NZX/ASX Announcement



8 March 2024

TruScreen Market Access Developments - Indonesia and Kenya

TruScreen Group Limited (NZX/ASX:TRU) is pleased to announce planning in progress for clinical evaluation trials in Indonesia and Kenya which are a prelude to wider market access in future years. Indonesia has an addressable screening market of 95 million while Kenya has an addressable screening market of 17 million.

These initiatives are being driven by Key Opinion Leaders (KOL's) in these countries through private healthcare networks.

The proposal for Kenya is for a 1,000 women evaluation, while the Indonesian trial will initially cover 100 women.

TruScreen has also recently expanded sales in Saudi Arabia into public hospitals with the TruScreen Ultra2 cervical screening device demonstrating its value in timely diagnosis at a reduced cost compared with conventional screening methods.

Martin Dillon, CEO of TruScreen said "It is important that we continue with a growing pipeline of new market access activities to further grow the distribution of TruScreen cervical cancer screening technology. We expect Indonesia to be a key market for our technology in ASEAN, following our success in Vietnam. Similarly, Kenya is an important African market following our success in Zimbabwe"

This announcement has been approved by the Board.

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For more information, visit<u>www.truscreen.com</u> 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.



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. <u>https://www.cancer.net/navigating-cancer-care/diagnosing-cancer/tests-and-procedures/pap-test</u>

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 <u>https://www.cancer.net/cancer-types/cervical-cancer/diagnosis</u>

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, <u>conditioned</u> 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 (<u>Sensitivity and specificity Wikipedia</u>).

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

New Zealand: <u>National Cervical Screening Programme | National Screening Unit (nsu.govt.nz)</u> Australia: <u>Cervical cancer | Causes, Symptoms & Treatments | Cancer Council</u>