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UBI signs exclusive agreement for cancer biosensor, Tn Antigen

Universal Biosensors, Inc. (ASX:UBI) (**UBI**) is pleased to announce that it has entered into an exclusive license and supply agreement with Lubris BioPharma LLC (**Lubris**) to commercialize the Tn Antigen (**Tn**) biosensor used for the detection, staging and monitoring of cancer (**Agreement**). The Tn biosensor was developed by Deakin University (**Deakin**), Swinburne University of Technology (**Swinburne**) and The University of Wollongong (**UoW**) using technology supplied by Lubris.

Key details of the Agreement are as follows:

- it is a global exclusive perpetual license to commercial products using Lubricin and UBI's discrete single point measurement technology;
- it is for all intellectual property, commercialization, development and manufacturing rights, to all non-therapeutic products including Tn Antigen in various sample matrices including, but not limited to, blood, saliva, urine, beverages, effluent streams and chemical waste using Lubricin;
- UBI will own all new intellectual property and products developed;
- contains reasonable commercial endeavor clauses which if not met might mean the supply of Lubricin becomes non-exclusive;
- includes a non-material upfront payment;
- includes a non-material annual maintenance fee; and
- includes a single digit royalty on sales after deducting the cost of Lubricin.

There have been more than 1,000 clinical patient samples tested and researched which link Tn Antigen to the first mutation process of a healthy human cell as it becomes a cancer cell. Tn Antigen is an O-glycan which is rarely detected in human healthy tissues and is almost exclusively expressed in many, but not all cancers. Clinical research proves Tn Antigen expression correlates with identifying then measuring cancer progression and metastatic potential.

UBI's presentation detailing the clinical studies, published literature, global research and clinical possibilities for Tn Antigen is detailed below.

UBI has completed its proof-of-concept work on the Tn Antigen biosensor and confirms it is able to detect and measure the presence of Tn in "spiked samples" of whole human blood at a concentration of 200 picomolar using UBI's patented electrochemical platform technology, enhanced by Lubricin.

UBI has released a second ASX announcement today detailing its exclusive supply agreement with Lubris for Lubricin and the importance of this breakthrough development for UBI's technology into the future.

John Sharman, CEO of UBI said; "To be able to identify and measure, then monitor the rate of a healthy human cell becoming a cancer cell from a handheld point-of-care biosensor device is an exciting prospect for UBI. Putting aside the possibility for early screening and then staging of cancer from a handheld device, the blood testing market for the monitoring of cancer remission patients annually is estimated at $17 billion. It would be wonderful if this initiative could improve the lives of many of the 131 million cancer remission patients around the world."

Mr Sharman said; "Deakin, Swinburne and UoW have been working on the Tn Antigen biosensor for 5 years. Whilst the research and feasibility work has been successfully completed which means UBI's time to market is significantly reduced, UBI still must develop a commercial Tn Antigen biosensor on our hand-held platform ready for partnering or clinical trials. The next step to develop a commercial product is to ensure the Tn biosensor can be reproduced on our manufacturing line and measured reliably using patients' whole blood. Based on our initial feasibility we estimate this could take 3 years and cost between $5 - $7 million. UBI has $25 million of cash reserves and no debt."

Senior Fellow Dr. Wren Green at Deakin University said; "The idea of developing a biosensor for Tn Antigen was conceived in conjunction with Simon Moulton, Professor of Biomedical Electromaterials Science at Swinburne and has taken 5 years to complete. Our team has successfully developed a Tn biosensor that works on UBI's platform which is a very exciting development."

End

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Announcement authorised by the Board of Directors of Universal Biosensors, Inc.

About Universal Biosensors

For additional information regarding Universal Biosensors, Inc., refer to: http://www.universalbiosensors.com. Universal Biosensors, founded in 2001, specialises in the design and development of electrochemical cells (strips) used in conjunction with point of use devices that are used in various industries such as healthcare (point of care), food and drink and agriculture.

