

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.

Brain Surgery Breakthrough: New Zealand Neurosurgeon Pioneers NZ-First Technique

Auckland, New Zealand, 31 May 2017: A 33 year old Wellington mother of two has become the first New Zealand patient to be treated with a novel brain cancer visualisation drug that 'lights up' tumours during surgery to enable more complete removal of the malignant tissue.

GLIOLAN[®] (aminolevulinic acid: ALA) is taken as a drink three hours prior to surgery and works by causing cancerous tissue in the brain to fluoresce. This enables surgeons to more clearly see and better remove highly aggressive brain tumours known as glioblastoma multiforme, or GBM.

The drug will now be reimbursed for New Zealand patients at District Health Boards (DHB) hospitals from tomorrow, **1 June**, following PHARMAC's decision to

fund GLIOLAN for newly diagnosed, untreated patients.

It is expected around 100 NZ brain cancer patients a year will now benefit from this cutting-edge medicine, which has been shown to almost double the rate of complete resection and six-month progression-free survival in patients with GBM¹.

The first patient operated on using GLIOLAN is Wellington mother of two Alice Chambers-Smith, who was diagnosed with a brain tumour just weeks ago after moving back to NZ from England with her young family late last year.

Her doctors – who suspected her cancer may be glioblastoma multiforme – were able to access GLIOLAN on a compassionate basis prior to the public reimbursement.

The young mother, who has a 3 year-old daughter and 6 year-old son, said she hoped GLIOLAN would enable her doctors to remove as much of her cancer as possible.

“I just want to do every single possible thing I can to be the tiny statistic that doesn’t lose this battle,” she said.

“I think the PHARMAC decision to make this technology available can only be a good thing.”

Leading New Zealand neurosurgeon Mr Kelvin Woon was the first neurosurgeon to use the technology in New Zealand. “GLIOLAN provides a great opportunity for NZ patients who are affected by these highly malignant tumours,” he said.

“We are pleased to be pioneering this operation at the Wellington Regional Hospital as we endeavour to improve outcomes for patients with these aggressive brain tumours.

“Although not curative, GLIOLAN helps us to better visualise what can be poorly-defined tumour margins, which limits our ability to resect the tumour macroscopically.

“Using GLIOLAN, we can more clearly see what is brain tissue and what is tumour. This gives us the confidence to be more aggressive and strive for maximum resection. This is important, because the evidence points to maximum (complete macroscopic) resection and increases the chances of extending overall survival.” ²

GLIOLAN is given to patients as a drink prior to surgery. The drug is preferentially taken up by the malignant tumour tissue.

During surgery, a neurosurgical microscope fitted with a specialised blue operating light is used, which causes cancerous tissue containing the drug to glow fluorescent pink whilst normal brain tissue appears blue. This enables neurosurgeons to better visualise these tumours and more completely remove them, whilst sparing the neighbouring healthy brain tissue.

The drug is made available in New Zealand by international biopharmaceutical company Specialised Therapeutics Ltd, an affiliate of Specialised Therapeutics Asia (ST Asia).

Chief Executive Officer Mr Carlo Montagner applauded the PHARMAC decision to enable GLIOLAN to be used in complex neurosurgery cases for eligible patients.

“In this region and around the world, these patients have typically had a very poor prognosis,” he said.

“With current standard chemotherapy and radiation treatment, these patients have a median overall survival of 12, maybe 15 months.³

“GLIOLAN has been shown to help GBM patients survive longer without tumour progression compared to standard surgical procedures. Any drug or technology that enables patients additional time with their families is extremely valuable.”

International studies have shown that the use of GLIOLAN during brain tumour surgery has nearly doubled the rate of achieving a complete resection of the main tumour bulk, which in turn has resulted in a doubling of the number of patients without progression of their brain cancer six months after surgery.¹

The pivotal Phase III study published in The Lancet Oncology Medical Journal reported complete resection of malignant brain tumour tissue in 65% of patients receiving GLIOLAN compared to 36% of patients in the study's control arm (difference between groups 29% [95% CI 17-40], $p < 0.0001$). Six-month progression-free survival was achieved in 41% of patients receiving GLIOLAN compared to 21% of patients who were operated on without the use of the drug (difference between groups 20% [95% CI 9.1-30.7], $p = 0.0003$)¹.

