Teresa Hammer is Living with Triple Negative Breast Cancer

Teresa Hammer was 48 years old, recently re-married and "the happiest I had ever been" when she was diagnosed with triple-negative breast cancer almost three years ago. Despite her devastating diagnosis, she has tried to remain positive. She is now in remission and continues to work, as well as babysit her 8 month old grandson, Jed.

She dreams of travelling "and more grandchildren!" She says now: "My grandson Jed has given me so much life and unconditional love. He has helped me heal."

"I was 48 when I was diagnosed, through a general mammogram. My diagnosis came at a time when I was the happiest I had ever been. I was newly married again, with a wonderful husband. I also have two beautiful sons.

When I was told I had breast cancer, I was absolutely petrified and I felt very isolated. I remember it like it was yesterday. I thought, '*How am I going to tell my family, my children?*' I knew it would just break their hearts and that was so hard for me to accept.

When they said it was triple-negative, I thought maybe it was not that bad. But then you learn more as you go along the journey. It was not in my lymph nodes, so that was a plus.

I worked all the way through my treatment, as many hours as I could. My job is in administration and I do a lot of commercial quotes for the flooring industry, so it is a customer service role. Having 'chemo brain' was so hard to cope with on most days. But my work colleges supported me, and made me feel most welcome at work.

I do believe that still being able to work kept me strong.

The treatment was really hard. I had beautiful long hair and I lost it, along with my fingernails, my toenails, my eyelashes – I lost every hair on my body. My teeth

fell apart, so I had to have them fixed. My hair has grown back, but it is not the same hair. There is no curl. It is still very 'chemo burned' at the back and it came back quite grey.

My feet still get very tender. While going through the chemo my feet felt like I was walking on broken glass. When I finished the treatment, I thought that it had nearly killed me, so it must have done something!

I try to keep active and walk, to try and keep my body healthy. I have found that swimming has been my saviour to help with the soreness I still experience as a result of the treatment.

Having had triple-negative, you are always told there is a fair chance it will come back. So every night when I go to sleep I say a mantra. I say,

'*Cancer thank you for the visit, but you were never mine to keep.*

Thank you for the beautiful people I have met, thank you for the treatment I have had and thank you for the lessons I have learned.

But you must never return in my body'.

It's really important to share your stories because they can give hope to other people. When I was first diagnosed, I felt I was so different, because we were told triple-negative was less common.

But then I had a neighbour who told me his wife had been through triple-negative 20 years ago. When I heard she had survived, that gave me a lot of hope.

I would say to someone diagnosed today to cherish all of the good things.

My sister took six months off work to help support my husband and I. I will never forget what she has done; she is my world. She cooked dinner or cleaned the house so I did not have to worry about it.

My family helped out in the garden and took me to appointments when they could. I had great support from friends, my beautiful friends, and my hairdresser. My beautiful girlfriends would turn up with lasagnes or soups and just leave them on my doorstep.

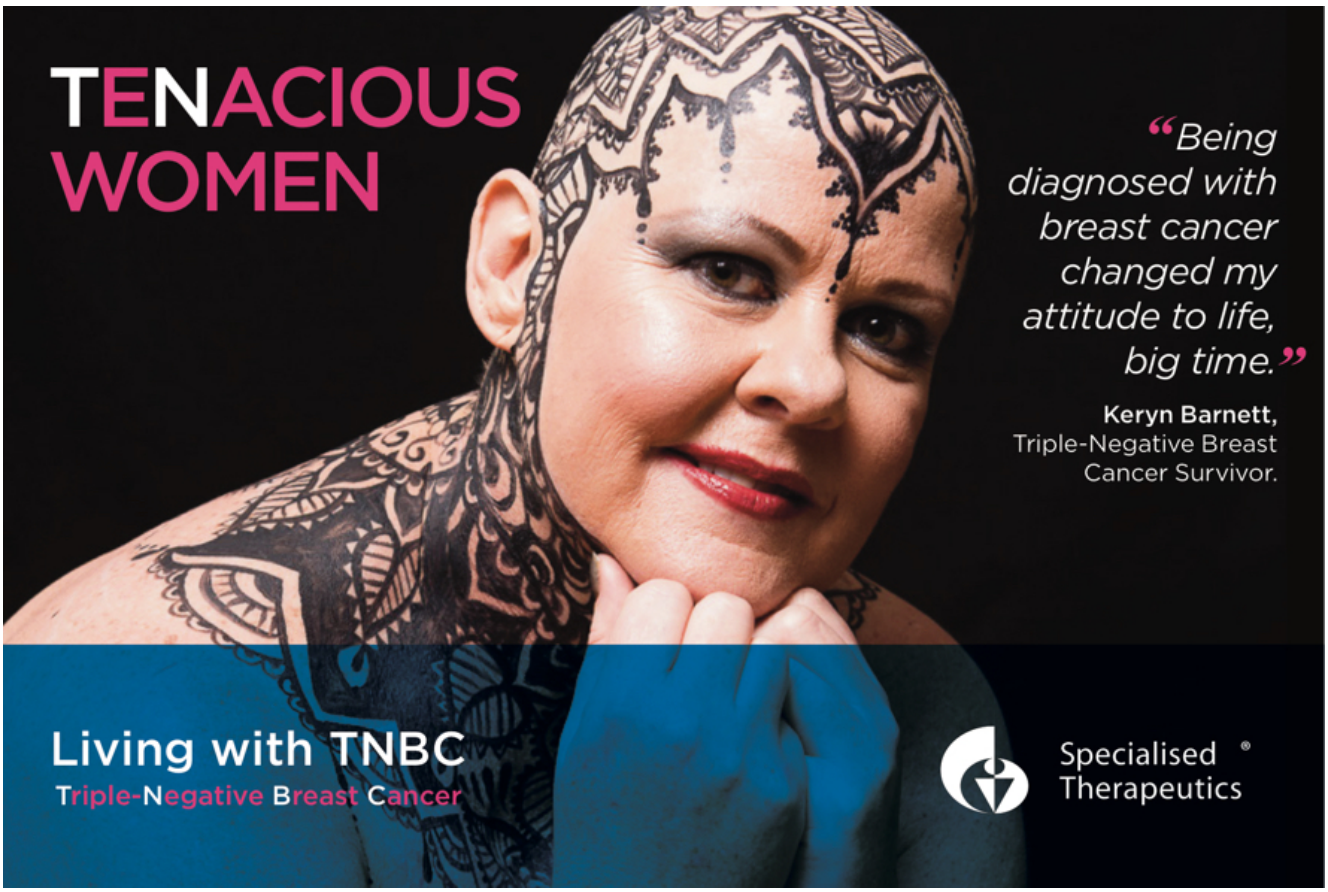
Those things are the things you cherish. It gives you good energy to get you through.

