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ASX RELEASE

Volpara presents at the FDA-hosted National Mammography Quality Assurance Advisory Committee (NMQAAC)

Wellington, NZ, 20th September 2016: Volpara Health Technologies ("Volpara"; ASX: VHT), a digital health company focused on early detection of breast cancer, is pleased to advise that it delivered a public presentation at the National Mammography Quality Assurance Advisory Committee (NMQAAC) meeting hosted by the United States Food and Drug Administration (FDA) on 15 September 2016.

Dr Ralph Highnam, CEO of Volpara said: "This meeting was very important as it gave us insights into how the FDA is moving with regards to quality control in mammogram screening and the need to report breast density to patients. It allowed us to present to the FDA and the wider Committee our new developments in these areas, namely Volpara Enterprise with its automated quality control functions."

The committee meets to discuss quality in mammography screening, and in particular to consider adjustments to the guidance for compliance to the Mammography Quality Standards Act (MQSA), which is a federally regulated set of requirements for breast imaging centres. The meeting was chaired by Dr Robert Rosenberg from the Radiology Associates of Albuquerque. It featured formal presentations from the FDA to the Committee, and seven presentations from the public. Volpara was the only provider of breast density screening to deliver a public presentation.

Members of the FDA delivered three presentations that were of particular importance to Volpara. The presentations "MQSA Analyses of Compliance Cases" by Rachel Evans and "MQSA: Beginning the Next Quarter Century with a Spotlight on Image Quality" by Dr Helen Barr, noted that most failures of MQSA inspections were due to positioning and compression issues. The FDA proposed that its inspectors look for evidence that screening sites are carrying out programs to monitor and improve positioning and compression (the new "EQUIP" program). Positioning assessment, compression evaluation, and performance tracking are three of the main features introduced into the recently launched Volpara Enterprise product.

The presentation "Breast Tissue Density, Cancer Risk and State Patient Notification Laws" delivered by David Lerner of the FDA, provided an overview of breast density and its relationship to risk of missing cancer, and risk of developing cancer. He noted that the FDA has previously agreed that it should be a requirement to require reporting of density in reports to health care professionals and summaries to patients (slide 48), and that now there was greater scientific consensus around dense breasts (slide 56). He said the "FDA intends to propose amendments to MQSA regulations … expected to address the issue of breast density notification" (slide 49). Currently, there are 27 states with laws requiring breast density notification, changes to MQSA regulations would effectively make it a federal law.

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In the public session, Volpara's Chief Marketing Officer, Julian Marshall, spoke about the company's recent availability of automated tools for quality assessment. The public presentations also featured several breast density advocates, including US television journalist Joan Lunden, a special correspondent to ABC's Good Morning America, who is advocating for a Federal law for breast density.

The FDA will consider the NMQAAC meeting discussion as it finalises its regulatory changes; any proposed changes will be first released for public comment, then adjusted based on those public comments, before being finally adopted.

The presentations from the meeting can be found at this link:

http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Radiation-EmittingProducts/NationalMammographyQualityAssuranceAdvisoryCommittee/ucm520364.htm

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