Latest developments on products and services from the industry. To have your news included contact Patricia McDonnell at Oncology News on T/F: +44 (0)288 289 7023, E: patricia@oncologynews.biz

## GenesisCare commences cancer treatments using Varian's TrueBeam system

Cancer patients on the Gold Coast of Queensland have gained access to treatments on an advanced TrueBeam™ radiotherapy and radiosurgery system from Varian Medical Systems. Queensland's first TrueBeam device commenced treatments at Genesis CancerCare Queensland's treatment center located at John Flynn Hospital in Tugun in November.

The Varian TrueBeam™ system, which integrates advanced treatment, imaging and motion management technologies to enhance the precision of treatments, is one of eight ordered earlier this year by Genesis CancerCare, the largest private radiotherapy provider in Australia.

"With a broad spectrum of advanced capabilities, the TrueBeam system's advanced image guided radiotherapy system makes it possible to deliver fast, targeted treatments to tumours even as they move and change over time." said Professor David Christie, radiation oncologist at Genesis CancerCare Queensland.

Radiation oncologist Dr Selena Young, added, "Cancer patients with complex conditions living at the southern end of the Gold Coast, Tweed and Northern Rivers regions will now have local treatment options, improving continuity of care and avoiding the burden of travel to access specialist cancer care."

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## PV-10 enhanced tumour-specific immunity with co-inhibitory blockade

Provectus Biopharmaceuticals, Inc recently announced that data on its investigational agent PV-10 for intralesional (IL) treatment of cancer was featured in a poster presentation at the Society for Immunotherapy of Cancer [SITC] 29th Annual Meeting. The poster, presented by Dr Shari Pilon-Thomas of the Moffitt Cancer Center, concludes that the new data "support combination therapy with IL PV-10 and co-inhibitory blockade."

In clinical trials, IL PV-10 has induced regression of both injected lesions and uninjected bystander lesions in patients with melanoma, and tumour ablation with PV-10 has been shown to increase certain T-cell populations in patients' peripheral blood. In the study reported at SITC, the team measured whether IL PV-10 and co-inhibitory blockade could improve anti-tumour immunity and regression of melanoma in mice.

The testing assessed response of injected and uninjected B16 melanoma tumours in mice receiving PV-10 alone or in combination with one of three agents designed for co-inhibitory blockade. The tested agents targeted either CLTA-4, PD-1 or PD-L1, the three most common clinical targets for co-inhibitory blockade. In each case, combination of PV-10 with co-inhibitory blockade led to improved tumour response and enhanced anti-tumour immunity of T-cells. Further testing with the anti-PD-L1 agent showed that these improvements could apply to both injected and uninjected tumours.

*The presentation is available at www.pvct.com/publications/SITCposter2014.pdf*

PROVECTUS BIOPHARMACEUTICALS, INC.

## Five cyclists bike against cancer for Teens Unite raising £18,512.61

Five budding cyclists embraced the ultimate challenge to raise money and awareness for Teens Unite; a charity that supports young people fighting cancer. The team consisted of Ian Dawe-Cheshunt, Hannah Charles-Broxbourne, Daisy Chandler-Sydenham and Yvonne Agha-Watford.

Over the course of five consecutive days, the team of bikers cycled 350km. Their journey started from Mount Kilimanjaro in Tanzania, through both Tarangire and Lake Manyara National Parks, through the Rift Valley until eventually finishing at the Ngorongoro Crater.

The team raised an incredible £18,512.61 between them, which will enable Teens Unite to continue to support more young people on their cancer journey. Teens Unite currently supports nearly 600 young people across the UK, who have battled, or are battling cancer.

Yvonne Agha, Chair Trustee of Teens Unite formed part of the team. When sharing her experiences she said: "The last few days have taken stamina, determination and a lot of heart. It has made us stronger as people in so many positive ways. We feel so fortunate to show our support for Teens Unite in this way and look forward to sharing more memories with you in the near future."

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## Patients, carers, scientists meet with MPs

On 15th December, 2014 a select group of MPs met with campaigners at the House of Commons to highlight the discrepancies in cancer research funding. During the event, hosted by Rebecca Harris MP, the charity Brain Tumour Research encouraged a discussion into how government can improve outcomes for the brain tumour patients.

Key policy changes were recommended, including: A pledge to increase research funding to £30-£35m a year over ten years and a call for a new national register of research, which tracks all research work and grants with the aim of reducing duplication and increasing transparency.