Cancer has changed me. I was always a person that worried about things and stressed about things. Now I don’t. I have too much to live for, I have a beautiful husband, a beautiful family and a beautiful grandson. Jed is now eight months old and he is amazing. He is my reason for living. I have everything I need in my life to keep me strong.

I believe I am cured. But with cancer there is always that doubt.”

– Teresa shared her story in April 2017.

Keryn Barnett is Living with Triple Negative Breast Cancer



TELL US ABOUT YOU AND WHEN YOU WERE DIAGNOSED.

I am 45 years old, I have two girls and I am a single mother. I was diagnosed with triple-negative breast cancer at the end of 2014. It was right on Christmas – the worst Christmas ever. My 12 year-old was just bawling her eyes out, because she equated cancer with dying.

In 2015 I had six months of chemotherapy followed by 28 days of consecutive radiation treatment. During that first chemotherapy session I bawled my eyes out for six hours straight. My sister was also diagnosed with triple-negative breast cancer last year, so now there is a big question as to why two sisters who don't carry the BRCA gene have both got triple-negative breast cancer.

HOW DID THE DIAGNOSIS CHANGE YOUR LIFE?

I had never known what to do with my life. I always just breezed along and while I was never unemployed, I didn't really know what I wanted to do. Now, I am actually studying radiation therapy.I am in my second year of a four-year course and I am loving it. I have found what I want to do.

DID YOU KNOW ANYTHING ABOUT TRIPLE-NEGATIVE BREAST CANCER BEFORE YOU WERE DIAGNOSED?

I knew nothing about it. I was like a deer in the headlights. I thought I just had to go with the flow and do as I was told. My cancer was a grade 3.

I had a lumpectomy but I did not need a mastectomy. I don't let it consume my life, but yes, I know I am at higher risk of the cancer returning.

I have a fantastic oncologist and I just love her to death, because she is straight up and down. When I asked her what triple-negative meant, she said, 'put it this way, if you had to choose any one, you don't want this one.' I just said, 'I don't do things by halves, do I?

WHAT HELPED YOU TO STAY POSITIVE THROUGHOUT YOUR CANCER DIAGNOSIS AND TREATMENT?

Without the help of the local community, I would not have got through it. The Hunter Breast Cancer Foundation organised lawn mowing, house cleaning and things like that.

HOW ARE YOU GOING NOW?

I am a very optimistic person and I surround myself with positive people.

I steer clear of people who dwell on things or hold grudges.

I was forced into a position where I was supporting two children as a single parent and not earning an income because I was sick. But you can make it work and that's why I am at university now.

I try to stay fit and active, because I put on 40 kilograms as a result of the steroids I took along with the chemotherapy drugs. I used to be a size 6-8 and now I am a size 16. But I am fit and healthy, playing softball on a Saturday and dragon boating on a Sunday.

I am a very positive person and being diagnosed with breast cancer has changed my attitude to life, big time.

– Keryn shared her story in March 2017.

ST Supporting Private Cancer Physicians of Australia

Meet Joel Wight – PCPA Profile

Final year advanced trainee Joel Wight had his heart set on a surgical career, but as his medical training progressed, he realised this was not a long term passion. A "fortuitous" haematology rotation placement finally provided what he was looking for – cutting edge medicine with a strong focus on people. "I absolutely loved it, I fell in love with it straight away," he recalls. With only one exam remaining and a final clinical year before his career takes full flight, he expects to combine both public and private haematology practice, admitting both systems have inherent advantages.

