

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](mailto:patricia@oncologynews.biz)



## a new standard in colposcopy

ZedScan uses Electrical Impedance Spectroscopy (EIS), to analyse tissue structure and identify pre-cancerous and cancerous cells in women suspected of having cervical neoplasia following an abnormal cervical smear test.

ZedScan is a non-optical device used as an adjunct during colposcopy and consists of a portable hand-held device, docking station, software for installation onto a PC and a single-use EIS Sensor. The results of ZedScan are immediately displayed on the handset. The clinician can make decisions about the clinical management of the patient at first visit. Dependent on the decision, they would treat the patient immediately, take a directed biopsy, or return to routine surveillance.

ZedScan clinical benefits are identifying the optimum biopsy site, reducing the number of cervical biopsies required while facilitating a wider use of 'See & Treat'.

Five clinical trials in the UK and EU have supported the clinical efficacy of ZedScan, including a pivotal multi-centre trial of 429 women across three hospitals in the UK and Ireland. An independent health economics further demonstrates the benefits for a healthcare system.

For information please contact Rob Atkinson

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## Milan Cancer Centre introduces wider range of treatments using Varian's Edge™ Radiosurgery System



Humanitas Cancer Center in Milan has become one of the first hospitals in the world to commence cancer treatments using the new Edge™ radiosurgery system from Varian Medical Systems. This precise, non-invasive alternative to conventional surgery has been used to treat several patients with lung, prostate, brain, and liver lesions.

"Edge radiosurgery gives us the opportunity to further minimise damage to healthy tissues and increase the dose per treatment session, making it a valid alternative to surgery, especially for inoperable patients," says Dr Marta Scorsetti, director of the hospital's radiotherapy and radiosurgery department. "In particular, Edge allows us to start new protocols for treating prostate cancer patients in just four daily sessions rather than the six to eight weeks typically required with conventional radiotherapy."

The Edge radiosurgery system enables clinicians to attack tumours from outside the body using carefully shaped high-energy X-rays. There are no incisions and patients contend with few of the healing, pain, and recovery issues typically associated with conventional surgery.

"In addition to enabling us to introduce new treatment protocols for prostate cancer patients, Edge Radiosurgery in combination with the Calypso system allows us to treat lung lesions more precisely by tracking the tumour in real time during treatment delivery," adds Stefano Tomatis, head of radiotherapy physics at Humanitas Cancer Center.

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## FUJIFILM SonoSite X-Porte™ offers real benefits for interventional radiology



The Radiology Department at the Royal Surrey County Hospital NHS Foundation Trust has recently taken delivery of its first FUJIFILM SonoSite X-Porte™ point-of-care ultrasound system for use in the interventional radiology suite. Dr Alex Horton, Consultant Radiologist, commented: "I was lucky enough to see the new X-Porte at a pre-launch event, and knew straightaway that it was particularly well suited to interventional radiology. The image quality is probably the best of any point-of-care ultrasound machine I've seen; it has a large, full-screen display and the resolution is comparable to many much larger instruments, but at a third of the cost. The very rapid boot-up time and good battery life are also perfect for interventional procedures, particularly as the system is so portable and robust, meaning it is always available where and when we need it."

"The X-Porte is very easy to use – it has one of the most intuitive interfaces of any point-of-care system – and the built-in electronic manuals and online help mean that virtually no training is required. It has few controls, allowing you to quickly set the gain, brightness, depth and colour Doppler very quickly, which, again, is perfect for interventional radiology use."

For more information please contact:

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E: [ukresponse@sonosite.com](mailto:ukresponse@sonosite.com) or W: [www.sonosite.co.uk](http://www.sonosite.co.uk)

## SonoSite's X-Porte™ ideal for critical care

The Neurosurgical Critical Care Unit at the Royal Hallamshire Hospital in Sheffield has recently taken delivery of its first FUJIFILM SonoSite X-Porte™ point-of-care ultrasound system, giving staff the ability to perform transthoracic echocardiograms (TTEs) on demand. Dr David Turnbull, a consultant anaesthetist specialising in neurosurgical care, explained: "Bedside TTE is becoming increasingly commonplace in a critical care setting, providing valuable information about a patient's pre- or post-operative condition that can help to direct their care. Previously, we have relied on borrowing a portable instrument from the radiology or cardiology departments, but the systems are in high demand, making availability an issue."



