NZX/ASX Announcement

27 May 2025

TruScreen appointed to distribute DaltonBio's HPV detection products in India

- **TruScreen signs agreements with Hangzhou Dalton Bioscience Limited ("DaltonBio"), for TruScreen to distribute DaltonBio's HPV-related In Vitro Diagnostics ("IVD") products in India**
- **Co Testing with both TruScreen and HPV DNA testing has been shown (see COGA trial results below) to significantly increase the sensitivity of TruScreen standalone screening**
- **Cervical cancer is the second most common cancer among women in India, and it is estimated that one woman dies from cervical cancer every eight minutes in the country**
- **Cervical cancer screening currently covers only 2% of women in India**
- **India is the world's second most populous country, with an estimated screening population of over 468 million women***
- **Future agreements expected to be made for other countries following this breakthrough agreement for India.**

TruScreen Group Limited (NZX/ASX: TRU), ("TruScreen" or "the Company"), a global leader in AI-enabled cervical cancer screening, is pleased to announce that an Agreement has been signed with Hangzhou Dalton Bioscience Limited ("DaltonBio"), for TruScreen to distribute DaltonBio's HPV-related In Vitro Diagnostics ("IVD") products in India.

The agreement follows the signing of a Memorandum of Understanding in February 2025 with DaltonBio, a leading China-based manufacturer of high-performance HPV DNA tests and laboratory equipment for cervical cancer screening, in which both parties agreed to explore opportunities to leverage existing distribution networks.

This is the first of many agreements expected to be formalised by TruScreen and DaltonBio in their collaboration to enhance access to innovative cervical cancer screening and detection solutions by leveraging the technology strengths of both companies.

TruScreen recently re-entered the Indian sub-continent with the appointment of India medical products distributor Renovate Biologicals Pvt Ltd (RBL) in April 2025 to distribute TruScreen's unique AI enabled cervical cancer screening system in India. This agreement will see DaltonBio HPV test kits added to this Indian distribution.

India is the second most populous country in the world, with one-sixth of the world's population – a total of 1.4 billion people – and an estimated screening population of over 468 million women*.

Cervical cancer is the second most common cancer among women in India, despite being the fourth most common globally. One woman dies from cervical cancer every eight minutes in the country, making it a significant public health concern (albeit with regional variations in incidence and mortality).

According to 2023 estimates, 124,000 women are diagnosed with cervical cancer annually, and 77,000 die from the disease.**

The prevalence of cervical cancer screening is low at 2% in India***. India conducted approximately 7 million screening tests last year with about 85% conducted in the private health sector with a focus on quality health outcome. India's National Academy of Medical Sciences (NAMS) has recently recommended cervical cancer as a notifiable disease to focus on early detection and a target to achieve a 70% screening rate for cervical cancer by 2030. The distribution of both TruScreen's unique AI enabled technology and DaltonBio's IVD products will directly contribute to this target.

As demonstrated in the China Obstetricians and Gynaecologists Association (COGA) landmark study which results were released in 2023, co-testing lifted TruScreen's already impressive standalone sensitivity of 87.5% to a co-test sensitivity of 98.4%.

TruScreen's portability and its AI enabled algorithm which provides real time results without the needs of expensive laboratory infrastructure make it an ideal screening solution for such a populous nation with high mortality to cervical cancer. TruScreen technology is non-invasive and is culturally sensitive to Islamic Indian patients (14% of the Indian population) as it does not require a collection of cervical cells.

TruScreen CEO, Marty Dillon commented: *"The signing of this agreement officially opens a new chapter in TruScreen's commercial operations. It strengthens our product offering in the World's second most populous country and is a blueprint for similar agreements to be reached for other markets in which TruScreen is active or seeks to be active. The agreement adds to both our product suite and geographic depth. TruScreen and HPV DNA detection are natural partners in the fight to eliminate cervical cancer, as the results of the COGA clinical trial so emphatically demonstrate."*

DaltonBio Founder and President, Dr. Ben Hua commented: *"Both DaltonBio HPV tests and TruScreen AI enabled screening worked in conjunction with each other as a triage to confirm the positive result of a patient, prior to treatment for HPV cancerous lesions. This agreement is an affirmation of the value of both companies' technologies to offer best available solutions to healthcare clinicians globally. Our cost-effective high-performance HPV DNA tests and other IVD products for women's health are ideally suited for use in India as well as in many other countries where TruScreen has distribution. We look forward to completing more such agreements."*

This announcement has been approved by the Board.

*CIA World Factbook women aged 15-64 = 467,593,7814

**Human Papilloma Virus and Related Cancers Fact Sheet 2023

**Muthuramalingam MR, Muraleedharan VR. Patterns in the prevalence and wealth-based inequality of cervical cancer screening in India. BMC Womens Health. 2023 Jun 26;23(1):337. doi: 10.1186/s12905-023-02504-y. PMID: 37365552; PMCID: PMC10291770.

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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 typically 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 and the Philippines, among others and has distributors in over 20 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 and in 2024 was added to the Russian guidelines for the screening of cervical cancer.

In financial year 2025 alone, approximately 150,000[1] examinations were performed with the 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/.

[1]*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. 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