About Lubris Biopharma LLC

Lubris BioPharma LLC is a Delaware limited liability company, having its principal place of business at 316 3rd Avenue North, Naples, FL 34102, United States of America ("Lubris"). Lubris is a development-stage life science company producing and commercializing a recombinant version of the human protein, lubricin. Lubricin is expressed in numerous parts of the human body and plays an important role in protecting surfaces from damage and wear. Key opinion leaders and clinicians worldwide are focusing their research efforts on using lubricin to improve the lives of millions of people with a host of unmet medical needs including dry eye, osteoarthritis, surgical adhesions, xerostomia and pericarditis.

A cornerstone of Lubris commercialization plan is the establishment of partnerships, joint ventures and licensing arrangements with other innovative and successful companies, both large and small. The company currently has a number of commercial partners committed to the successful development of products containing lubricin as part of their strategic plan for creating innovative new products and/or improving or growing existing products and markets. The company continues to solicit interest from potential partners for all indications for which lubricin may be useful.

Forward-Looking Statements

The statements contained in this release that are not purely historical are forward-looking statements within the meaning of the US Securities Exchange Act of 1934. Forward-looking statements in this release include statements regarding our expectations, beliefs, hopes, intentions or strategies. All forward-looking statements included in this release are based upon information available to us as of the date hereof, and we assume no obligation to update any such forward-looking statement as a result of new information, future events or otherwise. Our actual results could differ materially from our current expectations. We cannot assure you when, if at all, the proposals outlined in this release will occur, and the terms of any such proposal are subject to change. Factors that could cause or contribute to such differences include, but are not limited to, factors and risks disclosed from time to time in reports filed with the SEC.

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Tn Antigen

Placing the universal power of biosensors into the hands of those who need it

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Important Disclaimer

Presentation

This presentation is intended to provide a general outline only and is not intended to be a definitive statement on the subject matter. This presentation is not financial advice and has been prepared without taking into account the objectives, financial situation or needs of a particular person.

Company

Neither the Company, nor its officers or advisors or any other person warrants the accuracy of the analysis herein or guarantees the investment performance of the Company. Investors must make their own independent assessment of the Company and undertake such additional enquiries as they deem necessary or appropriate for their own investment purposes.

Statements

The statements contained in this presentation that are not purely historical are forward-looking statements within the meaning of the United States Exchange Act. Forward-looking statements in this presentation include statements regarding our expectations, beliefs, hopes, intentions or strategies.
All forward-looking statements included in this presentation are based upon information available to us as of the date hereof, and we assume no obligation to update any such forward-looking statement as a result of new information, future events or otherwise. Our actual results could differ materially from our current expectations.

Risk

The Company is subject to a number of risks. For a summary of key risks, refer to the Company's most recent Form 10-K filed with the United States Securities and Exchange Commission and the Australian Securities Exchange.

Securities

Under applicable United States securities laws all of the shares of our common stock are "restricted securities" as that term is defined in Rule 144 under the Securities Act of 1933, as amended. Restricted securities may be resold in the public market to United States persons as defined in Regulation S only if registered for resale or if they qualify for an exemption from registration under the Securities Act. We have not agreed to register any of our common stock for resale by security holders.

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UBI & Tn Antigen

UBI has successfully:

- Secured a global exclusive License with Deakin University, Swinburne University of Technology, University of Wollongong and Lubris BioPharma for the development of a monitoring, staging and detection biosensor using its handheld electrochemistry platform technology for Tn Antigen.
- Completed proof of concept for the detection of Tn Antigen on its hand-held platform technology. Tn Antigen was detected at 200 Picomolar in spiked whole blood samples.
- Secured a global exclusive License with Lubris BioPharma for the supply of Lubricin which is a substance that increases UBI's detection limits by 1 million times (or better), allowing Picomolar detection of analytes of interest.

