Federal Government Rejects Funding Bid for Novel Breast Cancer Test That May Spare Women from Chemotherapy

Oncotype DX® breast cancer assay may spare thousands of women from chemotherapy
Medical Services Advisory Committee has now rejected five funding applications for Oncotype DX

Melbourne, Australia, 4 October 2017: THE Federal Government's peak advisory committee for Medicare funding has rejected calls from doctors, patients and the pharma industry to fund a novel breast cancer test that may spare thousands of Australian women from enduring unnecessary chemotherapy.

The Health Department's Medical Services Advisory Committee (MSAC) recommended against funding the expensive Oncotype DX breast cancer assay for Australian women – despite it being reimbursed and freely available to women in many other countries, including the United States, Canada, the United Kingdom and throughout Europe.

This genetic test identifies those women who could safely avoid chemotherapy, by analysing the activity of specific cancer genes taken from a single sample of tumour tissue. It is suitable for breast cancer patients who have hormone receptor positive, HER2 negative, early stage breast cancer, which is a common form of breast cancer affecting thousands of Australian women.

The test provides a prognosis of the likelihood the cancer will recur. It is also able to provide medical teams with predictive information, identifying tumours that would be more sensitive to chemotherapy.

Specialised Therapeutics Australia has made the test available in Australia since 2014 to those women who are able to afford the $4500 out of pocket cost. Since

2014, more than 1,000 men and women diagnosed with breast cancer have paid for an ODX test allowing them and their medical team to make a more informed decision about their treatment.

In the US, Canada, the UK and Europe, the Oncotype DX test is reimbursed, widely available and consistently shown to be cost-effective. It has spared many patients from enduring unnecessary and debilitating chemotherapy.

Respected Australian surgical oncologist and specialist breast surgeon, Professor Bruce Mann said he was “very disappointed” by the decision, noting the test had been shown to change treatment decisions in many cases. He said that most frequently, it enabled patients to avoid chemotherapy. But sometimes, test results indicated that chemotherapy was the best treatment path.

“Many breast cancer patients simply cannot afford the high costs of this test and so are making treatment decisions without all potentially available information,” Professor Mann said.

“Having access to funded tests would allow limited health resources to be directed towards those who will benefit most.”

Australian breast surgeon Miss Jane O’Brien said that while the test frequently helped identify those women who could avoid unnecessary chemotherapy, it was also able to identify those for whom chemotherapy should be recommended.

“Without Oncotype, some patients may face the prospect of being under-treated,” she said.

“I have had patients who have taken the test and been advised to proceed with chemotherapy, when perhaps medical oncologists would have been confident in recommending anti-hormone therapy alone, based on the standard criteria that we have historically used. I think it is a great pity this test is not widely funded for all appropriate Australian patients.”

The Oncotype DX breast cancer assay measures the expression of 21 cancer-related genes to provide a Recurrence Score® result, a number between 0 and 100.

A low Recurrence Score result is associated with a better prognosis and the

likelihood that there would be little to no benefit in being treated with chemotherapy. Conversely, a high result would indicate a poorer prognosis, however chemotherapy is likely to be effective and reduce the risk of recurrence.

The Oncotype DX breast cancer assay is suitable for women diagnosed with hormone-receptor positive, HER-2 negative breast cancer. The test is performed on tumour tissue removed during original surgery and patients are advised to have the test soon after surgery and before commencing follow up treatment.

The Oncotype DX test was developed by Genomic Health, Inc. (NASDAQ: GHDX) a world leading provider of genomic-based diagnostic tests that optimise treatment for early stage cancer. The company is based in California in the USA.
The Oncotype DX breast cancer assay is made available in Australia by international biopharmaceutical company Specialised Therapeutics Australia at a cost of $4,500.

Specialised Therapeutics' Chief Executive Officer Mr Carlo Montagner said he was dismayed and frustrated by the latest MSAC decision, which follows five funding applications for Oncotype DX in Australia.

"This simply means that Australian women continue to be at a disadvantage," he said. "This test is widely available and reimbursed for women in most developed countries, including the United States and the United Kingdom.

"It seems that in Australia, only the 'haves' of our society can benefit from this cutting edge technology. What a pity, in this age of personalised medicine and especially at a time when the Government has acknowledged a commitment to innovation. Our belief in this technology is validated by clinical data and the experience of doctors and patients from around the world. We are lagging behind."

Specialised Therapeutics Australia will now seek to meet with health department authorities to reconsider the funding application.

Ends.

About the Specialised Therapeutics Group

The Specialised Therapeutics (ST) group of companies collaborates with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life changing healthcare solutions to patients affected by a range of diseases in Australia, New Zealand and throughout South East Asia. ST is committed to making new and novel therapies available to patients around the world, with a broad therapeutic portfolio spanning oncology, hematology, urology and ophthalmology. Further information can be found at www.STAbiopharma.com

About Oncotype DX®

The Oncotype DX portfolio of breast, colon and prostate cancer tests applies advanced genomic science to reveal the unique biology of a tumour in order to optimise cancer treatment decisions. The company's flagship product, the Oncotype DX Breast Recurrence Score® test, has been shown to predict the likelihood of chemotherapy benefit as well as recurrence in invasive breast cancer. With more than 800,000 patients tested in more than 90 countries, the Oncotype DX tests have redefined personalised medicine by making genomics a critical part of cancer diagnosis and treatment. To learn more about Oncotype DX tests, visit www.OncotypeIQ.com or www.MyBreastCancerTreatment.org.

About Genomic Health

Genomic Health, Inc. (NASDAQ: GHDX) is the world's leading provider of genomic-based diagnostic tests that help optimise cancer care, including addressing the overtreatment of the disease, one of the greatest issues in healthcare today. With its Oncotype IQ® Genomic Intelligence Platform™, the company is applying its world-class scientific and commercial expertise and infrastructure to lead the translation of clinical and genomic big data into actionable results for treatment planning throughout the cancer patient journey, from diagnosis to treatment selection and monitoring. The Oncotype IQ portfolio of genomic tests and services currently consists of the company's flagship line of

Oncotype DX® gene expression tests that have been used to guide treatment decisions for more than 800,000 cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid- and tissue-based tests, including the recently launched Oncotype SEQ® Liquid Select™ test. The company is based in Redwood City, California, with international headquarters in Geneva, Switzerland. For more information, please visit, www.GenomicHealth.com and follow the company on Twitter: @GenomicHealth, Facebook, YouTube and LinkedIn.