

ASX RELEASE

European Society of Breast Imaging releases new breast density-based screening recommendations following DENSE trial using VolparaDensity software

Highlights:

- **The European Society of Breast Imaging (EUSOBI) now recommends European women be informed about their breast density and, if they have extremely dense breasts and are aged 50–70 years, should be offered breast MRI screening every 2–4 years.**
- **The EUSOBI also states that in order “to minimize variability in the selection of women for supplemental or alternate screening based on breast density, automated methods may be preferable.”**
- **The DENSE trial’s exclusive use of Volpara®Density™ software underscores Volpara’s leadership in developing world-class software products for personalised breast care.**
- **Europe presents a significant commercial growth opportunity over the coming years as public screening programs implement these new recommendations.**

Wellington, NZ, 10 March 2022: Volpara Health Technologies (“Volpara,” “the Group,” or “the Company”; ASX:VHT), a global health technology software leader providing an integrated platform for the delivery of personalised breast care, announced the release of new screening recommendations by the EUSOBI for women with extremely dense breast tissue as a direct result of findings from a research study (the “DENSE trial”) using VolparaDensity breast density assessment software.

The new recommendations represent a significant shift from the biannual mammography exams currently advocated by most European screening organisations and offer further clinical and commercial validation of Volpara’s technology, designed to improve women’s health outcomes through personalised mammographic care.

The DENSE trial was a 10-year Dutch nationwide multicentre randomised trial in women with extremely dense breast tissue, as automatically assessed by a computer program (VolparaDensity).

The results of the DENSE trial have recently been modelled in a microsimulation model (MISCAN) to determine the long-term impact of offering breast MRI screening to women with extremely dense breasts. The results of this microsimulation model suggest that adding biannual MRI to biannual mammography, as performed in the DENSE trial, would save 8.6 additional lives per 1,000 women invited, at a cost of 150,000 Euro per life, or 22,500 Euro per quality-adjusted life-year (QALY), indicating a cost-effective method.¹

The EUSOBI explains the advantages associated with breast MRI screening in women with extremely dense breasts by the following statements derived from the DENSE trial:

- A woman with extremely dense breasts who is never screened has a chance of dying from breast cancer of a little over 5 percent.
- Participation in mammography screening every other year leads to early detection of cancer in about 7 percent of women, reducing the likelihood of dying of breast cancer to just over 4 percent, a reduction of 20 percent.
- According to epidemiological modelling of DENSE trial results, participation in screening with MRI every other year leads to early cancer detection in about 10 percent of women and reduces the risk of dying from breast cancer to a little over 3 percent, a mortality reduction of about 40 percent.
- The modelling suggests that when MRI prevents a woman from dying from breast cancer, she gains on average 15 years of good health before dying of another cause.

The EUSOBI now recommends that all European mammography providers offer breast MRI to women with extremely dense breasts. The recommendation considered the mounting evidence of the risks associated with extremely dense breast tissue—notably the twice-greater likelihood of developing breast cancer and the significant reduction in mammographic sensitivity—and in particular the results of the DENSE trial, which showed a significant reduction in interval cancers in women identified by VolparaDensity as having extremely dense breasts and then receiving breast MRI.

The recommendation urging European mammography providers to notify women of their breast density at the time of screening, along with a greater awareness of the risks of extremely dense breast tissue, presents a significant opportunity for Volpara to expand its European footprint to capitalise on the potential increased use of breast density screening software. The market is sizable, as each year 17.9 million women in Europe are screened for breast cancer.²

The EOSOBI's full recommendation can be found [here](#).

Volpara CEO Ralph Highnam said: "The EUSOBI's new recommendations are a major step toward widescale European implementation of personalised breast care for women with extremely dense breasts. Volpara has long advocated the informing of women about their dense breast tissue and offering them additional imaging as needed. It's gratifying to see a major group of breast imaging experts base its new guidance on the results generated by our automated density assessment software in the groundbreaking DENSE trial, and I'm hopeful that other public health bodies will now follow the EUSOBI's lead."

Authorisation & Additional Information

This announcement was authorised by the CEO of Volpara Health Technologies Limited.

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About Volpara Health Technologies Limited (ASX:VHT)

VHT is a health technology software company founded in 2009 on research originally conducted at Oxford University. VHT's clinical functions for screening clinics provide feedback on breast density, compression, dose, and quality, while its enterprise-wide practice-management software helps with productivity, compliance, reimbursement, and patient tracking.

VHT's technology and services have been used by customers and/or research projects in 39 countries and are supported by numerous patents, trademarks, and regulatory clearances, including FDA clearance and CE marking. Since its listing on the ASX in April 2016, VHT has raised A\$132 million, including A\$37 million in April/May 2020, and has made two significant acquisitions in MRS Systems, Inc. (patient tracking software), and CRA Health, LLC (risk and genetics software). VHT is based in Wellington, New Zealand.

For more information, visit www.volparahealth.com

¹ Mann, R.M., Athanasiou, A., Baltzer, P.A.T. *et al.* Breast cancer screening in women with extremely dense breasts recommendations of the European Society of Breast Imaging (EUSOBI). *Eur Radiol* (2022). <https://doi.org/10.1007/s00330-022-08617-6>

² <https://www.signifyresearch.net/medical-imaging/breast-imaging-market-revenues-declined-15-2020/>

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