He expects to eventually move to a regional centre, where his skills can be of benefit to patients in both streams and where he will strive to really make a difference.

Tell us about your journey to a haematology career.

Since I was a kid I wanted to be a doctor and never grew out of it.

When I first started as an intern I wanted to be a surgeon and all through medical school I wanted to be a surgeon. But then surgery lost its lustre for me.

I had a second surgical rotation at the end of my intern year, which I swapped out of. As it happened the thing I swapped into was a haematology rotation. It was quite fortuitous because I really enjoyed it; I fell in love with it straight away.

What did you love about it?

I think you fall in love with a specialty because of the people who inspire you. I had a few really good mentors who practised such good medicine and I just wanted to be like them. But there are other things that made haematology really attractive. It is very cutting edge.

For example, if you look at CML (Chronic Myeloid Leukaemia), it has gone from a death sentence to a manageable, curable disease. CML is the poster child, but there are other haematological diseases where we have made some massive inroads in the past 20 years.

I also like the variety. When you do a general clinic, if you see 15 patients you might see 15 different diseases, which is kind of exciting.

The other thing I love about haematology is the 'completeness' of it. If you are a medical oncologist (and I say this with no disrespect at all), then by the time a patient comes to you to you, the surgeon has chopped out the tumour, the pathologist has diagnosed the tumour and the radiologist has staged the tumour. When they come to the medical oncologist, they manage the treatment. Where as in haematology, usually you get a GP referral, and then the haematologist does the bone marrow biopsy, goes to the lab, examines the blood cells and the bone marrow and makes a diagnosis. Then you come back to the patient and you give them the diagnosis and tailor a management plan that fits for them. And then you journey with them through that treatment from start to finish. Sometimes you get

to cure people and you don't need to see them again. The hard part is when people, particularly young people, have a really nasty diagnosis. But even in that, it's nice to be there for them when the chips are down.

What in your view are the pros and cons of public versus private practice, and what path do you expect to follow?

I think my career will probably entail both. I think the way the medical market has gone for jobs, if you want to be in a big public hospital, you need to be in the research space with a university attachment.

I am not a particularly academic person. Being in a big research institution, even though I see the importance of it, is probably not where my skills are best used. I can see myself in a regional centre, working in both public and private systems and doing laboratory medicine as well.

The advantage of private practice is that things are much more efficient and you get that continuity with your patients. In the public system, it's much harder to stay across everything.

I believe in public medicine, and if you want to keep your skills up in the "heavier" parts of haematology such as bone marrow transplantation you need substantial public work. But I also believe in the efficiency of the private system. Each system has its advantages and I would like to work in both. When it comes to preparing for private practice, support from the PCPA has been an invaluable part of my advanced trainee experience and in particular, their therapy based training programs.

What in your opinion will be the next big advances in haematology that you are likely to be part of in the next 20 years?

Things are moving really quickly and in low-grade lymphoproliferative diseases like CLL, follicular lymphoma and mantle cell lymphoma, we are making real inroads. These have been considered incurable diseases, although people can live a long time. With more modern therapies like targeted therapies and immunotherapies, I think we are starting to change our paradigms. We are starting to talk about cures for these diseases.

In combination, targeted therapies and immunotherapies will probably take the

place of chemotherapy in the next 10 years. In the future it would be really nice if someone comes to you with lymphoma or CLL, to be able to say 'you don't need chemotherapy'.

What I would really like to see take off is immunotherapy in the aggressive tumour space.

With AML, (Acute Myeloid Leukaemia) the fact is we haven't made any real inroads for a long time. We have improved how well we can manage it (in terms of supportive care, prognostication, stem cell transplantation etc.), but we are still using the same two drugs we were using 40 years ago. In 2017, more people still die from AML than live from it. This will be the biggest challenge for haematology in the next 20 years.

Do you have a patient who has left a lasting impression?

I have so many. One springs to mind. Mr H was an Iraqi refugee. There are very few Christians in Iraq. During the time of the first Iraq war, he was quite heavily persecuted. At some point in the war, he ended up with a brain injury at the back of his brain that controls vision. He could think normally and he could speak, but he could not see. Functionally, his eyes were fine but his brain could not interpret the signal. Mr H ended up coming to Australia as a refugee. I met him when he developed lymphoma. He was on the ward and he did not speak a word of English. His family was not there most of the time. It was a huge challenge as we had literally no way of communicating with a blind man who couldn't speak the language unless we happened to have a family member or an interpreter. Despite everything he remained cheerful, even though he had been through so much. He was so accepting of everything. All you could do was hold his hand to let him know everything was okay, but he handled it all with such grace. The resilience of some people astounds me. I believe he is still in remission.