The result is that UBI may be able to detect, stage and monitor cancer patient's health from a handheld device using a small sample of blood.

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Tn Antigen

Importance

Tn antigen is almost exclusively associated with the development and progression of cancer.

Tn antigen is an O-glycan that is rarely expressed in healthy blood cells or peripheral tissues[1].

Tn antigen has been studied in 1012 patient samples in the reference articles included in this presentation.

Tn antigen may be used:

- As a biomarker for Early Detection of Cancer [1,2,3,4,5].
- To measure the Aggressiveness and Progression of Cancer[1,2,3,6,7,8,9,10,11,12].
- To measure the Effectiveness of Cancer Treatment[10,11,12].
- To monitoring the State of Cancer Remission[10,12,13].
- In Research and Development markets[5].

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Tn Antigen

Importance

Tn antigen is known to be expressed in many human carcinomas [1,2,6,14,15]. False positives are rare.

Cancer	Expression
Pancreas	93 - 100% [3,4,16]
Colorectal	70 - 100% [1,3,6,7,14,17]
Breast	90 - 96% [3,6,14,18]
Stomach	70 - 92% [3,6,14]
Lung	70 - 90% [3,6,14]
Prostate	70 - 90% [6,14]
Ovary	70 - 90% [6]
Bladder	70 - 90% [3,6,14]
Cervical	45 - 90% [3,6,14]
Thyroid	61 - 89% [19,20]

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Measure Aggressiveness and Progression of Cancer

As Tn antigen is expressed in a wide range of human carcinomas its use as a biomarker to determine the aggressiveness of a cancer as well as track cancer progression has been found.

- Lenneke Cornelissen and Sandra van Vliet confirm their data indicates that Tn antigen expression can be linked to tumour progression[7].
- Tongzhong Ju and Richard Cummings confirm that Tn antigen was expressed at higher levels during tumor development when compared to early lesions[1]. They also state there was a link between Tn antigen expression and cancer progression[14].
- Matthew Kudelka, Tongzhou Ju, Jamie Heimburg-Molinaro and Richard Cummings have found that “Tn antigen is expressed early in cancer development and its expression correlates with clinical progression”[3].
- T Freire and E Osinga state that several studies have suggested “there is a direct link between carcinoma aggressiveness and the density of Tn antigen”[12].

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Measure Effectiveness of Cancer Treatment

Tn antigen is expressed in a wide range of human carcinomas and so its use as a biomarker to determine whether a cancer treatment, such as chemotherapy, is working effectively has been shown.

- Jun Liu and Hongchuan Jiang have proven that Tn antigen has “a close connection to tumour growth, differentiation, and metastasis, and thus, the levels of Tn antigen displayed in a tumour could be a crucial prognostic indicator”[21].
- Parimal Desai reported that Tn was expressed more strongly as breast cancer proceeded through stages and that increasing Tn levels were associated with metastasis and poor survival[22].
- Shin-ichi Hamada and Toshihiro Aono found that “Tn antigen expression is a useful marker of the potential metastasis of uterine cervical cancers” and “may be a prognostic indicator”[23].

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Monitoring State of Cancer Remission

Tn antigen is expressed in a wide range of human carcinomas and its use to monitor a patient's state of remission has been shown.

- Niels Langkilde and Torben Ørntoft linked Tn antigen to the reoccurrence of bladder cancer finding that over 90% of people that had a reoccurrence of bladder cancer had detectable levels of Tn antigen[24].
- Jun Liu and Hongchuan Jiang have shown that Tn antigen has "a close connection to tumour growth, differentiation, and metastasis, and thus, the levels of Tn antigen displayed in a tumour could be a crucial prognostic indicator"[21].
- Shin-ichi Hamada and Toshihiro Aono found that "Tn antigen expression is a useful marker of the potential metastasis of uterine cervical cancers" and "may be a prognostic indicator"[23].