GLIOLAN was first approved in Europe in 2007 and is marketed by medac GmbH

in Europe, Africa, South America and Asia (excepting Japan and Korea). Around 500 Australian patients have been operated on using GLIOLAN since 2012.

About GLIOLAN®

The active substance in GLIOLAN, aminolevulinic acid (ALA), is a photoreceptive compound which is absorbed by cells in the body, where it is converted by enzymes into fluorescent chemicals, particularly protoporphyrin IX (PPIX). Since glioma cells take up more of the active substance and convert it more rapidly into PPIX, higher levels of PPIX accumulate in the cancer cells than in normal tissue. When illuminated under blue light of a specific wavelength, the PPIX in the tumour glows an intense red, while the normal brain tissue appears blue. This enables the surgeon to see the tumour more clearly during brain surgery and to remove it more accurately, sparing healthy brain tissue.

Like all medications GLIOLAN may cause side effects. GLIOLAN should not be used in patients with hypersensitivity to ALA or porphyrins, or in cases of acute or chronic porphyria, or in pregnancy. Cardiac disorders, gastrointestinal disorders and skin and subcutaneous disorders are all reported as being uncommon.

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

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3. Stupp R, et al. N Engl J Med 2005; 352: 987-996

Specialised Therapeutics Asia to License a Promising Anti-Cancer Compound Lurbinectedin (PM1183) for South East Asia, Australia and New Zealand

SINGAPORE and MELBOURNE, Australia, May 17, 2017: International biopharmaceutical company Specialised Therapeutics Asia (ST Asia) is set to commercialise a promising new anti-cancer drug throughout South East Asia, after signing a second major licensing deal with European pharmaceutical company PharmaMar.

The latest agreement allows ST Asia marketing and distribution rights to new

anti-cancer compound lurbinectedin (PM1183) in Australia, New Zealand and throughout SE Asia.

This promising agent is currently in final stage (Phase 3) trials as a potential new therapy for various solid tumours, including platinum-resistant ovarian cancer and small cell lung cancer. In addition, it is in a Phase 2 trial for metastatic breast cancer with BRCA1 and BRCA2 mutations.

Commercial terms of the new license agreement are not being disclosed by ST Asia, but PharmaMar will receive an upfront payment, royalties and additional remunerations for regulatory and sales milestones achieved in these new markets.

An ST Asia affiliate company will also make an equity investment in PharmaMar.

PharmaMar will also retain development and production rights for lurbinectedin (PM1183), and pending completion of all regulatory processes, will supply the finished product to ST Asia for exclusive commercial use in all agreed regions.

ST Asia Chief Executive Officer Mr Carlo Montagner said this new licensing deal cemented the company's existing strong relationship with PharmaMar and demonstrated high confidence in the partner company's development pipeline.

"We have the highest regard for PharmaMar and are pleased to partner once again, pursuing development of this highly promising oncology compound," he said.

"We eagerly await data from these final stage studies and look forward to making new therapies like this available to patients throughout our regions who are affected by difficult to treat cancers."

Lurbinectedin (PM1183) is the third marine-derived organism in development by PharmaMar.

Data from the Phase 3 study of lurbinectedin (PM1183) in resistant ovarian cancer (CORAIL) is expected to be available later this year, following the completion of patient recruitment in October 2016.

A Phase 3 trial in small cell lung cancer (ATLANTIS) was initiated in August 2016.

PharmaMar Chairman José María Fernández Sousa-Faro said: “We are proud to enter into a new agreement with ST Asia, enabling us to reach new populations of cancer patients who may benefit from our novel therapies.

“We remain committed to advancing the development of innovative therapies that may benefit society.”