Also, I remember a guy who was very rough, previously using intravenous drugs and heavily involved in a bikie gang. Really serious stuff. He got a very nasty form of AML. It was just amazing to see the walls come down over a series of weeks while I was on the ward. He started off saying, 'If you don't cure me I am going to come after you'. But day after day, by being gracious and trying to help him, the walls came down. He left hospital in remission and he was just crying. He gave me a big hug and said, "If you ever need anything you just let me know". That's

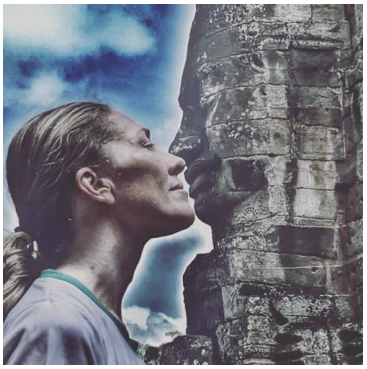
just a couple of people who I remember out of many.

STA spoke to Joel Wight in January 2017.

Sports Broadcaster Takes on New Sporting Challenge

Specialised Therapeutics Australia (STA) has a particular interest in pancreatic cancer and is committed to supporting efforts to advance understanding and improve clinical outcomes in this disease.

Testimony to this commitment, we recently sponsored well-known television personality and sports broadcaster Tiffany Cherry to participate in the GI Cancer Institute's 'Gutsy Challenge' – a seven day cycling challenge across Cambodia to raise awareness and vital funding for Australian research into GI cancers.




Monies raised by our rider Tiffany are being specifically directed into a fund for Australian pancreatic cancer research.

Tiffany rode as part of a cycling team including oncologists, cancer survivors and others who have been touched by GI cancers.

STA shared highlights of Tiffany's Cambodian journey on our LinkedIn page. She interviewed others in her group and shared their stories. We encourage you to follow STA and like and share our posts by clicking here.



STA was proud to support this fantastic initiative. For more information about the GI Cancer Institute click here.

First Australian Patients Treated with New Brain Tumour Drug – Gliolan®

Melbourne, Australia: Two Australian patients have undergone surgery with the aid of a new drug which assists neurosurgeons to visualise and remove high grade gliomas – brain tumours which typically have a poor prognosis.

Neurosurgeons at Brisbane's Wesley Hospital and the Royal Melbourne Hospital have pioneered the use of Gliolan® (5-aminolevulinic acid), describing it as "breakthrough technology".

The drug is given to patients three hours prior to surgery and causes cancerous tissue to glow fluorescent red during brain surgery. This enables improved visualisation of the boundary between healthy and diseased brain tissue, and aids the surgeon to more thoroughly remove the tumour. International studies have shown the use of Gliolan during surgery has nearly doubled the rate of achieving a complete resection, and has doubled the number of patients without progression of their brain cancer six months after their surgery.[1]

Melbourne bio-pharmaceutical company Specialised Therapeutics Australia Ltd (STA) has licensed the drug for use in Australia and New Zealand. CEO of STA, Carlo Montagner said the availability of this drug in Australia will potentially benefit hundreds of brain tumour patients.

"We are pleased to make Gliolan available to Australians and expect it to be readily adopted by the neurosurgery community, so patients around Australia may benefit from the most sophisticated available technology," he said.

Mr Montagner added: "We have made clear our strategy of building Specialised Therapeutics Australia through the recent acquisition and continued growth of several specialist medicines which offer unique clinical benefits to patients."

The pivotal Phase III registration study published in The Lancet Oncology medical journal demonstrated complete resection of malignant high grade glioma tissue in 65% of patients receiving Gliolan, compared with 36% of patients in the control arm. Additionally, 6-month progression-free survival was achieved in 41% of patients receiving Gliolan compared to 21.1% of patients who were operated on without the use of the drug.[1]

The principal investigator of this pivotal trial, German neurosurgeon Professor Walter Stummer, has been in Australia to provide education and training using Gliolan for fluorescence-guided surgery. Nineteen Australian neurosurgeons are now trained and have been certified in this method, which will enable them to offer fluorescence-based resection of brain tumours to their patients.

Melbourne neurosurgeon, Dr Kate Drummond from the Royal Melbourne Hospital commented: “We hope that by using this breakthrough technology we will be able to improve the outcomes for Australian brain tumour patients.”

“In my first surgery using this drug, we found additional pockets of fluorescent pink tissue that I was able to remove, and that I may not have seen in a routine surgery. Using Gliolan allowed me to see the contrast of the pink and red fluorescing tumour tissue compared to the healthy non-fluorescing brain tissue. I was able to protect the normal brain tissue from damage during the surgery. ”

“We are pleased to be pioneering this operation at the Royal Melbourne Hospital and expect our neurosurgery colleagues around the country to follow suit.”

The active substance in Gliolan, 5-aminolevulinic acid, 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).[2]

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.[2]

The drug is approved for use in 27 countries across Europe, and Korea. Gliolan was first approved in Europe in 2007 and is marketed by Medac in Europe, Africa, South America and Asia (excluding Japan and Korea). Gliolan is not yet approved by the Therapeutic Goods Administration (TGA). The drug will be made available to Australian neurosurgeons who have undergone training, through the federal government’s Special Access Scheme (SAS) until TGA approved.