"When we looked at purchasing our own instrument, we asked the radiology department for a recommendation, and they performed a side-by-side comparison between the X-Porte and two portable instruments from another manufacturer. Despite the sonographer having no previous experience with SonoSite equipment, the X-Porte was the clear winner in terms of image quality and ease of use. The large screen makes it easy to see the structures of interest – it is really well thought through and easily tips and tilts to the right angle – and the probes are very robust."

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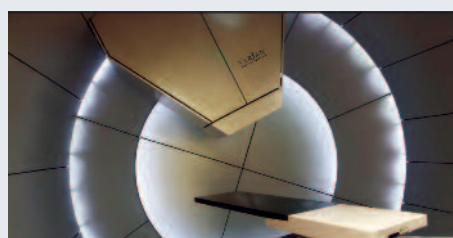
## PSI extends R&D collaboration with Varian and expands capacity for clinical research

Varian Medical Systems and the Paul Scherrer Institute (PSI) are announcing an extension of their existing collaboration in the field of proton therapy to offer patients more precise cancer treatments using intensity modulated proton therapy (IMPT). Under the agreement, Varian will also supply PSI with a state-of-the-art proton therapy delivery gantry to help meet a growing demand for clinical research and treatments at PSI.

Proton therapy targets tumours with concentrated doses of radiation while offering superior protection of surrounding healthy tissue. IMPT, which was pioneered using pencil-beam scanning at the Paul Scherrer Institute and made commercially available by Varian Medical Systems, is a radiation delivery technique that enables clinicians to optimise precision when treating tumours.

"This multi-year R&D collaboration will enable Varian and PSI to continue their productive research activities in the areas of advanced pencil beam scanning delivery systems, on-board imaging, clinical workflow optimisation, and accelerator technology to further develop high proton treatment technology over the coming years," says Moataz Karmalawy, head of Varian's Particle Therapy group. "Our original collaboration led to the commercialisation of IMPT and we are delighted to expand our partnership to develop more revolutionary technologies."

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## Provectus Biopharmaceuticals' PV-10 data to feature in Poster Presentation by Moffitt Cancer Center at ASCO



Provectus Biopharmaceuticals, Inc., development-stage oncology and dermatology biopharmaceutical company, announced today that data on its investigational drug PV-10 will be featured in a presentation by investigators from Moffitt Cancer Center in a Poster Highlights Session of the American Society of Clinical Oncology (ASCO) Annual Meeting at McCormick Place, Chicago, IL, May 30-June 3, 2014. The time and date of the presentation are available on the ASCO website, <http://am.asco.org>

The poster, based upon abstract #9028, is entitled "Assessment of immune and clinical efficacy after intralesional PV-10 in injected and

uninjected metastatic melanoma lesions," and is authored by Amod Sarnaik, MD and colleagues of Moffitt.

Craig Dees, PhD, CEO of Provectus said, "We value our relationship with Moffitt greatly, and we are excited by the assessment Dr Sarnaik has made on clinical and immunologic activity of intralesional PV-10."

Provectus has recently submitted an application to the FDA for breakthrough therapy designation for PV-10 based on the results from its Phase 2 clinical study of melanoma and is researching its efficacy for other indications.

For further information visit [www.pvct.com](http://www.pvct.com)

## One first in Europe to treat patients using Varian's TrueBeam 2.0 System with six degrees of freedom couch

Kaiser-Franz-Josef Hospital in Vienna has become one of the first oncology departments in Europe to introduce clinical treatments using the PerfectPitch™ six-degrees-of-freedom robotic couch from Varian Medical Systems. The hospital has introduced this enhanced patient positioning device, which enables more flexibility during radiotherapy treatments, as an integrated element of its latest TrueBeam™ 2.0 treatment system.