About Specialised Therapeutics Asia

Specialised Therapeutics Asia Pte Ltd (ST Asia) is an international biopharmaceutical company established to provide pioneering healthcare solutions to patients throughout South East Asia, as well as in Australia and New Zealand. The company is a close affiliate of Specialised Therapeutics Australia (STA), which also 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. ST Asia is committed to making new and novel therapies available to patients around the world, with a broad therapeutic portfolio spanning oncology, haematology, urology and ophthalmology. Additional information can be found at www.STAbiopharma.com

About PharmaMar

Headquartered in Madrid, PharmaMar is a world-leading biopharmaceutical company in the discovery and development of innovative marine-derived anticancer drugs. The company has an important pipeline of drug candidates and a robust R&D oncology program. PharmaMar develops and commercialises YONDELIS® in Europe and has three other clinical stage programs under development for several types of solid and haematological cancers PM1183, plitidepsin, and PM60184. PharmaMar is a global biopharmaceutical company with subsidiaries in Germany, Italy, France, Switzerland United Kingdom, Belgium and the United States. PharmaMar fully owns three other companies: GENOMICA, Spain's leading molecular diagnostics company; Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi); and two other chemical enterprises, Zelnova and Xylazel. To learn more about PharmaMar, please visit us at www.pharmamar.com.

About lurbinectedin (PM1183)

PM1183 is a compound under clinical investigation. It is an inhibitor of RNA polymerase II. This enzyme is essential for the transcription process that is over-activated in tumours with transcription addiction. The antitumour efficacy of lurbinectedin is being investigated in various types of solid tumours.

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Brain Tumour Visualisation Drug GLIOLAN to be Listed on NZ Hospital Medicines List from 1

June

Singapore, Melbourne and Auckland, 28 April 2017: A NOVEL drug which 'lights up' malignant brain tumours to help surgeons more thoroughly resect the cancer tissue will be widely available to New Zealand patients from **1 June**, after a leading neurosurgeon applied for its reimbursement.

The drug, GLIOLAN (aminolevulinic acid HCl), assists neurosurgeons to more completely remove malignant brain tumours (gliomas) by causing them to become fluorescent during surgery.

It is expected around 100 NZ brain cancer patients a year will be operated on using this cutting-edge technology, which has been demonstrated to improve complete resection rates and almost double six-month progression free survival in patients with the most serious form of brain tumours, Glioblastoma Multiforme, or GBM¹.

It will be made available to newly diagnosed, untreated patients who are eligible for fluorescence-guided surgery.

GLIOLAN will be reimbursed subject to the following hospital restrictions:

- Patient has newly diagnosed, untreated, glioblastoma multiforme
- Treatment to be used as adjuvant to fluorescence-guided resection
- Patient's tumour is amenable to complete resection

Leading New Zealand neurosurgeon Dr Kelvin Woon made an application to PHARMAC seeking reimbursement and ensuring GLIOLAN's broad accessibility.

He has described the PHARMAC decision to list GLIOLAN on the hospital medicines list as "a big step forward".

"This is a great opportunity for NZ patients who are affected by these highly malignant tumours," he said.

"Although not curative, GLIOLAN helps us to better visualise what can be poorly-defined tumour margins, which limits our ability to resect the tumour macroscopically.

“Because we can more clearly see what is brain tissue and what is tumour, it gives us the confidence to be more aggressive and strive for maximum resection. This is important, because the evidence points to maximum (complete macroscopic) resection and increases the chances of overall survival.” ²

GLIOLAN is given to patients as a drink prior to surgery. The drug is preferentially taken up by the malignant tumour tissue.

During surgery, a neurosurgical microscope fitted with a specialised blue operating light is used, which causes cancerous tissue containing the drug to glow fluorescent pink whilst normal brain tissue appears blue. This enables neurosurgeons to better visualise these tumours and more completely remove them, whilst sparing the neighbouring healthy brain tissue.

The drug is made available in New Zealand by international biopharmaceutical company Specialised Therapeutics Ltd, an affiliate of Specialised Therapeutics Asia (ST Asia).

Chief Executive Officer Mr Carlo Montagner said several NZ hospitals had already upgraded operating theatre equipment to enable the use of GLIOLAN and neurosurgeons were preparing to use this technology as soon as the PHARMAC approval and listing takes effect.

“We are delighted to be able to provide another tool for NZ neurosurgeons to use in complex brain tumour cases,” he said.

“In this region and around the world, these patients have a very poor prognosis. With current standard chemotherapy and radiation treatment, these patients have a median overall survival of 12, maybe 15 months.³ GLIOLAN has been shown to help GBM patients survive longer without tumour progression compared to standard surgical procedures. Any drug or technology that enables patients additional time with their families is extremely valuable.”

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GLIOLAN was first approved in Europe in 2007 and is marketed by medac GmbH in Europe, Africa, South America and Asia (excepting Japan and Korea). Around 500 Australian patients have been operated on using GLIOLAN since 2012.