Discussions took place around what more could be done to fund PhD research scholarships, the need to ring fence the medical research budget and a call to streamline the process for repurposing drugs.

Sue Farrington Smith, Chief Executive of Brain Tumour Research, said: "We took a clear set of recommendations to the MPs that represent the voice of our supporters. We need a clear plan from government to kick start the changes needed to give patients the knowledge that more effective treatments are being identified and ultimately cures found."

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## Provectus Biopharmaceuticals' protocol for phase 3 study of PV-10 as treatment for melanoma now available online

Provectus Biopharmaceuticals, Inc recently announced that the protocol for its phase 3 study of PV-10 as a treatment for melanoma is now available online. The protocol states that the study is "an international multicenter, open-label, randomised controlled trial (RCT) of single-agent intralesional PV-10 versus systemic chemotherapy with dacarbazine (DTIC) or temozolomide (TMZ) to assess treatment of locally advanced cutaneous melanoma in patients who are BRAF V600E wild-type and have failed or are not otherwise candidates for ipilimumab or another immune checkpoint inhibitor. Subjects in the comparator arm will receive the Investigator's choice of dacarbazine or temozolomide as determined by Investigator preference and/or local availability of the agent. Effectiveness will be assessed by comparison of progression-free survival (PFS) between all intent-to-treat (ITT) subjects in the two study treatment arms."

The Primary Outcome Measure is progression-free survival (PFS) to be assessed every 12 weeks up to 18 months. The Secondary Outcome Measures include complete response rate (CRR) and its duration (to be assessed every 12 weeks up to 18 months); the change in total symptom score from baseline using the patient reported Skindex-16 instrument (to be assessed 12 weeks after Day 1); Overall survival to be assessed every 12 weeks up to 18 months; and number of participants with adverse events assessed every 4 weeks until 28 days after last treatment.

*For further information visit: www.pvct.com and clinicaltrials.gov/ct2/show/study/NCT02288897?term=provectus&rank=6*

## New cancer centre at Guy's Hospital in London to be equipped with Varian TrueBeam treatment machines

One of London's leading cancer centres has selected eight TrueBeam™ medical linear accelerators from Varian Medical Systems to deliver advanced radiotherapy and radiosurgery treatments. Six TrueBeam devices will be installed at the new Guy's Hospital Cancer Centre while two further machines will equip a satellite centre at Queen Mary's Hospital in nearby Sidcup, Kent.

Guy's and St Thomas' NHS Foundation Trust is replacing its existing treatment machines with TrueBeam systems as radiotherapy services are centralised at the new flagship centre, which is due to start treating patients in 2016. In addition to the equipment, the Trust is also acquiring a full suite of Varian's Eclipse™ treatment planning software.

"We selected TrueBeam because it fully met our requirements and in particular has additional motion management functionality with 4D gating, which is important to us," said Angela Francis, head of radiotherapy at Guy's and St Thomas'. "The TrueBeam platform has strong potential for future innovation, it's user-friendly, and the overall system offers an efficient workflow, making it possible to treat more patients in a day. With TrueBeam, we will be able to offer our patients a full range of the latest radiotherapy and radiosurgery treatment options."


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## Elekta's MOSAIQ oncology information system ranks number one in KLAS Oncology 2014 report

According to a survey by KLAS, an independent research firm, Elekta's MOSAIQ® Oncology Information System earned the number one ranking in the medical and/or radiology oncology category of KLAS' "Oncology 2014: Integration is Key" report. The survey of 247 customers of various vendors said that "Elekta has improved their MOSAIQ interfaces to take a commanding lead over their competitors." MOSAIQ scored 82.4 out of 100, 93 percent of customers said they would buy again and 96 percent confirmed that MOSAIQ is part of their long-term plans.

This is the second year that it has received this recognition. It was also ranked highest in the KLAS' "Oncology 2013: Eyes Wide Open" report.

This year, the report indicated that in the "interface race," in which integration is more critical than functionality in the eyes of customers, providers were more pleased with Elekta's MOSAIQ pharmacy interfaces than they were in the 2013 KLAS oncology report, achieving a rating of 8.0, eclipsing last year's mark of 7.1. "Elekta's single database for radiation and medical oncology continues to be a strength for the continuity of oncology care," the report states.

