NZX/ASX Announcement

3 October 2024

WHO agency UNITAID features TruScreen in its technology landscape report

- **UNITAID, a World Health Organisation (WHO) agency featuring health solutions for Low- and Middle-Income countries has included TruScreen in its report "Screening and treatment of pre-cancerous lesions for secondary prevention of cervical cancer"**
- **TruScreen is the only opto-electrical device included in the technology report**
- **Report was prepared by UNITAID in collaboration with the Clinton Health Access Initiative (CHAI)**
- **The report reinforces previous inclusions in national guidelines by,**
  - **the China Obstetrics and Gynaecology Association (COGA) Blue Paper,**
  - **the Chinese Society for Colposcopy and Cervical Pathology (CSCCP)) China Cervical Cancer Screening Management Guideline,**
  - **the Vietnam Ministry of Health National Technical List, and**
  - **COFEPRIS approval for use in Mexico's public health system.**

TruScreen Group Limited (NZX/ASX:TRU) is pleased to announce that our TruScreen Ultra cervical cancer Screening device is included in the UNITAID "Screening and treatment of pre-cancerous lesions for secondary prevention of cervical cancer" technology landscape report.

Full report can be found at: https://unitaid.org/news-blog/unitaid-unveils-new-report-on-technologies-to-prevent-cervical-cancer-a-leading-killer-of-women-worldwide/#en

The report features TruScreen Ultra as the only opto-electrical device recognized in its section on screening by visual assessment or opto-electrical methods and notes the training and validation of the TruScreen algorithm in over 40,000 women in multiple geographical and ethnic settings.

The landscape report was prepared by the Daffodil Centre at the University of Sydney (in partnership with Cancer Council NSW), Australia and the Australian Centre for Prevention of Cervical Cancer (ACPCC) on behalf of UNITAID.

The inclusion in the UNITAID report follows similar inclusions in major national health guidelines

- the China Obstetrics and Gynaecology Association (COGA),
- the Chinese Society for Colposcopy and Cervical Pathology (CSCCP),
- the Vietnam Ministry of Health National Technical List, and
- COFEPRIS, the Mexican public health regulator.

CEO, Mr Martin Dillon commented:

"It is pleasing that TruScreen is included in this global authoritative report, from UNITAID, the Clinton Health Access Initiative, the Daffodil Centre and the Australian Centre for Prevention of Cervical Cancer.

UNITAID's focus is to close the gap for health access in Low-and-Middle-Income countries. The inclusion in this report aligns with our strategy to focus on countries with poor or no screening capabilities. A Saudi Arabia study concluded that TruScreen "represents a reliable, practical screening tool for cervical neoplasms" and that their results "provide an evidence-based approach for policymakers when selecting the optimal cervical cancer screening strategy in countries without an established national screening program."

This announcement has been approved by the Board.

Ends

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

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About TruScreen:

TruScreen Group Limited (NZX/ASX: TRU) is a medical device company that has developed and manufactures an AI-enabled device for detecting abnormalities in the cervical tissue in real-time via measurements of the low level of optical and electrical stimuli.

TruScreen's cervical screening technology enables cervical screening, negating sampling and processing of biological tissues, failed samples, missed follow-up, discomfort, and the need for costly, specialised personnel and supporting laboratory infrastructure.

The TruScreen device, TruScreen Ultra®, is registered as a primary screening device for cervical cancer screening.

The device is CE Marked/EC certified, ISO 13485 compliant and is registered for clinical use with the TGA (Australia), MHRA (UK), NMPA (China), SFDA (Saudi Arabia), Roszdravnadzor (Russia), and COFEPRIS (Mexico). It has Ministry of Health approval for use in Vietnam, Israel, Ukraine, and the Philippines, among others and has distributors in 29 countries. In 2021, TruScreen established a manufacturing facility in China for devices marketed and sold in China.

TruScreen technology has been recognised in CSCCP's (Chinese Society for Colposcopy and Cervical Pathology) China Cervical Cancer Screening Management Guideline.

TruScreen has been recognised in a China Blue Paper "Cervical Cancer Three Stage Standardized Prevent and Treatment" published on 28 April 2023.

In Dec 2023 TruScreen technology was added to the Vietnam Ministry of Health approved National Technical List, for use in Vietnam's public and private healthcare sectors

In financial year 2024 alone, over 200,000* examinations have been performed with TruScreen device. To date, over 200 devices have been installed and used in China, Vietnam, Mexico, Zimbabwe, Russia, and Saudi Arabia. TruScreen's vision is "A world without the cervical cancer"©.

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

**Based on Single Use Sensor sales.*

truscreen
a world without cervical cancer

Glossary:

Pap smear (the Papanicolaou smear) test involves gathering a sample of cells from the cervix, with a special brush. The sample is placed on a glass slide or in a bottle containing a solution to preserve the cells. Then it is sent to a laboratory for a pathologist to examine under a microscope. https://www.cancer.net/navigating-cancer-care/diagnosing-cancer/tests-and-procedures/pap-test

LBC (the liquid-based cytology) test, transfers a thin layer of cells, collected with a brush from the cervix, onto a slide after removing blood or mucus from the sample. The sample is preserved so other tests can be done at the same time, such as the human papillomavirus (HPV) test https://www.cancer.net/cancer-types/cervical-cancer/diagnosis

HPV (human papilloma virus) test is done on a sample of cells removed from the cervix, the same sample used for the Pap test or LBC. This sample is tested for the strains of HPV most commonly linked to cervical cancer. HPV testing may be done by itself or combined with a Pap test and/or LBC. This test may also be done on a sample of cells which a person can collect on their own. https://www.cancer.net/cancer-types/cervical-cancer/screening-and-prevention

Sensitivity* and *specificity mathematically describe the accuracy of a test which reports the presence or absence of a condition. If individuals who have the condition are considered "positive" and those who don't are considered "negative", then sensitivity is a measure of how well a test can identify true positives and specificity is a measure of how well a test can identify true negatives:

- **Sensitivity** (true positive rate) is the probability of a positive test result, conditioned on the individual truly being positive.
- **Specificity** (true negative rate) is the probability of a negative test result, conditioned on the individual truly being negative (Sensitivity and specificity – Wikipedia).

For more information about the cervical cancer and cervical cancer screening in New Zealand and Australia, please see useful links:

New Zealand: National Cervical Screening Programme | National Screening Unit (nsu.govt.nz)

Australia: Cervical cancer | Causes, Symptoms & Treatments | Cancer Council