The PerfectPitch system enables the patient to be positioned more flexibly during treatments, taking advantage of 'pitch and roll' positioning to optimise the treatment. "If the couch can pitch and roll as well as moving up, down and sideways, it gives us more precision and flexibility while imaging and treating, and it helps to reduce the time it takes to set-up the patient," says Dr Anne-Marie Schratter-Sehn, head of radiation



oncology at KFJ Hospital. "These additional positioning capabilities in combination with TrueBeam's advanced image guidance and motion management tools introduced with the TrueBeam 2.0 upgrade will enable us to extend our stereotactic radiosurgery capabilities and offer more patients a wider range of high precision radiotherapy and radiosurgery treatments."

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## Provectus Appoints Dr Joseph Chalil to Strategic Advisory Board

Provectus Biopharmaceuticals, Inc, a development-stage oncology and dermatology biopharmaceutical company, announced that it has appointed Dr Joseph M Chalil, MD, MBA, FACHE, to its Strategic Advisory Board.

Dr Chalil is Associate Director, Health Science Executives of Boehringer Ingelheim, the world's largest privately held pharmaceutical company. In addition to his responsibilities at Boehringer Ingelheim, Dr Chalil is the Co-Chair for the Industry Physician Committee of the American Association of Physicians of Indian Origin (AAPI) and has served as Scientific Advisor to AAPI for the past three years.

A veteran of the United States Navy Medical Corps, Dr Chalil is also board certified in healthcare management, and has been awarded Fellowship by the American College of Healthcare Executives.



Craig Dees, PhD, CEO of Provectus Pharmaceuticals said, "Adding Dr Chalil to our Strategic Advisory Board will strengthen our collective expertise in healthcare marketing, sales and business development. His depth and breadth of experience in these fields will enable Provectus to take greater advantage of the opportunities that lie ahead."

Dr Chalil said, "I am honoured to join the Provectus Strategic Advisory Board at this critical juncture of the company's development as it brings PV-10 and other treatments through the developmental regulatory approval processes."

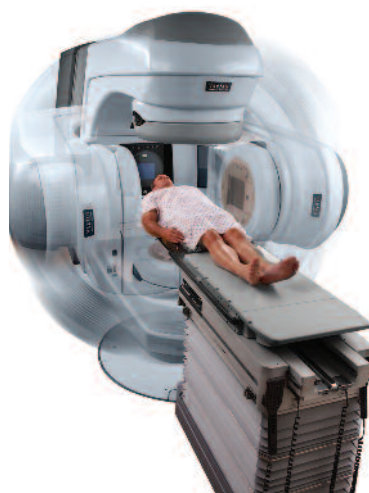
For further information visit [www.pvct.com](http://www.pvct.com)

## Fast and precise RapidArc® radiotherapy treatments introduced for benefit of cancer patients in Greece

A 37-year-old patient with advanced tongue cancer has become the first person in Greece to be treated using fast and precise RapidArc® radiotherapy technology from Varian Medical Systems. The pioneering treatment took place at Metropolitan Hospital in the south of Athens.

The RapidArc capabilities, which were installed on one of the hospital's two Varian Clinac® radiotherapy treatment machines, deliver precise image-guided IMRT (intensity modulated radiotherapy) up to four times faster than was possible with earlier generations of technology. With RapidArc, the machine quickly delivers the treatment while continuously rotating around the patient, and the beam is constantly shaped and reshaped during the rotation to match the shape and size of the tumour. RapidArc makes it possible to deliver these sophisticated treatments in as little as two minutes. Studies show that faster treatments allow for greater precision, since there is less chance of patient or tumour movement during treatment delivery.

