Cutting Edge Breast Cancer Test 'Should Be Reimbursed' – Medical Experts

Melbourne, Australia, 3 September 2015: A BREAKTHROUGH genetic test that could spare thousands of Australian women with early stage breast cancer from chemotherapy and its toxic side effects will be considered for reimbursement later this year.

The multi-gene test, known as the Onco*type* DX® Breast Cancer Assay, predicts a patient's likely benefit from chemotherapy and the overall risk of breast cancer recurrence.

Internationally endorsed and reimbursed in many other countries, the test helps a patient and her doctor make more informed, personalised treatment decisions about whether or not to proceed with chemotherapy.

The test is currently available in Australia but costs patients $4,500. Medical experts are now joining calls for reimbursement so it is accessible to all Australian breast cancer patients.

Leading Australian breast cancer surgeon, Associate Professor Michael Hughes, said that for many patients, chemotherapy did not reduce the chances of cancer recurrence.

"Patients are often placed in the situation where they need to balance the side effects of chemotherapy against any potential benefit," he said.

"Chemotherapy comes at a cost physically, psychologically, socially and financially. Very occasionally the health side effects can be catastrophic. The usual immediate physical effects of chemotherapy are fatigue, nausea, hair loss, nerve changes and low immunity leading to infections and hospital admissions. In the long term chemotherapy can result in infertility and premature menopause as well as permanent changes in the blood cells. Chemotherapy also means time away from work for the patient and often for their carers as well. There is a significant disruption to family life.

“Genomic DNA profiling of breast cancers in appropriately selected patients predicts the likely benefit of chemotherapy in reducing the risk of relapse. We have found that many ladies that would normally have had chemotherapy, do not need to have it. If genomic DNA profiling demonstrates that chemotherapy is likely to improve outcomes, then we would advise this course of action.

“Tests like this are likely to be increasingly useful in the future, allowing improved tailoring of treatment based on the biology of the individual’s tumour.”

Recent studies have demonstrated that Onco*type* DX has changed treatment decisions in approximately 50% of women with early-stage ER-positive, HER2-negative breast cancers.

The Onco*type* DX test was developed in the USA by Genomic Health, Inc. Women diagnosed with hormone receptor-positive, HER2-negative breast cancer are advised to have the test soon after surgery and before commencing follow-up treatment. The test is performed on tumour tissue that was already removed during the original surgery.

Results are available within 3 weeks and are reported as a Recurrence Score®, with each patient given a number between 0 and 100 based on their own tumour biology. Women with a low Recurrence Score result have a low risk of their cancer returning and derive little to no benefit from chemotherapy. Women with higher Recurrence Score results have a greater risk of their breast cancer returning and are more likely to benefit from chemotherapy.

Women in many countries including the United States, Canada, England, Ireland, Switzerland, Spain, Israel and Greece can have the test free of charge as it is reimbursed by governments in these regions. In Australia, where the test is not yet reimbursed by the Federal Government, the test costs $4,500.

In countries where the test is funded, studies have demonstrated it is cost effective. In some instances, it has been cost-saving due to reduced use of chemotherapy.

Fewer than 400 Australian women take this test every year, with some doctors reluctant to discuss the technology with patients because of the high cost involved.

The Onco*type* DX Breast Cancer Assay is the only such test recommended for use in clinical practice by the United Kingdom's National Institute of Health and Care Excellence (NICE) and is recommended in the 5 major international oncology treatment guidelines.

Specialised Therapeutics Australia, a biopharmaceutical company which has been distributing the test in Australia since 2014, made a reimbursement submission to the Medical Services Advisory Committee (MSAC) in June 2015.

A final decision on whether Onco*type* DX will be reimbursed for Australian women will be made at the Medical Services Advisory Committee meeting in Canberra on November 26-27.

STA Chief Executive Officer Mr Carlo Montagner said he looked forward to a positive outcome.

"We would like to see a level playing field," he said. "Women in other parts of the world have affordable access to this important technology that in many cases, changes treatment decisions.

"We want Australian women to have the same affordable, government reimbursed access and avoid unnecessary chemotherapy treatment where possible."

About Specialised Therapeutics Australia

Specialised Therapeutics Australia Pty Ltd (STA) is a biopharmaceutical company dedicated to working with leading international pharmaceutical and diagnostic companies to provide patient access to innovative healthcare solutions. The STA therapeutic portfolio and pipeline at present encompasses oncology, haematology, supportive care and genomics. STA also has interests in the therapeutic areas of ophthalmology, respiratory, dermatology, endocrinology and central nervous system (CNS). Additional information can be found at www.specialisedtherapeutics.com.au