NZX/ASX Announcement

7 February 2024

TruScreen receives Approval in Mexico to enter public health sector

Highlights

- **TruScreen received Cofepris approval in Mexico, a major milestone and endorsement of the TruScreen technology**
- **Cofepris is Mexico's national regulator and the approval grants TruScreen access to the country's public health sector.**

Truscreen Group Limited (NZX/ASX:TRU) is pleased to announce that the national regulator of Mexico, Cofepris has approved TruScreen access to the public health sector.

The approval allows TruScreen to expand its cervical cancer screening, currently, in the private health clinics to the wider public health sector. A 2020 census identified that only 2.3% of the population have private healthcare while 70.9% of the population accessed the public health system. Mexico has an addressable market of 65 million women.

HPVcentre.net estimated that 9,400 women are diagnosed annually with cervical cancer with a mortality rate of 46% - 4,300 deaths. Cervical cancer is the second most prevalent cancer amongst women in Mexico.

The CEO, Dr Beata Edling commented:

"The Cofepris approval highlights the accelerating acceptance of the TruScreen technology globally. I am delighted that women in Mexico will have access to faster, more efficient, and reliable cervical cancer screening with TruScreen. We congratulate our partner, Sunbird on achieving this significant milestone and look forward to advancing cervical cancer screening in Mexico".

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 financial year 2023 alone, over 140000* 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