NZX/ASX Announcement

20 October 2021

Clinical trial results highlight efficacy of TruScreen cancer screening technology[1]

Key Highlights

- A new study, published in the European Journal of Obstetrics and Gynaecology and Reproductive Biology[1], concludes that TruScreen's cervical cancer screening technology meets or exceeds the effectiveness of alternative cervical cancer screening methods
- The study evaluated the efficacy of TruScreen in screening for cervical abnormalities, in a real world, primary cervical cancer screening setting in China
- The TruScreen screening device was found to be very effective at detecting cervical intraepithelial neoplasia grade 2 or worse (CIN2+ or CIN3+).

TruScreen Group Limited (NZX/ASX: TRU) ('TRU' or 'the Company') is pleased to inform the market of a study conducted in China, the results of which indicate that TruScreen's cervical cancer screening technology has demonstrated to be an effective alternative to cervical cytology.

TruScreen matches or outperforms cytology for cervical screening

A recently published study conducted in China has confirmed the efficacy of TruScreen's cervical cancer screening devices versus human papillomavirus (HPV) testing, cytological testing using the ThinPrep cytology test (TCT). The study recruited 458 women aged between 25 and 65 years, who received cervical cancer screening using all three methods. The clinical performance of TruScreen, alone and in combination with HPV testing, was evaluated to detect cervical intraepithelial neoplasia grade 2 or worse (CIN2+ or CIN3+).

The study concluded that for detection of CIN2+, the sensitivity and specificity of TruScreen were 83.78% and 78.86%, respectively. The specificity of TruScreen was significantly higher than those of HPV testing (50.59%, $P < 0.001$) and TCT (55.58%, $P < 0.001$). In high-risk HPV-positive women, the specificity of HPV testing combined with TruScreen was significantly higher than that of HPV testing combined with TCT (50% vs 39.9%, $P = 0.004$). Importantly, the sensitivity of HPV testing combined with TruScreen was comparable to that of HPV testing combined with TCT (93.94% vs 87.88%, $P = 0.625$). Similar patterns were also observed for CIN3+, demonstrating that TruScreen could be an alternative method to cytology.

Key findings of the study are outlined in the table below. For CIN2+, TruScreen had specificity of **78.86%,** significantly higher than both HPV testing and TCT (50.59% and 55.58% respectively). TruScreen's sensitivity of **83.78%** was comparable to HPV testing and once again significantly higher than TCT (89.19% and 55.58% respectively).

The PPV for TruScreen (**25.83%**) was significantly higher than those for HPV testing (13.69%) and TCT (12.62%). TruScreen's NPV figure (**98.22%**) was similar to that of HPV testing (98.16%) and TCT (95.90%). Similar trends were apparent for results reported for CIN3+ cases.

In women who were high-risk HPV-positive, the specificity of HPV combined with TruScreen was **50%** (HPV + TCT 39.9%) the sensitivity for HPV and TruScreen combined was 93.94% (HPV + TCT 87.88%).

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[1] Yingting Wei, Wenjing Wang, Mengxing Cheng, Zubei Hong, Liying Gu, Jiaxin Niu, Wen Di, Lihua Qiu, Clinical evaluation of a real-time optoelectronic device in cervical cancer screening, Yingting We et al., European Journal of Obstetrics & Gynecology and Reproductive Biology, 2021, ISSN 0301-2115, https://doi.org/10.1016/j.ejogrb.2021.09.027. (https://www.sciencedirect.com/science/article/pii/S0301211521004826)

CIN2+[2]	**TruScreen**	HPV	TCT	TRUSCREEN + HPV	HPV + TCT
Sensitivity	**83.78%**	89.19%	55.58%	93.94%	87.88%
Specificity	**78.86%**	50.59%	55.58%	50.00%	39.90%
PPV	**25.83%**	13.69%	12.62%	22.96%	18.83%
NPV	**98.22%**	98.16%	95.90%	98.11%	95.40%

The study concluded that TruScreen has the potential for screening high-grade cervical precancerous lesions and may replace cytological tests as a cervical cancer screening method in China. TruScreen minimises the inherit subjectivity of interpretation of cytological tests and the dependency on pathology infrastructure.

TruScreen CEO Juliet Hull said: *"It is pleasing to see an ever-increasing number of published studies coming through that highlight the effectiveness of the TruScreen screening device in detecting cervical cancer. It adds to the body of evidence already available, with a substantial amount of the publishes studies undertaken in China, our major offshore market. But the full set of advantages the TruScreen screening device provides to both patients and clinics do not get reflected in these studies. When measured against other screening options, our device is non-invasive, affordable, quick, easy to learn and independent from laboratory infrastructure, making it a cost-effective alternative to expensive cytology methods. At the same time, we remain intent on building on these existing competitive advantages. We are now in the process of releasing a Firmware update to TruScreen devices already in the market, which enhances their data security and more effectively interfaces with compatible hospitals' systems. This determination to continually evolve our unique product offering bodes well for TruScreen's growth potential over coming years."*

ENDS

This announcement was approved for release by the Board.

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[2] **Specificity**, with a high reading resulting in fewer false positives in the screening process. **Sensitivity**, where a high sensitivity print means fewer false negatives. **Positive predictive value (PPV),** a gauge that examines the probability that subjects with a positive screening test truly have the disease. **Negative predictive value (NPV)**, which is the probability that subjects with a negative screening test truly do not have the disease

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a world without cervical cancer

About TruScreen:

TruScreen Limited (NZX/ASX:TRU) is a New Zealand-based medical device company that has developed a device that can accurately detect precancerous and cancerous cervical cells in real-time via optical and electrical measurements of cervical tissue.

TruScreen's cervical screening technology effectively resolves many of the ongoing issues with conventional cytology tests, 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.

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