References:

1. Stummer W, Pichlmeier U, Meinel T, et al., Fluorescence-guided surgery with 5-aminovulinec acid for resection of malignant glioma: a randomised controlled multicentre phase III trial, Lancet Oncol, 2006;7:392-401
2. European Public Assessment Report

About Gliolan®

The active substance in Gliolan, 5-aminolevulinic acid. It 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.[2]

Like all medications Gliolan may cause side effects. Gliolan should not be used in patients with hypersensitivity to 5-ALA or porphyrins, 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 Specialised Therapeutics Australia, Pty Ltd

Specialised Therapeutics Australia Pty Ltd (STA) was established to identify, develop and commercialise innovative anti-cancer and other specialised therapies for the Asia-Pacific market. Currently STA markets two world leading cancer and cancer supportive care therapies, ABRAXANE® (nab-paclitaxel) and ALOXI® (palonosetron) respectively. Based in Melbourne, Australia, the privately held company is currently developing several more important therapeutic agents for release in the Asia-Pacific region.

Shelli’s Story: How Breast Cancer Inspired ‘Kit for Cancer’

Two and a half years ago, Melbourne based high flyer Shelli Whitehurst was diagnosed with Stage 4 breast cancer. The devastating diagnosis inspired her to found a business that's now helping other cancer patients around the world.

Shelli Whitehurst was at the pinnacle of her career, enjoying the success of the marketing business she founded when her life changed in an instant.

It was May 2014. Her strategic digital marketing company 'Code Name Max' was generating millions of dollars, she was working 15 hours a day, doing business in New York and loving every second.

She had experienced some pain – it was dismissed for months as an infection – then she visited an ophthalmologist with an eye so sore it was difficult to see.

Further investigation revealed two tumours behind each of her eyes and they were not primary cancers.

“My diagnosis was very rapid and very rare,” Shelli reflects.

“I was in New York, doing business, at the top of my game. I was a business owner, an entrepreneur, doing the whole thing and literally within seconds, my world just stopped.

“I could not get into a doctor for six weeks and I was having a mental breakdown, because when you put into ‘Doctor Google’ that cancer has left the primary area, you know that is not a good sign. You don’t die of Stage 1 to 3 cancer anymore, you die of Stage 4.”

Through a friend of a friend, Shelli was able to book into a breast surgeon a little earlier than expected. A day of extensive medical tests followed and she soon received terrible news: the cancer was in both breasts and her bones. She had rib and shoulder fractures. Her breast tumours were massive.

“I was full of cancer – when they scanned me I lit up like a Christmas tree,” Shelli says.

“You go from being a person to a patient. I had never been sick in my life.”

Because the cancer had spread so far, it was decided a double mastectomy would be of very little benefit.

“So we decided not to do surgery but we would monitor everything very closely and do surgery when required.”

She was put on to a new drug that was not yet listed on the Pharmaceutical Benefits Scheme and subsidised by the Federal Government. It meant she had to come up with tens of thousands of dollars within days.

Shelli has since had seven lines of therapy, including immunotherapy.

Unfortunately, despite the hope of immunotherapy, it did not work for Shelli. Now, her cancer has spread to her brain, lungs and liver.

“There is no drug that will fix me because my cancer is so weird and rare. I am 18 months past my expiry date. Now, we are on a different system of drugs which attack the cancer in a different way – which is good – and we

have had five months of stability."

These days, Shelli remains a vital part of the business she founded, but concedes she works nowhere near the number of hours she once did.

She has moved home with her Mum and Dad and relishes spending time with her four year old niece Lyla and one year old nephew, Hudson. Travelling with them to Disneyland is really the only thing on her bucket list.

"I am 41 now. I have an incredible family and I love being around them. I try to be positive. It takes just as much energy being sad as being happy."

At the moment, her entrepreneurial energies are diverted not only into her original company Code Name Max, but also into a new business she founded just days after her diagnosis.

Kit for Cancer is an enterprise committed to helping other cancer patients by developing and selling custom-made care packages to support them while they undergo treatment.

Kit for Cancer also collaborates with corporate partners to custom design kits for specific patient groups.

It's an online business operating from her mother's home and Shelli has sold hundreds of kits around the world, including in Zimbabwe and Brazil.

Testimony to her drive, the business is rapidly growing and evolving into The KIT Foundation.

Shelli says "Kit" began when she realised that there was no one-stop online shop "to have everything I needed" delivered when she became sick.

"People send you flowers and it's lovely. While none of those sorts of gifts are unappreciated, it's just not practical. In that moment you are diagnosed you need lots of practical stuff. Sick is expensive! I just kept writing down everything I needed and a friend put it all together in a box and I said 'this is exactly what I need!'."

Shelli's kits sell for $150 and she tries to keep costs down but it's hard – "so the more help the better!". The business also keeps her mind off her cancer.

For the moment, Shelli is taking everything day by day and is hopeful that one day, her incurable cancer will be a chronic disease that can be managed.

“If I can get five more years that’s great, if I can get ten it’s awesome and if I get more than that it’s a miracle.

“The best time of the morning is when I wake up and I am still breathing.”

Whatever her future holds, she takes comfort that The KIT Foundation is being built to outlive her.

