ASX RELEASE

Volpara DENSE trial results published in the *New England Journal of Medicine*

Highlights:

- **Results of eight-year DENSE breast screening trial published in the *New England Journal of Medicine* (NEJM)**
- **The DENSE randomised controlled trial shows a halving of interval breast cancers in women identified as having extremely dense breasts by Volpara®Density™ software who are then offered breast MRI**
- **The publication of the DENSE trial results represents a significant milestone for screening—"high-quality data from a randomised trial where none existed," states the accompanying NEJM editorial**

Wellington, NZ, 28 November 2019: Volpara Health Technologies ("Volpara"; ASX: VHT), a SaaS medical technology company whose AI imaging algorithms assist the early detection of breast cancer, announced today that the results of the DENSE breast screening trial will be published in the print edition of the *New England Journal of Medicine* on November 28th in the United States.

The DENSE trial, which started collecting patients eight years ago and involved about 40,000 women, is the first randomised controlled study on the clinical utility of breast MRI supplemental screening for women with extremely dense breasts.

Volpara provided the Dutch researchers, led by epidemiologist Professor Carla van Gils of the University Medical Center Utrecht, with the VolparaDensity software used to automatically and objectively assess breast density in the DENSE trial. Women whose breasts were judged to be extremely dense were selected for breast MRI screening. The trial assigned 8,061 women to the MRI group, and 32,312 to the mammography-only control group.

The interval-cancer rate (the number of cancers not detected at screening but found between screenings) was 2.5 per 1,000 in the women invited to have MRI, compared to 5.0 per 1,000 in the control group ($P<0.001$). 80% of the interval cancers in the MRI group were from women who opted not to have MRI despite being invited. The positive predictive value was 17.4% for recall for additional testing and 26.3% for biopsy. The false positive rate was 79.8 per 1,000 screenings.

Volpara's founder and Chief Executive Officer, Dr Ralph Highnam, said the publication of the full results of the DENSE trial in the *New England Journal of Medicine* will draw attention to ways of making breast screening more effective and represents a significant milestone both for Volpara and women globally.

"The evidence from this study is quite clear: using VolparaDensity to assess breast density and then offering MRI screening to women with extremely dense breasts resulted in a significant reduction of 50% in interval cancers. Population-based screening programs now have solid evidence on which to consider the pros and cons of more personalized screening," Dr Highnam said.

"Women all over the world will benefit from the work of Professor van Gils and her colleagues. I am pleased that Volpara has been a long-term partner in this effort, as it fits perfectly with our mission to

Save Families from Breast Cancer. We look forward to discussing this study and the clear outcomes with screening programs globally."

Volpara's Chief Medical Officer, Dr Monica Saini, said addressing interval cancers is a priority for radiologists, given the cancer's aggressive nature and poor prognosis.

"The work of Professor van Gils and her colleagues provides a clear template for how organised screening programs can use automated density to triage women who are at greatest risk of developing interval cancers," Dr Saini said. "By identifying these women for intervention, we can reduce the emotional, physical, and financial costs of breast cancer."

The DENSE trial started in 2011 in the Netherlands, funded by Bayer and multiple Dutch organisations.

The abstract can be found at this link:
https://www.nejm.org/doi/full/10.1056/NEJMoa1903986?query=recirc_inIssue_bottom_article

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ABOUT VOLPARA HEALTH TECHNOLOGIES LIMITED (ASX: VHT)

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

VHT's technology and services have been used by customers and/or research projects in 38 countries and are supported by numerous patents, trademarks and regulatory clearances, including FDA clearance and CE marking. Since its listing on the ASX in 2016, VHT has raised A$95 million, including A$55 million in June 2019. VHT is based in Wellington, New Zealand.

At the end of June 2019, VHT acquired MRS, a company based in Seattle, WA. MRS provides mammography reporting systems to over 1,600 breast clinics and hospitals, and to VHT a much stronger US presence, experienced local headquarters, and accelerated sales through cross-selling opportunities.

For more information, visit www.volparasolutions.com