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Monitoring State of Cancer Remission Market

Approximately 131.4 million people in remission globally in 2019[25,26].

For the cancers that Tn has been shown to be expressed in there are 78 million people in remission globally in 2019[25,26,27].

25.7 million people were diagnosed less than 5 years ago[25,26].

52.3 million people were diagnosed more than 5 years ago[25,26].

Recommended monitoring during remission, and frequency of monitoring, depends on cancer type and length of time since diagnosis/successful surgery[28].

Monitoring is usually a combination of doctor's visits, blood tests and various scans[28].

Estimated addressable cancer remission monitoring market using Tn Antigen is $17 billion AUD[25,26,27,28].

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Early Detection of Cancer

Tn antigen may be used as an early cancer detection biomarker as it is expressed across a wide range of human carcinomas.

- Dr José Alexandre Ferreira from the Portuguese Institute of Oncology in Porto has stated that “A point of care Tn antigen device could be of importance and help provide valuable insights into global oncology research. This device could greatly improve on current testing methods in terms of timing and convenience. The device could aid early cancer detection, patient follow-up and stratification setting momentum for precision oncology”[5].
- Weiming Yang and Hui Zhang “Tn antigen is an attractive molecular target for cancer diagnosis[4].”
- Liliana Loureiro and Paula Videira stated “the Tn antigen is detected at early stages of tumour development and may serve as a biomarker, since its expression is associated with invasive and highly proliferative tumors, and metastasis”[2].

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R&D Markets

The development of a point of care Tn Antigen device has the potential to be used worldwide in the global oncology research industry. This could include universities, research centers and institutes focused on the oncology field.

Dr José Alexandre Ferreira from the Portuguese Institute of Oncology in Porto has stated that:

- “A point of care Tn antigen device could be of great importance and help provide valuable insights into global oncology research”[5].
- “This device could greatly improve on current testing methods in terms of timing and convenience”[5].
- The device could aid early cancer detection, patient follow-up and stratification setting momentum for precision oncology”[5].

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Appendices

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Cancer Overview

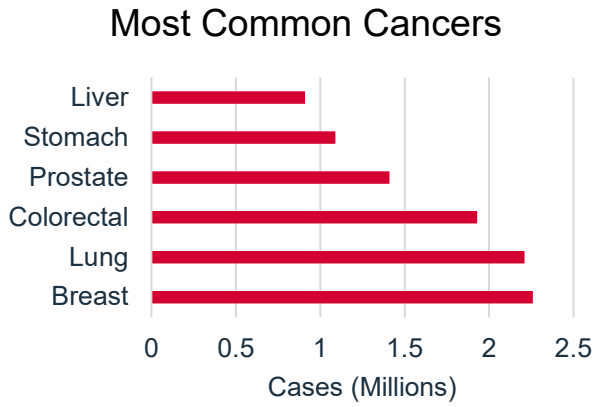
Cancer is the second leading cause of death globally[29].

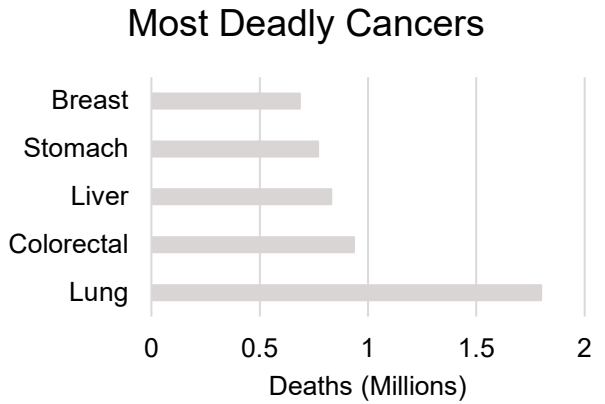
Cancer was responsible for an estimated 9 million deaths in 2020[29].

1 in 6 deaths each year are due to cancer[29].