According to radiation oncologist Dr Johannes Athanasios Dimopoulos, conventional IMRT for head and neck cancer patients is usually performed with static beams delivered from nine



different angles over a 15-20 minute time period. "RapidArc significantly reduces the treatment time without compromising on the quality of the treatment," said Dr Dimopoulos.

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## PV-10 Selected for Poster Highlights Session



Provectus Biopharmaceuticals, Inc, a development-stage oncology and dermatology biopharmaceutical company, recently announced that data on treatment of cutaneous melanoma using its investigational drug PV-10 have been selected to be part of the Poster Highlights Session of the American Society of Clinical Oncology (ASCO) Annual Meeting this year at McCormick Place, Chicago, IL, May 30-June 3, 2014. The time and date of the session are available on the ASCO website, <http://am.asco.org>

Sanjiv S Agarwala, MD, is lead author of abstract #9027, entitled "Efficacy of intralesional Rose Bengal in patients receiving injection of all existing melanoma in phase II study PV-10-MM-02."

Craig Dees, PhD, CEO of Provectus said, "Being selected for the Poster Highlights Session is an honour, and we look forward to sharing the results of our Phase 2 study with attendees."

Provectus has recently submitted an application to the FDA for breakthrough therapy designation for PV-10 based on the results from its Phase 2 clinical study related to cutaneous melanoma and is researching its efficacy for other indications.

For further information visit [www.pvct.com](http://www.pvct.com)

## Provectus Biopharmaceuticals signs agreement with China's Tririver Capital



Provectus Biopharmaceuticals, Inc recently announced that it has entered into an advisory agreement with China's Tririver Capital to help identify distribution and joint venture partners for the Company's novel oncology drug PV-10 in China, as well as other therapeutics that Provectus is developing.

The Tririver agreement is intended to provide further reach into China for PVCT as it seeks partnering opportunities with pharmaceutical companies. The new agreement will further bolster the current initiatives by Provectus in conjunction with existing advisory groups to develop partnering opportunities in various countries in Asia including China, India and Japan, where the Company has held numerous detailed discussions with pharmaceutical companies over the last year.

Provectus believes significant opportunities exist for PV-10 and PH-10 in Asia including those for its lead melanoma indication, as well as for liver cancer treatment and other oncology and dermatology treatments. As an example, nearly 55% of world-wide cases of liver cancer occur in China each year and there is a tremendous unmet medical need.

For further information visit [www.pvct.com](http://www.pvct.com)

## PV-10 treatment decreases melanoma cells in tumours and boosts T-cells within 7-14 Days



Provectus Biopharmaceuticals, Inc has announced that a poster presentation detailing significant decrease in melanoma cells in patients' injected tumours 7-14 days after intralesional PV-10 treatment that was accompanied by similar decrease in uninjected bystander tumours was presented by researchers from the Moffitt Cancer Center at the American Association for Cancer Research Annual Meeting in San Diego, CA. These clinical and pathologic changes were accompanied by increases in important immune cell populations detected in the patients' peripheral blood.

The poster presentation, based upon abstract #630, entitled "Induction of anti-melanoma immunity after intralesional ablative therapy," was authored by Hao Liu, Krithika Kodumudi, Amy Weber, Amod A Sarnaik and Shari Pilon-Thomas of the Moffitt Cancer Center.

Provectus' investigational drug PV-10, a 10% solution of Rose Bengal, is currently being studied as a novel cancer therapeutic, and Provectus has applied to the FDA for breakthrough therapy designation of PV-10 for the treatment of melanoma based on a 7 center international single-arm trial. PV-10 is designed to selectively target and destroy cancer cells without harming surrounding healthy tissue, significantly reducing potential for systemic side effects. In melanoma patients, intralesional (IL) injection of PV-10 has led to regression of injected lesions as well as uninjected metastases. The mechanism of regression of uninjected lesions is under investigation at Moffitt Cancer Center (NCT01760499).