The survey also revealed high customer appreciation for the improved workflow automation that Elekta provides in MOSAIQ via IQ Scripts, which "has been immensely helpful in speeding up workflow."

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## Provectus Biopharmaceuticals to sponsor American Association of Physicians of Indian Origin

Provectus Biopharmaceuticals, Inc, recently announced that it has agreed to sponsor the activities of the American Association of Physicians of Indian Origin (AAPI). In addition, Provectus will participate at AAPI's 2015 Global Healthcare Summit in Mumbai, India, running from January 2-4, 2015, as well as at the Annual AAPI Conference in Orlando, Florida, running from June 17-21, 2015.

Peter Culpepper, COO and CFO of Provectus, said, "We are very pleased to be sponsoring AAPI in the coming year, and we believe the relationship will benefit both AAPI and our shareholders. One of the benefits to Provectus will be engaging the Indian market through trusted physicians for PV-10, our novel investigational cancer treatment. We expect this will not only assist us in gaining regulatory approval in India but also will support our patient recruitment efforts as we embark on our phase 3 clinical trial of PV-10 for the treatment of melanoma."

He continued, "AAPI is the umbrella organisation representing the interests of over 60,000 doctors of Indian origin in the USA, and there are over 25,000 medical residents and fellows currently in USA. This gives us tremendous reach in America as well as on the subcontinent. One in every seven American patients is seen by an Indian doctor, and this ratio is even higher in the smaller towns and underserved areas due to the larger proportion of Indian doctors in more remote locations. As a result, the Indian doctor also serves the most diverse group of patients in the USA including Caucasians, African Americans, Hispanics and other groups, which is important for clinical research and trials."

*For further information visit: www.pvct.com*

## Excellent sensitivity of M2-PK for polyps and bowel cancer

Newly published results from a multi-centre study of the ScheBo® M2-PK Quick™ test confirm its impressive sensitivity and specificity for detecting colorectal polyps and bowel cancer. Kim et al* investigated the innovative metabolic enzyme biomarker M2-PK in 139 colorectal cancer and 124 adenoma patients, alongside a population-based control group of 60 people (323 subjects in total). The sensitivity of the ScheBo® M2-PK Quick™ test was 92.8% for colorectal cancer and 69.4% for adenomas. Specificity was 83.3%. The study also included an immunological faecal occult blood test (also known as FIT). The ScheBo® M2-PK Quick™ test detected twice as many colorectal cancer cases and nearly six times the number of adenomas, with the same specificity, compared with FIT. These clinical results confirm the ability of the faecal ScheBo® M2-PK Quick™ test, which can be conducted in about 15 minutes without the need for dietary restriction or bowel preparation, to detect bowel cancer and colorectal polyps.


The faecal M2-PK test is available as a qualitative rapid test under the name ScheBo® M2-PK Quick™ and as a fully quantitative ELISA stool test.

*Kim YC et al. Gut and Liver, published online 5th December 2014. http://pdf.medrang.co.kr/ekjg/ekjg_1417674225.pdf.

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## Provectus to meet with FDA on operational aspects of PV-10 Phase 3 melanoma study with aim to maximise speed of enrollment

Provectus Biopharmaceuticals, Inc haved announced that it will be meeting with the U.S. Food and Drug Administration (the "FDA") to review certain operational aspects of the protocol for its planned phase 3 clinical trial of intralesional PV-10, its novel investigational drug for cancer, as a treatment for melanoma. No date for this meeting has been agreed upon as yet.

Eric Wachter, PhD, CTO of Provectus, stated, "When we submitted the protocol to the Agency in November, we included a brief list of questions about certain operational aspects of the protocol, in particular regarding eligibility requirements relevant to maximising the speed of enrollment of patients in the study. This is standard practice for a pivotal submission. The FDA has subsequently indicated that a formal meeting is appropriate to assure that these questions are addressed in a timely and documented manner. We hope the meeting will occur in January or early February 2015."

Dr. Wachter added, "We currently have eight sites, four in the U.S. and four in Australia, in our expanded access program that are using PV-10 for melanoma and other cutaneous malignancies. They will provide a path to quickly starting enrollment once this review period is finished.