Total annual economic cost of cancer well exceeds $1.53 trillion AUD[29].

Most common cancers are: Breast, Lung, Colorectal, Prostate, Stomach and Liver[30].





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Cancer Overview

Tn Antigen Importance

Cancer care in the US was $233 billion AUD in 2017, nearly 1% of GDP[27].

It is estimated that early cancer diagnosis in the US would deliver national cost savings of $34 billion AUD per year[27].

Early cancer diagnosis can also significantly increase the chance of survival[27].

In the US, the 5-year survival rate for women diagnosed when the cancer has not spread is 93%, compared to 15% when cervical cancer is diagnosed at an advanced stage[27].

Monitoring the effectiveness of treatment and early detection of failing therapies should save lives.

Monitoring remission patients and the early detection of any reemergence of cancer should save lives.

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Tn Antigen

Overview

Tn antigen is an O-glycan and other O-glycans include sTn (sialylated derivative of Tn) and T antigen[1].

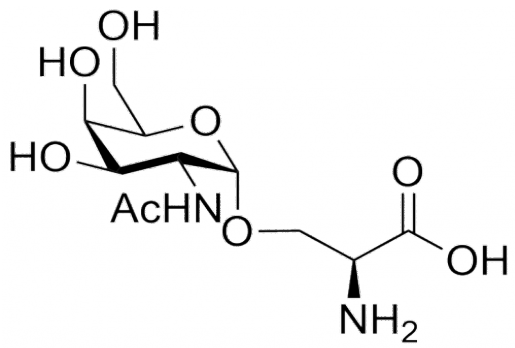
The Tn antigen is a tumor associated carbohydrate antigen that is very rarely expressed in blood cells or peripheral tissues[1].

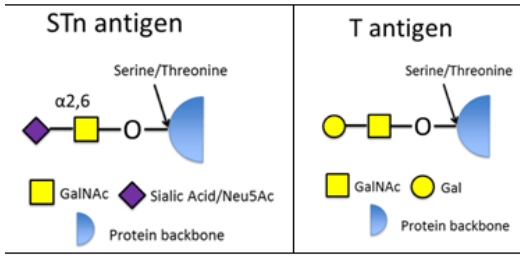
It was first observed on human tumour cells in 1969[6].

It is rarely detected in healthy tissues[2,3,4,14,31].

Tn antigen expression is correlated with cancer progression[3,14].

In many cancers Tn antigen expression is correlated to metastatic potential and poor prognosis[2,14].





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Tn Antigen

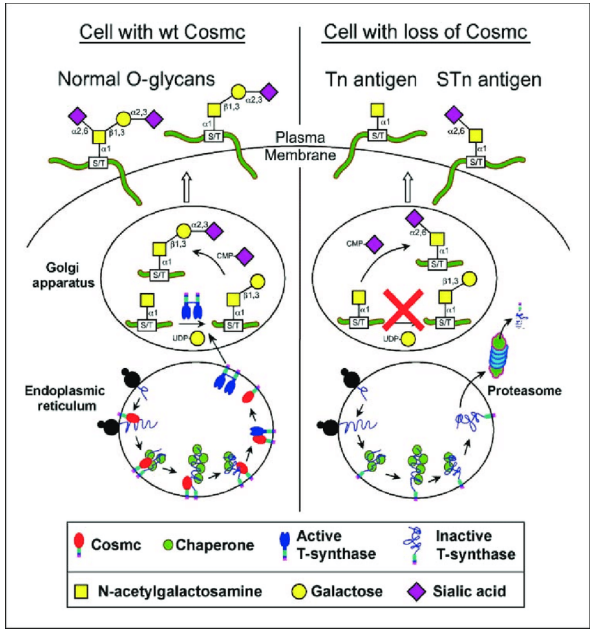
Overview

Expression of Tn antigen in human tumours results from mutations in Cosmc[1].

This leads to a loss of T-synthase activity and the consequent inability to modify the Tn precursor[1].

