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ASX Announcement

Permission Granted For Distributing China Guangdong Hecin's SARS-CoV-2 test kits in Malaysia And First Commercial Order

18th June 2021

- Holista has been granted permission to import and distribute a SARS-CoV-2 rapid test kits manufactured by Guangdong Hecin Scientific Inc of China in Malaysia
- Distribution will be through the channels of Holista's long-term partner, Zuellig Pharma with strict adherence to conditions imposed by Medical Device Authority (MDA) as stipulated in Appendix 2
- Initial order for 15,000 test kits worth $95,000 to be delivered in June 2021
- Permission has been granted to Holista to import up to 45,000 test kits to Malaysia within three months
- Holista is progressing the registration and licencing for the import and distribution to other countries

Holista Colltech Limited (ASX: HCT, "Holista" or "the Company") is pleased to announce that it has been granted permission under Special access under the Medical Device (Exemption) Order 2016, from the Medical Devices Authority ("MDA") of Malaysia's Ministry of Health ("MOH") to import and distribute for an antigen rapid test kit (RTK-AG) developed and manufactured by Guangdong Hecin Scientific Inc. ("Hecin") of China. With this approval, the Company has secured an initial order for 15,000 units worth $95,000.00 in Malaysia.

The test kits will be used to detect the presence of the SARS-CoV-2 viral antigen from nasal swabs within 15 minutes. It is for screening purposes by healthcare professionals and not the sole basis for diagnosis and exclusion decisions.

The maiden order was secured by the Company's wholly owned subsidiary Holista Biotech Sdn. Bhd. from Klinik Mutiara, which is part of Amegajaya Sdn Bhd, a medical consultancy that works closely with MOH and related agencies in Malaysia. With the MDA permission, Holista is only permitted to sell and supply the test kits to the registered healthcare professional at Klinik Mutiara.

MDA has stipulated that Holista can import up to 45,000 units of the antigen rapid test kits to Malaysia within the first three months of the permission for importation of medical devices for special access under the Medical Device (Exemption) Order dated 14 June 2021. The first 15,000 units will be shipped by end of June 2021. The order marks the first commercial transaction of SARS-CoV-2 test kits by the Company.

Based in Guangzhou, Hecin has developed diagnostic products for nucleic acid, immunofluorescence, flow cytometry, as well as medical reagents, amongst others. Hecin has conducted clinical trials for the antigen test kits. The clinical trial was carried out in Daye City Center for Disease Control and Prevention within China.

The clinical performance of Hecin RTK-Antigen test kit against Polymerase Chain Reaction (PCR) Comparator method using nasopharyngeal swabs specimens has obtained a sensitivity of 96.23% and specificity 99.07% [Note 1].

This is also the basis for obtaining the CE mark in Europe.

The MDA also conducted its own clinical trials in Malaysia prior to this approval.

Apart from the RTK-AG test kit, Hecin has granted Holista distribution rights for the Hecin RTK-Antibody test kit ("Hecin RTK-Antibody") which can test human serum, plasma or whole blood for levels of antibodies to assess immunity after vaccination. This test kits will only be granted special access permission by MDA for import and distribution in Malaysia upon Holista presenting confirmed customer orders.

Holista is only authorized to import and distribute the test kits in Malaysia with the said MDA permission received. Apart from Malaysia, Holista has rights to distribute the two Hecin products in Brunei, Thailand, Indonesia, Philippines, Taiwan, Vietnam, Cambodia, Laos, Myanmar, Singapore (from 22nd January 2021) and the United Kingdom (from 9th April 2021). The sales and distribution of the said test kits is also subjected to obtaining the respective country's regulatory approvals.

Hecin has granted exclusivity to Holista until 31 December 2021 subject to Holista achieving sales performance in the respective countries by July 2021. Due to current pandemic, it take time to obtain each country's regulatory approvals. However, Holista is in the process of negotiating with Hecin for further extension on the success of the Malaysian approval.

The MDA has included the following Hecin manufactured test kits on the list of kits that is recommended for use (based on the decision on the consensus of its Covid-19 Test Kit Expert committee.

i) Hecin RTK-Antigen Test Kit [Note 2]
ii) Hecin Antibody Test Kit [Note 2]

The MDA permission for the antigen test kits is subject to the following conditions :-

I. Ensure that all medical devices used in this special access comply with the safety and performance requirements as stipulated in Medical Device Act 2012 (AT 737);
II. Ensure that the devices are supplied only to the Healthcare Professional and at the Healthcare Facility as stated in Appendix 1;
III. Adherence to the conditions as stipulated in Appendix 2
IV. This Antigen Rapid Test Kit should be limited for screening. Testing shall be conducated in accordance with "*Garis Panduan Mengunakan Kit Ujian Pantas (RTK-Ag) Bagi COVID-19 di Sektor Swasta" ("*The Guideline for Antigen Rapid Test Kit (RTK-Ag) usage in Private Sector"). All the test result need further confirmation by RT-PCR.