For further information visit [www.pvct.com](http://www.pvct.com)

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## Varian demonstrated Motion Management and Radiosurgery Technologies at ESTRO 33 in Vienna

Varian Medical Systems, a world leader in radiotherapy equipment and software, demonstrated its full range of radiotherapy delivery systems and software at the 33rd ESTRO (European Society for Radiotherapy and Oncology) meeting recently in Vienna. The Varian booth featured the company's technology and products for radiotherapy, radiosurgery, brachytherapy, and proton therapy.

Varian's TrueBeam™ 2.0 platform for radiotherapy and radiosurgery were displayed along with the RapidArc® image-guided intensity-modulated radiotherapy system, the PerfectPitch™ six-degrees-of-freedom couch, and the Calypso® 'GPS for the Body' system, all of which are aimed at helping clinicians to deliver treatments with both precision and speed. Varian also exhibited its powerful new RapidPlan™ software for improving the quality and speed of treatment planning.

Visitors to the Varian booth learnt more about the company's new Edge Radiosurgery™ system, Varian's first dedicated, fully integrated end-to-end solution for planning and delivering advanced radiosurgery treatments using



new real-time tumour tracking technology and motion management capabilities. Clinicians from the first three hospitals to commence treatments with Edge Radiosurgery -- Champalimaud Center for the Unknown in Lisbon, Humanitas Cancer Center in Milan, and the Henry Ford Health System in Detroit, U.S. -- presented results from early treatments for lung, brain, spine and liver tumours at the Varian 'Cutting Edge' symposium on April 6th.

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## ONCOassist deployed in The Clatterbridge Cancer Centre as Enterprise system



The Clatterbridge Cancer Centre NHS Foundation Trust have today announced an enterprise agreement which will see ONCOassist, a revolutionary new CE approved software system, being deployed as the main oncology decision support system used within Clatterbridge.

ONCOassist was launched in January of last year following extensive development involving oncologists, system developers and compliance personnel in Europe and the United States. Since launch ONCOassist has garnered growing acceptance amongst oncology professionals throughout the UK and Ireland. In August of this year, the platform was offered as an enterprise system. This enables individual

trusts and institutions to integrate their guidelines and protocols and make them available throughout the trust in an easy to access and intuitive format.

Thomas Poulter, Head of IM&T at The Clatterbridge Cancer Centre, said: "Having ONCOassist available in clinics and on the wards will save our clinicians time. The oncology nurses and clinicians will have access to all of the key oncology decision support information and tools they need. For example, our nurses often need to reference protocols or treatment algorithms when delivering chemotherapy treatment. ONCOassist makes it easy to do this."

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## CyberKnife Centre officially opens at Hermitage Medical Clinic

Hermitage Medical Clinic officially opened its CyberKnife Centre on Saturday 1st March. The centre was opened by Prof Berndt Wowra, Professor of Neurosurgery, European Cyberknife Centre in Munich.

The official opening took place after the CyberKnife Symposium where speakers included Dr Alan Katz, Consultant Radiation Oncologist who presented on CyberKnife Radiosurgery for Early Prostate Cancer, Dr Ronald Beaney from the Cyberknife Unit, Harley St Clinic, London and Dr Geoff Heyes, Principal CyberKnife Physicist, OE Birmingham.

Dr Clare Faul, Radiation Oncologist also spoke of her experience to date of CyberKnife at Hermitage and the patient referral pathway. The



At the official opening Left to Right: Mr. Danny Rawluk and Prof Berndt Wowra.

event was chaired by Mr Danny Rawluk, Consultant Neurosurgeon and attended by Consultants from different specialties including Radiation & Medical Oncology, Neurosurgery, Neurology, Urology and Respiratory Medicine.

The Hermitage Medical Clinic's CEO, Mr Eamonn Fitzgerald, acknowledged the continued commitment and support of the investors in developing the hospital as a centre of excellence for patient care through the dedication of skilled and compassionate staff as well as cutting edge medical technologies.