Cosmc is a molecular chaperone that is required for the expression of active T-synthase[1].

T-synthase is the only enzyme that galactosylates (glycosylation involving galactose) the Tn antigen to form core T antigen during mucin type O-glycan biosynthesis[1].



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Pancreas

Detection and Monitoring of Cancer

Tn antigen is expressed in 93-100% of pancreatic cancers[3,4,8,16].

466,000 people died from pancreatic cancer in 2020[30].

The annual economic cost of pancreatic cancer exceeds $26 billion AUD.

Masahiko Osako and Eiichi Sato found Tn Antigen expressed in 36/36 pancreatic cancers that they investigated[8]. They also confirmed that Tn antigen is not expressed in normal pancreatic tissues[8].

Weiming Yang and Hui Zhang reported that Tn antigen was found in approximately 93% of pancreatic cancers[4].

Steven Itzkowitz and Mei Yuan found Tn antigen in 100% of the pancreatic cancers they examined[16].

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Colorectal

Detection and Monitoring of Cancer

Tn antigen is expressed in between 70-95% of colorectal cancers[1,3,6,7,14,17].

935,000 people died from colorectal cancer in 2020[30].

The annual economic cost of colorectal cancer exceeds $138 billion AUD.

Tongzhong Ju and Richard Cummings state that Tn antigens are expressed at early stages of colon carcinogenesis[1].

Lenneke Cornelissen and Sandra van Vleit's paper stated that Tn antigen is highly expressed in approximately 86% of colorectal cancers[7].

Steven H. Itzkowitz and Young S. Kim confirmed that normal colorectal tissue very rarely expresses Tn Antigen[17].

Tn antigen appears to be a useful marker for certain types of colorectal cancers that are otherwise hard to detect using other cancer associated antigens[17].

T Freire and E Osinaga have observed that "Tn expression in colon has been observed at a high frequency in pre-malignant lesions and may antedate the development of invasive neoplasm by several years"[12].

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Breast

Detection and Monitoring of Cancer

Tn antigen is expressed in between 90-96% of breast cancers[3,6,9,10,11,14,18].

685,000 people died from breast cancer in 2020[30].

The annual economic cost of breast cancer exceeds $173 billion AUD.

G Springer, M Murthy, P Desai and E Scanlon found in their study that the Tn antigen was expressed in 48/50 breast cancer tumours[3,9].

Previously G Springer, P Desai and I Bantawala had shown that 14/15 breast cancer tumours expressed Tn Antigen[3,10].

In a third study G Springer determined that Tn antigen was expressed in 51/55 breast cancer tumours examined[11,14].

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Stomach

Detection and Monitoring of Cancer

Tn antigen is expressed in between 70-92% of stomach cancers[3,6,13,14].

768,000 people died from stomach cancer in 2020[30].

The annual economic cost of stomach cancer exceeds $17 billion AUD.

L David, J Nesland, H Clausen, F Carneiro and M Sobrinho-Simões conducted a study which found that 80/87 stomach cancer tumours they investigated expressed Tn antigen[13].

They also confirmed that Tn antigen is not expressed in normal stomach tissues[13].

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Lung

Detection and Monitoring of Cancer

Tn antigen is expressed in between 70-90% of lung cancers[3,6,14,32,33].

1,796,000 people died from lung cancer in 2020[30].

The annual economic cost of lung cancer exceeds $121 billion AUD.

E Laack and U Schumacher found that Tn antigen was expressed in 84/93 lung cancer tumours that they studied[3,32].

Anna López-Ferrer, Carlos Barranco and Carme de Bolós have shown that 16/22 lung cancer tumours that they investigated expressed Tn antigen[33].

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Prostate

Detection and Monitoring of Cancer

Tn antigen is expressed in between 70-90% of prostate cancers[6,14,34,35].

375,000 people died from prostate cancer in 2020[30].