The products will be distributed through the channels of Holista's long-time partner, Zuellig Pharma with strict adherence to conditions imposed by Medical Device Authority (MDA) as stipulated in Appendix 2. Zuellig Pharma has all the facilities and licences granted by Medical Devices Authority to store and distribute all medical device and related products.

This announcement has been approved by the Board of Directors.

-Ends-

Note 1 : Guangdong Hecin Scientific Inc. Clinical Report, 2019 nCoV Antigen Test Kit (Colloidal gold method) p11

Note 2 : https://www.mda.gov.my/announcement/596-list-of-recommended-for-use-of-covid-19-ivd-test-kit.html

About Holista Colltech Limited

Holista Colltech Ltd ("Holista") is a natural wellness company with the following divisions:

- Dietary Supplements
- Healthy Food Ingredients
- Ovine Collagen
- Infection Control Solutions

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Appendix 1

Medical Device Details

Name of Device	:	**Hecin™ 2019-nCoV Antigen Test Kit (colloidal gold method)**
Brand/Model (Catalogue No./ Identifier)	:	Hecin™
Intended Use	:	This kit is only used for the in vitro qualitative detection of 2019-nCoV antigen from human nasopharyngeal swabs or oropharyngeal swabs specimens. This kit is suitable for the auxiliary diagnosis of COVID-19, the results are for clinical reference only and cannot be used as the sole basis for diagnosis and exclusion decision. The clinical diagnosis and treatment of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests and treatment responses. Positive test result needs to be further confirmed, negative result does not preclude 2019-nCoV infection. This kit is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of in vitro diagnostic procedures.
Brief Description	:	The kit is immunochromatographic and uses double-antibody sandwich method to detect 2019-nCoV antigen. The test kit consists of test card, sample diluent, sample extraction tube, droppers lid, sterile sampling swab. PACKAGE SPECIFICATION : 20 Tests/Kit
***Lot Number**	:	20210313
Manufacturer's name	:	Guangdong Hecin Scientific, Inc., Guangdong Province, P. R. China
Period of Importation	:	June 2021 – September 2021
Quantity to be imported	:	45,000 Tests Packaging size 2,250 Kits (20 Tests/Kit)
Healthcare Facility Details	:	**KLINIK MUTIARA** No 40A, Jalan Serunai 1, Taman Desa Utama, Klang 41200 Selangor Darul Ehsan.
Healthcare Professional Details	:	[redacted]

***Note** : Re-validation by Public or Private Pathology Laboratory / Hospital / Healthcare Facility is required if lot number to be imported is different than the lot number sent for local evaluation (by a recognised testing facility) and report need to be submitted to MDA for reference.*

Appendix 2

Conditions:

1. A person or establishment shall notify the Authority on the Special Access for importation of the medical device.
2. The exemption is only applicable to medical device and site as listed in Appendix 1 which is based on the information given by the applicant.
3. A person or an establishment shall submit any information requested by the Authority within the prescribed period.
4. A person or an establishment shall comply with any directions issued by the Authority from time to time.
5. The Authority reserves the right to make a visit or inspection to the person or establishment at any time without prior notice.
6. The Authority may take legal action if the person or establishment fails to comply with any conditions imposed by the Authority.
7. All information pertaining to this medical device including all supporting documents shall be kept at the premises and shall be made available upon request by the Authority.
8. A person or an establishment shall comply with the following requirements on the Good Distribution Practice for the Medical Device:
   (i) Provide suitable and adequate storage to ensure proper conservation of the medical device in accordance with the manufacturer's instruction;
   (ii) Inspection of breached primary packages shall be performed. Any breached packages should be disposed off;
   (iii) No secondary assembly activities are allowed unless the manufacturers instruction state otherwise;
   (iv) establish adequate precautions and control to prevent deterioration or damage of the medical devices;
   (v) maintain an updated distribution records of medical devices;
   (vi) provide documentation of all unregistered medical devices supplied to customers, the quantity supplied, the batch or lot number and/or model and serial number;
   (vii) keep the record of delivery transactions as the proof of medical devices supplied to customers;
   (viii) ensure the delivery of medical devices adhere to the conditions specified by the manufacturer;
   (ix) for the disposal of medical devices in accordance with regulatory requirements and any other applicable statutory requirements; and
   (x) dispose the expired medical devices in accordance with regulatory requirements and any other applicable statutory requirements and a documented dispodal procedure shall be established.
9. A person or an establishment shall establish and maintain a post-market surveillance system in order to monitor the traceability of the unregistered medical device throughout the supply chain.