NZX/ASX Announcement

1 May 2023

Growing Recognition for TruScreen Real Time Cervical Cancer Screening Device

Highlights

- **TruScreen to be listed on the Innovation Register by the Polish Ministry of Health**
- **COGA trial manuscript in review for publication in the Journal of the American Medical Association (15,661 patients in trial)**
- **Saudi Arabia, Al Habib clinical evaluation manuscript in review for publication in the European Journal of Gynaecology Oncology (507 patients in trial)**
- **China cervical cancer screening at pre-Covid levels. 20 devices shipped in April 2023 with further 20 devices to be shipped in May.**

Truscreen Group Limited (NZX/ASX:TRU) is pleased with the growing acknowledgement and acceptance of the TruScreen real time cervical cancer screening device. TruScreen is NMPA (China, formerly CFDA) and CE mark certified as primary cervical cancer screening tool, has had extensive clinical validation over a 10 year period, and recognition by Unitaid.

TruScreen is a real-time, AI enabled, objective screening device for detection of pre-cancerous and cancerous tissue of the cervix. TruScreen efficacy is supported by large body of evidence, demonstrating consistent and **comparable sensitivity to high quality cytology in a gynaecology clinic.**[1]

Poland

Cervical cancer is the second leading cause of cancer deaths in women aged 15-44 years in Poland, with an 'at risk' population of 17.1 million. Poland has an annual total of 3,513 cervical cancer cases, with an annual mortality of 1,858[2]. These relatively high cervical cancer rates (when compared to other European countries) can be attributed to Poland having no national screening or HPV vaccination programme. This contributes to the country's low early detection rate and higher rate of high-risk HPV infections, respectively.

TruScreen and its Distributor, Aspironix s.r.o. are making a positive contribution to reducing the high incidence of cervical cancer in Poland through partnering with a private network of medical clinics to roll out the TruScreen cervical cancer screening device to these centres.

TruScreen, previously awarded the Quality and Innovation Mark by the Polish Medical University of Lodz, is now to be listed on the Innovation Register by the Polish Ministry of Health. This will increase the specialists and clinicians' awareness of TruScreen technology and is one of several steps to facilitate TruScreen's acceptance and growth in Central and Eastern Europe.

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[1] J. Vet et al, A Performance Evaluation of an Optoelectronic Cervical Screening Device in Comparison to Cytology and HPV DNA Testing DOI: 10.31083/j.ejgo4302027 EJGO, Vol.43,Issue 2,April 2022 pp.213-218

[2] HPV Information centre (2017). Poland: Human Papillomavirus and Related Cancers, Fact Sheet 2017. ICO/IARC Information Centre on HPV and Cancer. Accessed on 12/11/2018 from: http://www.hpvcentre.net/statistics/reports/POL_FS.pdf

The Chinese Obstetricians and Gynaecologists Association (COGA) trial results to be published in the Journal of the American Medical Association (JAMA)

The COGA Trial screened 15,661 women across 64 hospitals in 9 provinces over 3 years, concluding in July 2021. The results, which highlighted the superiority of TruScreen Ultra ® against alternative screening methods, were previously released and presented at a research conference organised by ASCCP (American Society of Colposcopy and Cervical Pathology) held in San Diego, USA.

The COGA trial manuscript is currently being reviewed for publishing in the Journal of the American Medical Association (JAMA). The results of the study found that for detection of CIN2+:

- TruScreen's sensitivity[3] was higher than that for LBC (87.5% v's 66.5%), with a high degree of statistical significance (p<0.001).
- TruScreen's specificity[4] (88.4%) was higher than LBC (86.3%) and hrHPV testing (78.3%) (p<0.001).

Publication of TruScreen's outstanding results in this study in JAMA should further the acceptance of TruScreens innovative technology around the world.

Saudi Arabia, Al Habib clinical evaluation manuscript is aiming for submission to the European Journal of Gynaecology Oncology

The leading private medical services provider in Saudi Arabia , Dr. Sulaiman Al-Habib Medical Group (DSAMG), has concluded the clinical evaluation of TruScreen Ultra®. The manuscript has been submitted for publication in the European Journal of Gynaecology Oncology.

The Saudi Arabia study compared TruScreen Ultra® and LBC across multiple medical centres of DSAMG. The preliminary results demonstrated TruScreen's sensitivity of 83.3% (LBC: 66%) and specificity of 95% (LBC 98%). TruScreen anticipates that publication in this prestigious journal will further TruScreen's growth in the middle east and other regions.

China cervical cancer screening back to pre-Covid levels

TruScreen shipped the first 20 (order 40 – see ASX Announcement 8 March 2023) devices to its China distributor, Beijing Siweixiantai Tech Co. Ltd (SWXT), in April 2023, and is on schedule to ship the remainder in May 2023. Single Use Sensor (SUS) pull through demand is now growing strongly, and we anticipate further growth in the demand for new devices in China's growing public Health Check Sector in FY2024.

The first installation of the TruScreen cervical cancer screening device into a public Health Check Centre occurred in February 2023. The installation was within the PLA 360 General Hospital, one of the leading health check centers in the country.

This announcement has been approved by the Board

Ends

[3] Sensitivity measures correctly a positive result for patients who have the condition that is being tested for (also known as the "true positive" rate). A test that is highly sensitive will indicate patients who have the disease.

[4] Specificity measures correctly a negative result for people who do not have the condition that is being tested for (also known as the "true negative" rate). A high-specificity test will correctly rule out patients who do not have the disease.

For more information, visit www.truscreen.com or contact:

Dr Beata Edling
Chief Executive Officer
beataedling@truscreen.com

Guy Robertson
Chief Financial Officer
guyrobertson@truscreen.com

Julia Maguire
Investor Relations
julia@thecapitalnetwork.com.au

About TruScreen:

TruScreen Group Limited (NZX/ASX: TRU) is a New Zealand-based medical device company that has developed an AI-enabled device that can detect precancerous and cancerous cervical changes in real-time via optical and electrical measurements of cervical tissue. Unlike many cervical screening technologies that have only triage/adjunct functionality, the TruScreen device is registered as a primary screening tool.

TruScreen's cervical screening technology effectively resolves many of the ongoing issues with conventional cytology, including failed samples, poor patient follow-up, patient discomfort, and the need for supporting laboratory infrastructure.

The device is CE-marked, meaning it meets EU safety, health and environmental protection standards required for sale and use throughout Europe. It is also National Medical Products Administration approved for sale in China. In 2021, TruScreen established a manufacturing facility in China for devices marketed and sold in China.

TruScreen is currently targeting product sales to a range of low and middle-income countries, including China, Mexico, Vietnam, Russia, Zimbabwe and Saudi Arabia, where no large-scale cervical cancer screening programmes and infrastructure are currently in place. By doing so, the Company hopes to help improve the health and wellbeing of women worldwide.

To learn more, please visit: www.truscreen.com/