“We have an amazing advisory board and people just want to be involved. We are without a doubt, the best and the most awesome foundation to be involved with in the world! So join us!,” she laughs.

“The KIT Foundation is here to look after the patient in the here and NOW. The minute you are told ‘You have cancer’, that’s when we step in and start looking after you. We are here for the good times and the bad. This is real and raw and this is what happens. You don’t get away with no tears, trust me.”

‘Kits for Cancer’ come packaged in a vintage style suitcase and can be ordered online at www.kitforcancer.com.

Footnote: Shelli Whitehurst spoke to STA in September 2016. We are inspired by her story and look forward to working with Kit for Cancer in supporting patients.

Call to Screen Type 2 Diabetics for Pancreatic Cancer

“I think the biggest revolutions in pancreas cancer treatment are yet to come.”

Dr Lorraine Chantrill has been a medical oncologist for 10 years, with a particular focus on pancreatic cancer “because it is so terrible and there is so much room for improvement”.

She notes that average survival rates for pancreas cancer have improved but remain abysmal (only 7% of patients survive five years post diagnosis) “and we need to do a lot more work in the prevention space”. She is also calling for screening studies of patients who are newly diagnosed with Type 2 diabetes (possibly via ultrasound) to potentially assist early pancreas cancer detection in some patients. While no link between these two diseases has been established, Dr Chantrill says tumours can affect normal insulin production and a surprise diabetes diagnosis may sometimes be an early cancer warning.

What is your rationale for potentially screening patients who are newly diagnosed with Type 2 diabetes?

We know that probably about 25% of pancreas cancer is cigarette smoking related. Maybe up to 10% of cancers might be linked to inherited changes but that leaves two-thirds with no known cause.

What we do know is that there are some associations. There is an *association* – and I say that carefully – between new onset Type 2 diabetes and pancreas cancer. There is a reasonable rationale to do screening of the pancreas gland in people who are diagnosed with Type 2 diabetes who do not have other risk factors for diabetes.

It's quite simple. If you have a tumour in the gland, it may become dysfunctional so you might not be able to produce insulin as efficiently. As an oncologist I hear the story so frequently: 'I was diagnosed with Type 2 diabetes only a year ago' — so it is a very common story. But it just so happens that this is an age group of people where that can happen anyway. The median age for a diagnosis of pancreas cancer is 67 for primary disease and for metastatic disease it is 71 years old. That is also the age people are commonly diagnosed with diabetes. It is very hard to prove this connection, but I think it might be a place to start. Let's face it, we don't have a screening test for pancreatic cancer. At least start a discussion.

Pancreatic cancer continues to have one of the lowest survival rates in oncology. Is there hope on the horizon?

Definitely there is hope – there is much more hope than there used to be. For example, I have a patient that I have now known for almost four years. I understand that this is an exceptional patient. But this patient just happens to have had an amazing response to treatment and she continues to have an excellent response. She says to me, 'If I live long enough there may be a trial for

me with something new'. And she is absolutely right.

Have treatments for pancreas cancer improved in recent years?

It's true to say treatment (for advanced pancreas cancer) has improved enormously in the last three to four years, and part of that has been driven by a reduction in our nihilism towards the disease. (Previously) we weren't going to do biopsies on patients because they were too sick, or we thought the patients were too sick for combination chemotherapy clinical trials, these kinds of ideas. Fortunately, that has changed and there is much more appetite to do things aggressively for people with pancreas cancer. We have also seen more recent trials in the second-line therapy space, which was unheard of in the past. That constitutes a been a revolution in this disease.

I think the biggest advances in pancreas cancer treatment are yet to come. They are to do with selecting out sub-populations of cancers that respond to different treatments.

How many sub-populations of pancreas cancer might there be and what are the treatment benefits of identifying these patients?

There's still a lot of work to be done but I suspect there are more than four sub-types and maybe as many as 10.

I think the future will be about dividing pancreatic cancer into these sub-types and treating them differently. For example, there is a very small sub-type – representing 2% of patients – that have up-regulation of HER2 receptors and these patients may be responsive to anti-HER2 therapy, like *trastuzumab*. But that represents only 2% of cases. So screening and running a trial for only 2% is very difficult and very expensive. Similarly, BRCA mutated pancreatic cancers may respond better to platinum based therapy, but in Australia the percentage of BRCA mutated cancers is only about 4%. We also believe that the KRAS sub-type

makes up about 7% of cases.

What needs to happen to assist next stage research efforts into this disease?

We really need to do innovative trials using patient derived tissue, which we can't be shy about getting. I think there are a number of ways to do this, including a warm autopsy program, which is something we hope to do. That's a way we can get tissue from several sites to which the cancer has spread – or *metastatic* sites, which is very difficult to attain during life. While we have done a major catalogue of primary pancreatic cancers in terms of whole genome sequencing, we know very little about whether metastases are the same or not.

Is immunotherapy playing a role yet in the treatment of pancreas cancer?

We have seen very poor results with immunotherapy so far in pancreas cancer which is very disappointing but maybe there is a sub-type that may respond to immune-based therapy. We have not found that yet, but that is not to say we should not keep looking.

