TAILORx Trial Finds 99 Percent of Women with Low Oncotype DX Recurrence Score® Results are Free of Breast Cancer Recurrence After Five Years of Hormone Therapy Alone

MELBOURNE, Australia, REDWOOD CITY, Calif, USA and GENEVA, Switzerland, 29 September 2015: Specialised Therapeutics Australia and Genomic Health announce the presentation of the first results[1] from the **T**rial **A**ssigning **I**ndividua**L**ised **O**ptions for Treatment (**Rx**), or **TAILORx**, a large, prospectively conducted trial, designed and conducted by the ECOG-ACRIN Cancer Research Group under the sponsorship of the U.S. National Cancer Institute (NCI).

The study, published online in the *New England Journal of Medicine*, demonstrated that the group of trial participants with early-stage breast cancer and with low Oncotype DX Recurrence Score results of 10 or less, who received hormonal therapy alone without chemotherapy, had less than a 1% chance of distant recurrence at five years.

The results from 1,626 eligible patients with node-negative, oestrogen receptor-positive (or progesterone receptor-positive, or both), HER2-negative breast cancer who had a Recurrence Score result between 0 and 10 were presented at the 2015 European Cancer Congress (ECC2015). 99.3% of these patients had no distant recurrence at five years after treatment with hormonal therapy alone. These outcomes were consistent irrespective of patient age, tumour size, and tumour grade.

'This is the first prospectively conducted clinical trial evaluating this multi-gene

test – or any breast cancer multi-gene test for that matter – in which patients with early stage breast cancer were uniformly treated based on their test results,' said Joseph Sparano, MD, Montefiore Medical Center, Bronx, NY, and ECOG-ACRIN study chair. 'The compelling results seen in this global study provide unequivocal evidence supporting the clinical utility of Oncotype DX to risk-stratify patients with early stage breast cancer.'

The TAILORx trial enrolled 10,273 patients across 1,182 centres in the United States, Canada, Peru, Ireland, Australia and New Zealand. TAILORx used the Oncotype DX test on every patient to quantify individual risk of recurrence in order to assign them to the appropriate treatment. These results are from the patient group with Recurrence Score results from 0-10, who were assigned to receive hormone treatment alone. The data safety monitoring board of the TAILORx trial, as mandated by the study protocol, will continue to monitor outcomes in the primary study group of patients with a Recurrence Score result of 11 to 25 who were randomised to chemo-endocrine therapy or endocrine therapy alone. Previous Oncotype DX studies have already confirmed the benefit of adjuvant chemotherapy for those in the high Recurrence Score range.

Oncotype DX Recurrence Score used to select treatment and optimise outcomes

Complementing the data from TAILORx, Genomic Health announced the presentation of real-world clinical outcomes from a large cohort of patients in the Clalit registry.[2] Patients were followed up for a median of 5.9 years. Over half of the 930 patients in the analysis had a low Recurrence Score result (0-18) and were treated with hormonal therapy alone, showing very high 5 year breast cancer specific survival rates (99.8%) and low distant recurrence rates (0.5%).

Patients with high Recurrence Score results (greater than 31), most of whom (85%) received chemotherapy, showed 5 year breast cancer specific survival rates of 96% and distant recurrence rates of 4% while for patients in the intermediate Recurrence Score results (18-31) showed a 5 year breast cancer specific survival rate of 98.8% and distant recurrence rate of 2.3%.

'Results from our registry suggest that adding molecular information provided by

the Oncotype DX test is essential in order to spare low-risk patients the toxicity and side effects of chemotherapy,' said Prof Salomon Stemmer, Lead investigator of the study, Department of Oncology, Davidoff Center, Rabin Medical Center affiliated to Tel Aviv University, Israel. 'Knowing that Oncotype DX is predictive of chemotherapy benefit gave us confidence to move forward with appropriate, individualised treatment for each patient.'

This study, presented at the 2015 European Cancer Congress (ECC2015), is an analysis of medical records of patients receiving the Oncotype DX breast cancer test in four medical centres within Clalit Health Services, the largest health services organisation in Israel. Researchers will continue to follow patients and will report results and outcomes.

The Oncotype DX breast cancer test is the only genomic test validated for its ability to predict the likelihood of chemotherapy benefit as well as risk of recurrence in early-stage breast cancer.

Healthcare systems across Europe are recognising the value of the test, which is incorporated in all major international clinical guidelines. Most recently, the National Health Service (NHS) in England agreed to an access programme for the Oncotype DX breast cancer test which allows NHS hospitals to implement the National Institute for Health and Care Excellence's (NICE) guidance. NICE recommended the Oncotype DX breast cancer test as the only genomic test validated for its ability to predict the likelihood of chemotherapy benefit as well as risk of recurrence in early stage breast cancer. Other countries that reimburse the test include the USA, Canada, Switzerland, Ireland, Greece and Spain.

Specialised Therapeutics Australia submitted to the Medical Services Advisory Committee (MSAC) of the Department of Health for the Oncotype DX Breast Cancer Assay to be funded in Australia. This will enable equitable access to this important genomic test to Australians with early breast cancer. These new compelling data will be sent to the MSAC to support the submission which is currently under consideration.

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

About Genomic Health

Genomic Health, Inc. is a world-leading provider of genomic-based diagnostic tests that inform treatment decisions and help to ensure each patient receives appropriate treatment for early stage cancer. The company applies its state-of-the-art scientific and commercial expertise and infrastructure to translate significant amounts of genomic data into clinically actionable results for treatment planning throughout the cancer patient's journey; from screening and surveillance, through diagnosis and treatment selection. The company is based in Redwood City, California with European headquarters in Geneva, Switzerland. For more information, please visit, www.GenomicHealth.com.

To learn more about Oncotype DX, visit: www.OncotypeDX.com or www.specialisedtherapeutics.com.au/oncotypedx

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the benefits of the test to physicians, patients and payors. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: the ability of test results to change treatment decisions; the risks and uncertainties associated with the regulation of the company's tests; the

results of clinical studies; the applicability of clinical study results to actual outcomes; the risk that the company may not obtain or maintain sufficient levels of reimbursement, domestically or abroad, for its existing tests and any future tests it may develop; the risks of competition; unanticipated costs or delays in research and development efforts; and the other risks set forth in the company's filings with the Securities and Exchange Commission, including the risks set forth in the company's quarterly report on Form 10-Q for the year ended June 30, 2015. These forward-looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these forward-looking statements.

- Study results published today in the New England Journal of Medicine
- Additional clinical outcomes from large patient registry confirm accuracy of Oncotype DX test in guiding treatment decisions

References

1. Sparano JA, et al. "Prospective Validation of a 21-Gene Expression Assay in Breast Cancer" New Engl J Med 2015. This article was published on September 28, 2015, at NEJM.org
2. Stemmer S, et al. "First prospective outcome data in 930 patients with more than 5-year median follow up in whom treatment decisions in clinical practice have been made incorporating the 21-Gene Recurrence Score" (Abstract #1963. The European Cancer Congress 2015. Vienna, Austria)