GLIOLAN will be available to purchase from May 12 from ST's New Zealand distributor, Healthcare Logistics (HCL).

About GLIOLAN®

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For all inquiries, please phone Specialised Therapeutics Asia Communications Manager Emma Power on +61 149 149 525

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Specialised Therapeutics to Relaunch GELCLAIR in Australia

Singapore and Melbourne, Australia, 4 April, 2017: Independent pharmaceutical company Specialised Therapeutics Asia (ST Asia) will today relaunch a product used to relieve the pain of oral mucositis, a condition that can affect cancer patients undergoing chemotherapy and/or radiotherapy.

GELCLAIR is a bio-adherent oral gel that works by creating a protective film in the mouth, providing durable relief for the painful mouth ulcers that characterise the condition, as well as improving a patient's ability to eat, drink, swallow and speak.¹⁻³

ST Asia will market and distribute the product under license from partner, Helsinn Healthcare SASwitzerland.

Chief Executive Officer Mr Carlo Montagner said GELCLAIR was a welcome inclusion to the company's expanding oncology and supportive care portfolio.

"This product has been available in Australia before, but has been in hiatus since 2015," he said.

"We know there is continued demand for this important supportive care product and we are delighted to make GELCLAIR available once more to patients suffering from oral mucositis in Australia."

Internationally regarded oral mucositis expert Professor Dorothy Keefe said the condition could be extremely debilitating, even leading to malnutrition in some cases, with 20 to 40% of patients receiving conventional chemotherapy affected, as well as up to 100% of patients receiving radiation therapy for head and neck cancer.⁴

"Pain in your mouth, or ulceration in your mouth, makes it hard to eat and to swallow," Professor Keefe said.

"Both of these factors have an impact on quality of life and people can lose 5-10% of their body weight if they are badly affected. GELCLAIR provides a protective barrier that reduces the pain experienced by patients, which is an important part of oral mucositis management."

Australian journalist and broadcaster Julie McCrossin suffered the debilitating effects of oral mucositis while undergoing treatment for oropharyngeal cancer.

She described the damage inside her mouth as “catastrophic”.

“I would highly recommend GELCLAIR as a soothing, nurturing mouth treatment that helped me both physically and psychologically in my recovery, when I was suffering the pain and discomfort of treatment for throat cancer,” she said.

“With GELCLAIR, I actually felt it was helping me to start the road to recovery because I felt better. When you are going through weeks and weeks of trauma to your soft tissue, that is worth a million bucks.”

GELCLAIR is available without prescription. Ordering information is available at www.STAbiopharma.com/gelclair. GELCLAIR can be purchased online only at <http://www.chemistwarehouse.com.au> or <http://www.epharmacy.com.au>

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About Gelclair

Gelclair® is a viscous oral gel for the management and relief of pain associated with oral lesions, particularly oral mucositis/stomatitis, which may be caused by chemotherapy or radiation therapy and irritation from oral surgery.¹ Gelclair® forms a protective coating over the oral mucosa which shields exposed or sensitised nerve endings from over-stimulation and provides oral pain relief.¹⁻³ It does not irritate or sting and is non-numbing.¹

About the Helsinn Group

Helsinn is a privately owned pharmaceutical group with an extensive portfolio of marketed cancer care products and a broad development pipeline. Since 1976, Helsinn has been improving the everyday lives of patients, guided by core family values of respect, integrity and quality. The Group works across pharmaceuticals, biotechnology, medical devices and nutritional supplements and has expertise in research, development, manufacture and the commercialization of therapeutic and supportive care products for cancer, pain and inflammation and gastroenterology. In 2016, Helsinn created the Helsinn Investment Fund to support early-stage investment opportunities in areas of unmet patient need. The company is headquartered in Lugano, Switzerland, with operating subsidiaries in Ireland and the US, a representative office in China as well as a product presence in about 90 countries globally. For more information, please visit www.helsinn.com.

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Specialised Therapeutics to Remove Territory Sales Incentives from Staff Bonus Plan

Melbourne, Australia, 1 February 2017: International biopharmaceutical company Specialised Therapeutics will today launch a new company business model, as part of a bold plan to improve relationships with healthcare professionals.