For further information contact: Hermitage CyberKnife Centre, T: +353 (0)1 645 9045, F: +353 (0)1 645 9128, E: [radiotherapy@hermitageclinic.ie](mailto:radiotherapy@hermitageclinic.ie)

## Meet the scientists and take a guided tour of the UK's first dedicated brain tumour research laboratory

Find out more about the ground-breaking science being carried out at the Brain Tumour Research Centre of Excellence in the University of Portsmouth.

The charity Brain Tumour Research helps fund long-term and sustainable research, supporting the UK's largest team of Neuro-oncologists. The Brain Tumour Research lab tour is a fantastic chance to see the extremely interesting and valuable research taking place every day. You will be able to ask questions about the research and how the work is helping get closer to a cure. One of the charity's Regional Fundraisers is also on hand to talk about the role of the charity.

Lab Tours often coincide with a formal placement of plaques on our Wall of Hope, a permanent recognition of the funds raised



through the efforts of our amazing supporters.

Dates for the Lab Tours can be found on the Brain Tumour Research website here [www.braintumourresearch.org/portsmouth-centre-lab-tours](http://www.braintumourresearch.org/portsmouth-centre-lab-tours)

To register for your visit, contact Brain Tumour Research via email [sarah@braintumourresearch.org](mailto:sarah@braintumourresearch.org) or call +44 (0)1296 733011.

## FDA expected to make determination within 60 days upon receipt



Provectus Biopharmaceuticals, Inc, a development-stage oncology and dermatology biopharmaceutical company, announced today that it has applied to the FDA for Breakthrough Therapy Designation (BTD) for PV-10 for the treatment of melanoma. FDA guidelines state that the Agency will make a decision on the application within 60 days of receipt. The Agency's records for FY 2013 show that the Agency's Center for Drug Evaluation and Research (CDER) met that guideline 97% of the time.

Craig Dees, PhD, CEO of Provectus said, "The decision to apply for BTD stems from our Type C meeting held with the FDA's Division of Oncology Products 2 in December 2013. At the meeting FDA expressed willingness to work with Provectus toward initial approval for the novel investigational oncology drug PV-10 in locally advanced cutaneous melanoma. This included a statement in the minutes that data in a cohort of patients that received PV-10 to all existing lesions should be submitted in a formal BTD application."

Dees concluded, "We are confident that the studies done thus far illustrate the effectiveness and safety of PV-10: if you inject PV-10 into melanoma tumours, the tumours go away. For recurrent, aggressive skin cancers this unique mechanism confers tangible benefit to patients."

For further information visit [www.pvct.com](http://www.pvct.com)

## Faecal M2-PK – highly sensitive adenoma detection for improved bowel cancer screening

Faecal M2-PK detects colonic adenoma (polyps) in more than 2 1/2 times as many subjects as the faecal immunochemical test (FIT – OC Sensor), according to a major study from Dublin\*. Invitations went to 1800 asymptomatic 50 to 74 year old residents, and both M2-PK and FIT (only a single sample was required for M2-PK, but two samples for FIT) were tested in nearly 1000 subjects to screen for colorectal cancer.

Only 23 subjects were "double positive", reflecting the different principles behind the tests. Raised faecal M2-PK concentrations result from a switch in glucose metabolism, whereas FIT detects blood in the stool.

Importantly, in 186 patients who proceeded



to colonoscopy, adenoma were detected in 40 (of 157) patients with raised faecal M2-PK (M2-PK > 4 U/ml), but in only 15 (of 51) FIT-positive patients (one or both FIT sample > 100ng/Hb/ml). Fifty patients had adenoma if either faecal M2-PK or FIT was elevated.

This far greater sensitivity of faecal M2-PK for detecting polyps (using only a single sample) is of great importance considering that polyp detection and removal is a primary goal in bowel cancer screening and prevention.

\*Leen R et al. Eur J Gastroenterol Hepatol 2014; 26: 514 – 518.

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