How important is it to encourage new trials in this disease?

I went to a trials meeting recently and there was debate about how hard it is to get tissue samples from people with pancreatic cancer. Doctors were saying biopsies are hard because patients are too sick and because pancreas tumours can be technically difficult to access. For too long health professionals have been saying 'I don't want to put the patient through that, it is too difficult and these people have a short life expectancy. But patients are saying 'you should be asking us'. For example, if we were able to get biopsies after treatment or during treatment, we might be able to work out some of the clues which enable tumours

to respond to chemotherapy. We don't even know those simple answers, because it is very difficult to obtain tissue, especially for those patients for whom treatment is not working.

What inspires your oncology career?

If you talk to most oncologists you don't have to scratch the surface very deeply to find people have a personal connection with cancer. Most people do these days. My mother died of cancer and I was determined to do something in this field because I thought there was so much need. The other thing that appeals to me about oncology is the amount of research being done. I did a science degree and worked in molecular biology before I did medicine. Oncology is the most exciting part of medicine because molecular biology is having a real influence on diagnosis and treatment. My ambition is to be a clinician scientist, literally trying to do research that informs treatment in the clinic. It is a model that has become more acceptable in Australia but it has not been a very common model until now. In US and European public academic institutions it has been pursued for some time.

The way in which our system is set up has hampered this career path, but it is developing now.

Dr Chantrill is based at the Kinghorn Cancer Centre in NSW and is a Director of the Australasian Gastro-Intestinal Trials Group. She spoke with STA in September 2016.

Oral Mucositis – Expert Opinion,

Prof Dorothy Keefe

“Oral mucositis is quite debilitating, because pain in your mouth, or ulceration in your mouth, makes it hard to eat and to swallow.”

“Pretty much every cancer agent can cause some degree of mouth or gut damage. But it all depends on which drugs and what doses you are using. The range of incidence is from as low as 10% for one drug to as high as 60% for another drug. If you are using a high-risk drug or you are using head and neck radiotherapy it certainly goes up towards 100%.

Oral mucositis is quite debilitating, because pain in your mouth, or ulceration in your mouth, makes it hard to eat and to swallow. So, what happens is you get malnutrition and you get pain and both of those have an impact on your quality of life, so it can be a really big deal. There are some patients, particularly in the head and neck cancer area, who have to have naso-gastric feeding during their treatment because of their mucositis.

Head and neck cancer patients and lung cancer patients are particularly prone to

weight loss anyway and the mucositis just adds to that. How much is due to the mucositis is hard to determine, but people can lose 5-10% of their body weight if they are badly affected.

In this era of personalised cancer medicine, we need to look at the tumour AND the patient. It's about holistic care for the patient and that is what people want, ultimately, including the management and prevention of oral mucositis."

- Professor Dorothy Keefe, August 2016.

From Big Pharma to Small Starts: Risking it All on a Life-Saving Cancer Drug to Win

SARAH-JANE TASKER | THE AUSTRALIAN| MARCH 19, 2016 12:00AM

From Big Pharma to Small Starts: Risking it All on a Life-Saving Cancer Drug to Win

Bozena Zembrzuski and Carlo Montagner reflect on their decision to found Specialised Therapeutics and bring Abraxane to Australia. Picture: Aaron Francis

After years working for big pharma in the US, Carlo Montagner and Bozena Zembrzuski risked their life savings to bring a leading cancer drug to Australia.

The two, who met at university, sold everything almost eight years ago — share portfolios and investment properties — and lived in rented accommodation when they returned to Australia to start their own pharmaceutical company, Specialised Therapeutics.

Montagner, who became chief executive, says he and his wife — parents to three children — took a risk on the Melbourne start-up. The early days of the business were a stark reminder of these risks.

The first drug they wanted to bring into Australia, Abraxane, developed to treat breast cancer, was originally rejected by the Pharmaceutical Benefits Scheme — the system under which the government subsidises the cost of medicine.

“I called my wife after I was told the PBS had rejected it and her first words were ‘we’re — ruined’,” Montagner says.

“I said we weren’t because ‘it is too good a drug not to get through, so let’s play it

through'."

The couple, like most Australians, have watched friends and family battle cancer. Montagner's father died last September from mesothelioma and the oncology expert says that, given his role, he is often approached by friends and family for advice on the deadly disease.

"When I receive a call from a friend for advice, it's usually not for financial advice, so I generally tense up," he says.

"For most patients given cancer diagnosis, and I went through this myself with my father last year, it's just mind numbing, you don't know where to turn and there's a lot of information out there," Montagner says.

The privately owned company — Montagner has no interest in attracting third-party investors — generated more than $35 million in revenue last year but he says it isn't just about money.

"I'm very passionate about this. I really do believe that this (Abraxane) is the chemotherapy that all Australian women should receive."

Bringing a drug to the Australian market is usually reserved for those with deep pockets and time on their side. Drugs have to be licensed, which involves significant testing to secure the right local approvals. The testing needs to be done regardless of a drug's use or approval in other jurisdictions.