For a detailed list of the current inclusion and exclusion criteria and further details regarding the endpoints of the study, visit: https://clinicaltrials.gov/ct2/show/NCT02288897?term=pv-10&rank=5

*For further information visit: www.pvct.com*

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## New xSPECT technology improves diagnostic confidence at St George's


St George's Healthcare NHS Trust has become the first in the UK to install the new Symbia Intevo™ xSPECT technology from Siemens Healthcare. The Trust has installed two of the systems, a Symbia Intevo Excel and Symbia Intevo T16 as part of a major upgrade within its nuclear imaging diagnostic facility. The Intevo technology is joined by a Symbia® S multi-purpose SPECT system with the three new installations helping to meet present and future workload requirements within the Trust.

The Symbia systems have replaced three gamma cameras within the department and are being used for a wide range of procedures, including tumour, infection and skeletal imaging. The xSPECT technology integrates high sensitivity single-photon emission computed tomography (SPECT) and high specificity CT, combining them to provide anatomical and functional information. The excellent image quality and additional available information has improved diagnostic confidence to clinicians in the department.

"We are delighted to be the first site to install the latest Intevo technology from Siemens Healthcare," states Andy Irwin, Consultant Clinical Scientist at St George's Healthcare NHS Trust. "We have completely revitalised the department, and Siemens were on hand to help with the design of a joint control room."

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## Prague leads the way in European proton therapy

The story of Ashya King, a five year old boy from Great Britain has lifted the interest in the gentle form of radiation at Proton Therapy Center Czech (PTC), a high end facility, which is conveniently located in the heart of Europe and which also allows the EU patients to claim the reimbursement of proton therapy within the S2 form.

PTC has seen a growing interest from world healthcare specialists as well as healthcare providers. Located in beautiful city of Prague, the centre has been leading the way together with the top world proton therapy facilities. Having treated altogether 750 patients from 22 world countries, the centre has gradually opened most of its treatment rooms and launched a two shift operation – all this in reaction to the growing demand for proton beam therapy. Moreover, it has been recognised by the world health care specialists.

PTC accepts both children and adult patients with various brain tumours, head and neck tumours, gastrointestinal tumours, prostate cancer and malign lymphoma.

*For further information visit*
*www.proton-cancer-treatment.com*
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## Varian Medical Systems announces intention to acquire Mevis Medical Solutions AG through a public tender offer

Varian Medical Systems has announced it intends to submit an offer to acquire MeVis Medical Solutions AG, a company based in Bremen, Germany that provides image processing software and services for cancer screening. VMS Deutschland Holdings GmbH, a Varian affiliate, will make a voluntary public tender offer to all MeVis shareholders to acquire their non-par value registered shares at a price of €17.50 per share, for an expected total payment of €30 million if all outstanding shares [1] are tendered.

MeVis develops innovative software for the analysis and processing of image data which is marketed to imaging equipment manufacturers for screening breast cancer as well as lung, liver, prostate, and colon cancer. The acquisition would also include the proprietary MeVisLab™ software platform, a research and development environment facilitating the efficient realisation of tailored software solutions using a rapid prototyping approach. MeVis software for breast cancer screening has been sold to some 10,000 clinics around the world. Varian's Imaging Components business is a premier global provider of X-ray tubes, flat-panel detectors, and image processing software and workstations for digital imaging.

[1] Registered share capital excluding treasury shares.

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## Provectus Biopharmaceuticals' protocol for phase 2 study of mechanism of action of PH-10 on immunologic markers of psoriasis now available online

Provectus Biopharmaceuticals, Inc recently announced that the protocol for its phase 2 study of the mechanism of action of PH-10 in psoriasis is now available online.

The protocol states that the multicenter study is designed to assess treated psoriatic plaque for "changes in immunologic, structural and hyperproliferative state and for any evidence of cellular atypia" when treated with PH-10 and to "correlate observed changes in the skin with clinical response to treatment." These assessments are expected to advance the understanding of the mechanism of action of PH-10 in psoriasis and other inflammatory dermatoses, such as atopic dermatitis, and further substantiate the safety profile of the agent.

The study will enroll up to 30 subjects with mild to moderate plaque psoriasis. Subjects will apply vehicle daily for 28 consecutive days followed by active PH-10 daily for 28 consecutive days to their psoriatic plaques. Biopsies of one plaque will be collected at baseline and immediately after completion of vehicle application and PH-10 application. This will allow data from each subject to serve as an internal control for assessment of clinical and cellular response to PH-10.

*For further information visit: www.pvct.com and ClinicalTrials.gov, Identifier NCT02322086: https://www.clinicaltrials.gov/ct2/show/NCT02322086*