Under this plan, sales teams will no longer be paid bonuses based on the number of prescriptions written. Instead, in field representatives will be rewarded for demonstrated customer service excellence, as well as high level product and disease knowledge.

Chief Executive Officer Carlo Montagner said similar sales models had been introduced by some of the world's most successful companies - including Apple and Tesla - with the focus on relationships and quality information exchange rather than a singular sales outcome focus.

"By removing the pressure of individual territory sales targets, we believe our team members can engage in more genuine and meaningful discussions with the healthcare professionals we are regularly interacting with, who at this stage are predominantly oncologists and haematologists," he said.

"We believe that by doing business in this way, we will actually improve commercial outcomes, because it removes the 'elephant in the room' which is the sales message that can make both parties feel uncomfortable. This is simply a transparent and ethical way of doing business."

ST is believed to be among the first pharmaceutical companies in the region to break away from the traditional pharmaceutical business model, which has long rewarded representatives with bonuses tied to the number of product prescriptions in their territories.

Mr Montagner added: “This model is about putting patients and the health care professionals we interact with first. It means our staff are a valuable resource across their therapeutic areas.

“Our in field liaison teams are wholeheartedly in favour of this new business model and we look forward to engaging with the medical community in a way that is transparent, genuine and meaningful as we move into 2017.”

About Specialised Therapeutics Asia

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Study Finds ABRAXANE Combination Chemotherapy is Superior to Other Chemotherapy Combinations in Women with Metastatic Triple Negative Breast Cancer

Melbourne, Australia and Singapore, 23 December 2016: An international study has found that women with metastatic triple-negative breast cancer (mTNBC) demonstrated improved progression-free survival when treated with a combination of ABRAXANE (nanoparticle albumin-bound paclitaxel) and carboplatin, compared to other chemotherapy combinations.

Aeterna Zentaris and Specialised Therapeutics Asia Sign Exclusive License Agreement for the Potential Marketing of Zoptrex™ in Australia and New Zealand

Charleston, South Carolina and Singapore, October 12, 2016: Aeterna Zentaris Inc. (NASDAQ: AEZS, TSX: AEZ) (the “Company”) and Specialised Therapeutics Asia (“STA”) today announced the signing of an exclusive license

agreement for the Company's lead investigational anti-cancer compound, Zoptrex™ (zoptarelin doxorubicin), for the territories of Australia and New Zealand (the "Territory"). Zoptrex™, a novel synthetic peptide carrier linked to doxorubicin, is currently undergoing a fully-enrolled Phase 3 clinical trial to evaluate the compound in endometrial cancer. The Company expects to complete the Phase 3 clinical trial in 2016 and, if the results of the trial warrant doing so, to submit a new drug application for Zoptrex™ to the United States Food and Drug Administration (FDA) in the first half of 2017. Zoptrex™ is the Company's proposed tradename for zoptarelin doxorubicin. The proposed tradename is subject to approval by the FDA.

Under the terms of the License Agreement, Aeterna Zentaris will be entitled to receive a non refundable upfront payment in consideration for the license to STA of the Company's intellectual property related to Zoptrex™ and the grant to STA of the right to commercialize Zoptrex™ in the Territory. STA has also agreed to make additional payments to the Company upon achieving certain pre-established regulatory and commercial milestones, as well as double-digit royalties on future net sales of Zoptrex™ in the Territory. STA will be responsible for the development, registration, reimbursement and commercialization of the product in the Territory. The Company and STA have also entered into a supply agreement, pursuant to which the Company will supply Zoptrex™ to STA for the duration of the license agreement.

David Dodd, President and CEO of the Company, stated, "I am very pleased that we have now concluded four agreements for the commercial rights to Zoptrex™, if approved, outside the United States. We believe that the interest in Zoptrex expressed by our licensees supports our view that Zoptrex™, if it is approved by the FDA for its initial indication, could be an important treatment option for women with the most severe form of endometrial cancer. We are particularly pleased to have a company of the caliber of STA as a licensee. STA enjoys the highest reputation in its markets and, with its existing portfolio of oncology products, it has the capability to position Zoptrex™ very well in the market."