The annual economic cost of prostate cancer exceeds $130 billion AUD.

G Springer, P Dasai and E Scanlon have stated that Tn antigen is expressed in over 70% of prostate cancers[6,14,34].

S Zhang and P Livingston showed in their study that 18/20 prostate cancer tumours expressed Tn Antigen[35].

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Ovary

Detection and Monitoring of Cancer

Tn antigen is expressed in between 70-90% of ovarian cancers[6,36].

207,000 people died from ovarian cancer in 2020[30].

The annual economic cost of ovarian cancer exceeds $52 billion AUD.

S Ricardo and L David found in their study that the Tn antigen was expressed in 78% of the ovarian cancer tumours that they studied[36].

They also confirmed that Tn antigen was not expressed in non-cancerous lesions[36].

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Bladder

Detection and Monitoring of Cancer

Tn antigen is expressed in between 70-90% of bladder cancers[3,6,14,24].

212,000 people died from bladder cancer in 2020[30].

The annual economic cost of bladder cancer exceeds $43 billion AUD.

Niels Langkilde and Torben Ørntoft undertook a study which has shown that Tn Antigen was expressed in 27/34 of the bladder cancer tumours that they studied[24].

They also determined that Tn antigen is not expressed in normal bladder tissue[24].

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Cervical

Detection and Monitoring of Cancer

Tn antigen is expressed in between 45-90% of cervical cancers[3,6,14,23].

341,000 people died from cervical cancer in 2020[30].

The annual economic cost of cervical cancer exceeds $13 billion AUD.

Shin-ichi Hamada and Toshihiro Aono found that Tn antigen was expressed in 17/29 and then 24/29 cervical cancer tumours that they investigated[23].

They demonstrated that Tn antigen levels were higher in metastatic tumors (83%) than in primary tumors (59%)[23].

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Thyroid

Detection and Monitoring of Cancer

Tn antigen is expressed in between 61-89% of thyroid cancers[19,20].

43,000 people died from thyroid cancer in 2020[30].

The annual economic cost of thyroid cancer exceeds $13 billion AUD.

E Fonseca, S Castanhas and M Sobrinho-Simões undertook a study which found that Tn antigen was expressed in 39/44 thyroid cancer tumours[19].

They also confirmed that Tn antigen was very rarely expressed in normal thyroid tissues[19].

P Alves, P Soares, E Fonseca and M Sobrinho-Simões found Tn Antigen in 16/26 thyroid carcinomas that they studied[20].

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Measure Aggressiveness and Progression of Cancer

As Tn antigen is expressed in a wide range of human carcinomas its use as a biomarker to determine the aggressiveness of a cancer as well as track cancer progression has been found.

- Parimal Desai reported that Tn was expressed more strongly as breast cancer proceeded through stages. They also reported a “positive correlation between density of Tn antigen and carcinoma aggressiveness”[22].
- Shin-ichi Hamada and Toshihiro Aono found that “Tn antigen expression is a useful marker of the potential metastasis of uterine cervical cancers” and “may be a prognostic indicator”[23].
- Liliana Loureiro and Paula Videira have also linked Tn antigen expression to cancer progression[2].

Measure Aggressiveness and Progression of Cancer

As Tn antigen is expressed in a wide range of human carcinomas its use as a biomarker to determine the aggressiveness of a cancer as well as track cancer progression has been found.

- Fung Xu and Hongchuan Jiang explain that Tn antigen “Is a kind of carbohydrate antigen associated with tumour development”[37].
- G Springer stated that the extent of Tn antigen expression in breast cancer is highly correlated with tumour stage and therefore is a reliable indicator of the progression of the cancer[11].
- Jun Liu and Hongchuan Jiang have shown that Tn antigen has “a close connection to tumour growth, differentiation, and metastasis, and thus, the levels of Tn antigen displayed in a tumour could be a crucial prognostic indicator”[21].

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Glossary

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