most common antipsychotic drugs***
- ***MyCare Insite point-of-care (POC) device, which measures the level of antipsychotic drugs in patients' blood, is under review and could be approved in H1-2021***
- ***Health Canada issued a Notice of Deficiency for Trinomia***

TORONTO, Dec. 16, 2020 /CNW/ - HLS Therapeutics Inc. ("HLS" or the "Company") (TSX:HLS), a specialty pharmaceutical company focusing on central nervous system and cardiovascular markets, announces updates on its filings with Health Canada for MyCare and Trinomia.

The Company is pleased to report that Health Canada has approved five MyCare™ Psychiatry Lab Assay diagnostic tests from Saladax Biomedical, Inc. ("Saladax") for use in measuring blood levels in patients taking any of the six most common antipsychotic drugs. HLS is the exclusive distributor of these products in Canada. Regarding Trinomia, a polypill of three common medications that is intended for secondary cardiovascular prevention, Health Canada issued a Notice of Deficiency ("NOD") indicating that additional scientific data may be required for approval.

MYCARE LAB ASSAYS AND MYCARE INSITE

The approved **MyCare Psychiatry Lab Assays** are diagnostic tools that can be used on most large high-speed lab analyzers. They allow for the measuring and monitoring of blood drug concentration levels of clozapine, risperidone, paliperidone, aripiprazole, olanzapine, and quetiapine. For the first time, the timely monitoring of those hematological parameters is possible, and this diagnostic capability is considered an important step towards optimizing therapy for patients who are taking those medications.[1]

Currently under review at Health Canada is **MyCare Insite,** a complementary device that will enable the performance of similar tests *at the point of care*. Similar to a blood glucose test, MyCare Insite will be simple to use and require only a single drop of blood taken by a finger stick to measure patient drug levels, providing results in just minutes. Such 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 antipsychotic drugs could provide information to help healthcare practitioners determine if a patient is taking their medication, if optimal drug concentrations are being achieved and ultimately whether the proper therapy is being pursued. Approval of the MyCare Insite point-of-care device is expected in the first half of 2021.

"The MyCare product line is a natural fit within our CNS franchise and reflects our commitment to bringing highly valuable clinical tools to practitioners to help them make informed decisions and enhance their level of patient care," said Gilbert Godin, CEO of HLS. "With this approval, we will leverage our commercial infrastructure in the Canadian psychiatric market to launch the MyCare line of diagnostic tests in the first half of 2021 followed by the introduction of the MyCare Insite device once it is approved."

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 and patients suffering with the condition face various challenges in the health care system. Providing practitioners with diagnostic tools like those in the MyCare product line, which simplify and optimize the treatment process, could help those who contend with this serious illness.

Similarly, the MyCare products may be used with bi-polar disorder patients to measure their blood concentrations of the indicated drug products. Bi-polar disorder affects up to 2.6%[5] of the population, or approximately 910,000 Canadians.

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

TRINOMIA

HLS received an NOD from Health Canada for its pending submission for Trinomia that may require additional scientific information pertaining to safety and efficacy to support the approval of the application. In addition, Health Canada noted that there is an on-going study using Trinomia, and that "…a regulatory decision for Trinomia should await these study results."

The ongoing study is titled, Secondary Prevention of Cardiovascular Disease in the Elderly (SECURE), a prospective randomized clinical trial comparing a polypill versus standard of care treatment strategies in post-myocardial infarction elderly patients, which has an estimated completion date of November 2021.

"HLS is disappointed to learn Health Canada's decision since the application was submitted after consultation with Health Canada and its agreement with the defined strategy," said Gilbert Godin, CEO of HLS. "HLS will be working closely with the licensor of the product to assess the pathway required to address the deficiency noted by Health Canada, and we will provide more information as it becomes available. In the interim the focus of our Cardiovascular franchise will remain firmly on the success of Vascepa in Canada."

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 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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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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