STA Chief Executive Officer Mr. Carlo Montagner said Zoptrex™ had demonstrated great potential and was poised to add further value to the company's expanding oncology portfolio. "All results to date suggest Zoptrex™ is a potent new compound and we look forward to collaborating closely with Aeterna Zentaris to maximise its full potential in our key markets," he said.

About Zoptrex™

Zoptrex™ (zoptarelin doxorubicin) is a complex molecule that combines a synthetic peptide carrier with doxorubicin, a well-known chemotherapy agent. The synthetic peptide carrier is (D)-Lys6-LHRH, a modified natural hormone believed to have a strong affinity for the LHRH receptor. The design of the compound allows for the specific binding and selective uptake of the cytotoxic conjugate by LHRH receptor-positive tumors. Potential benefits of this targeted approach include enhanced efficacy and a more favorable safety profile with lower incidence and severity of side effects as compared to doxorubicin.

About Specialised Therapeutics Asia

Specialised Therapeutics Asia Pte Ltd (“STA”) is an international biopharmaceutical company established to provide pioneering healthcare solutions to patients throughout South East Asia, as well as in Australia and New Zealand. The company is a close affiliate of Specialised Therapeutics Australia, which also 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. STA 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. Additional information can be found at www.specialisedtherapeutics.com.au.

About Aeterna Zentaris Inc.

Aeterna Zentaris is a specialty biopharmaceutical company engaged in developing and commercializing novel treatments in oncology, endocrinology and women’s health. We are engaged in drug development activities and in the promotion of products for others. We are now conducting Phase 3 studies of two internally developed compounds. The focus of our business development efforts is the

acquisition or license of products that are relevant to our therapeutic areas of focus. We also intend to license out certain commercial rights of internally developed products to licensees in territories where such out-licensing would enable us to ensure development, registration and launch of our product candidates. Our goal is to become a growth-oriented specialty biopharmaceutical company by pursuing successful development and commercialization of our product portfolio, achieving successful commercial presence and growth, while consistently delivering value to our shareholders, employees and the medical providers and patients who will benefit from our products. For more information, visit www.aezsinc.com.

Forward-Looking Statements

This press release contains forward-looking statements made pursuant to the safe harbor provisions of the US Securities Litigation Reform Act of 1995. Forward-looking statements may include, but are not limited to statements preceded by, followed by, or that include the words “expects,” “believes,” “intends,” “anticipates,” and similar terms that relate to future events, performance, or our results. Forward-looking statements involve known and unknown risks and uncertainties that could cause the Company’s actual results to differ materially from those in the forward-looking statements. Such risks and uncertainties include, among others, the availability of funds and resources to pursue R&D projects and clinical trials, the successful and timely completion of clinical studies, the risk that safety and efficacy data from any of our Phase 3 trials may not coincide with the data analyses from previously reported Phase 1 and/or Phase 2 clinical trials, the rejection or non-acceptance of any new drug application by one or more regulatory authorities and, more generally, uncertainties related to the regulatory process, the ability of the Company to efficiently commercialize one or more of its products or product candidates, the degree of market acceptance once our products are approved for commercialization, the ability of the Company to take advantage of business opportunities in the pharmaceutical industry, the ability to protect our intellectual property, the potential of liability arising from shareholder lawsuits and general changes in economic conditions. Investors should consult the Company’s quarterly and annual filings with the Canadian and US securities commissions for

additional information on risks and uncertainties relating to forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements. The Company does not undertake to update these forward-looking statements. We disclaim any obligation to update any such factors or to publicly announce the result of any revisions to any of the forward-looking statements contained herein to reflect future results, events or developments, except if required to do so.

Specialised Therapeutics Strikes Deal with World Courier Australia to Manage Logistics for Specialty Pharma Products

Melbourne, Australia 16 June 2016: International biopharmaceutical company Specialised Therapeutics Australia has struck an important agreement with global logistics partner World Courier Australia (WCA) to manage and handle its growing portfolio of specialist healthcare products around the country.

Novel Multiple Myeloma Drug APLIDIN® Shows Positive Results

in Pivotal Phase 3 Study

Singapore, Madrid and Melbourne, Australia, 31 March 2016: International biopharmaceutical company Specialised Therapeutics Asia Pte Ltd (ST Asia) will seek regulatory approvals for novel multiple myeloma drug Aplidin® (plitidepsin) following the release of positive results in a pivotal Phase 3 study.