Montagner tells The Weekend Australian the original financial risk they took as a family was worth it because he had a strong belief in Abraxane, which he had launched in the US in his previous role as president of the drug's developer, Abraxis Bioscience.

Prior to the introduction of that drug into Australia in 2009, Montagner said breast cancer patients were using older chemotherapies that had been around for 20 years.

He says that today, Abraxane is one of the leading therapies for metastatic breast cancer and pancreatic cancer. Since the drug became available in Australia, more than 10,000 cancer patients have been treated with Abraxane.

The drug, which is now owned by US pharma Celgene, has been approved for

distribution in about 50 countries, including the US, Europe, Japan and India.

Montagner says the early take-up of the drug in Australia had exceeded their expectations “several fold”.

“We got caught in the first 18 months never really having enough stock,” he says.

“I couldn’t believe how quickly it was being adopted. We put the manufacturing plant in Phoenix under pressure … the plant once pulled out all stops, working 24-7 for a week to make a batch for Australia because we were selling so much of it.”

Zembrzuski says while the company was started with some trepidation, they took the view that if it didn’t work, they would simply get jobs again.

“We had a lot of faith in all the training and experience we’d built up in our previous roles in Australia and overseas,” she says.

The company co-founder, who previously worked for global drug giant Novartis, says it’s a different dynamic to have a married couple as the bosses, which she said had the potential to go terribly wrong.

“We were very aware right from the start that being married should not cause any confusion or stress to people,” she says.

“If this was going to be a credible and professional venture then that couldn’t happen.”

Zembrzuski jokes that she was worried if she could take direction from her husband given he had taken on the CEO role. She says she decided to treat him at work as she would any of her previous managers.

“We both have strong opinions, are both self-motivated and have always worked for other people, never together,” she says. “But we bring different strengths to the table and we do complement each other.”

The company was originally started because Montagner says it was difficult to get a role in Australia that matched the remuneration he was accustomed to in the US as the president of a Nasdaq-listed biotech. He and his wife are passionate about conveying that they don’t take the success of the company for granted.

“We feel very lucky that we are able to provide for the kids and are our own bosses,” Zembrzuski says.

Teaching their three children, aged 9, 12 and 14, about giving and not just taking is central to the values they want to pass on as parents.

Montagner says that before they went to the US, they were like most Australians and saw people who sprouted philanthropic endeavours as “show-offs”.

“Then we went to the US and there it’s in the DNA of all successful people. We saw that and we completely changed our view and bought into the concept that people who do well and have the opportunity to give back should give back,” he says.

“Plus, we both grew up in working class families that didn’t have the opportunities to do what we do now, so the last thing we want is our kids to grow up in a privileged household where they became too materialistic and focused on themselves than others in greater need.”

The family started its philanthropic efforts with a $1m donation to the Olivia Newton-John cancer research centre based at Melbourne’s Austin Hospital. They have also donated $US250,000 ($328,000) to build a trade school in East Timor.

Zembrzuski adds they are a “proud” Australian-owned company and while they will always maintain their head office in Melbourne, part of being entrepreneurial was looking at new options.

They expanded into Southeast Asia last year with the distribution of a drug to treat myeloma, a type of blood cancer.
“We aim to bring drugs to Australia and South East Asia that fulfil unmet medical needs,” Montagner says.

“We say no to drugs that don’t provide a unique benefit because then it becomes a pure marketing exercise if it doesn’t and we’re not interested in that.”

The company was founded on oncology drugs but it is also targeting haematology, urology and supportive care.

The rapid growth of Specialised Therapeutics has put it on the radar of larger companies but Montagner says he has no plans to sell.

“I love the fact we’re in a position where we can help others with some of the wealth we are generating and I love coming to the office each day and doing what we do. I see Rupert Murdoch and Warren Buffett … what I take from them is they love what they do, it’s not a job, it’s what you do every day.”

ICLUSIG™ to be PBS Listed November 1, 2015

ICLUSIG will be listed for the treatment of the following patients:

- Chronic Myeloid Leukaemia (CML) patients who are resistant or intolerant to both nilotinib and dasatinib
- CML patients who are expressing the T315I mutation after prior TKI therapy
- Philadelphia positive Acute Lymphoblastic Leukaemia (Ph+ ALL) patients who are expressing the T315I mutation after prior therapy with chemotherapy (with or without a TKI)

The Authority Required listing will commence from 1st November. For more information regarding the PBS listing please refer to the PBS website http://www.pbs.gov.au/pbs/home

As a result of the PBS listing the current ICLUSIG Access Program (IAP) will close prior to the effective listing date. Existing PBS eligible patients on the program

will transition to PBS reimbursed drug at the listing date. The final date for supply of ICLUSIG to current registered IAP patients will be on Friday 16th October.

A revised IAP will be offered to Australian patients with Ph+ ALL who are not expressing the T315I mutation. Access under this program will be on the basis of a co-payment for the initial four bottles of supply.

For more information regarding the PBS listing or for information on the Access Program please contact Elwyn Rayson of STA vi email: erayson@specialisedtherapeutics.com.au or call the STA Customer Service Team on 1300 798 820.