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

Provectus Biopharmaceuticals establishes Australian subsidiary

Provectus Biopharmaceuticals, Inc have formed an Australian subsidiary, Provectus Biopharmaceuticals Australia Pty Ltd. In addition, the Company is opening a Sydney office in New South Wales.

Peter Culpepper, Interim CEO, stated, "The creation of an Australian entity is a fundamental part of our plans for extended global reach in conjunction with planned partnering for commercialisation of PV-10."

He noted, "Provectus has already been very active in Australia for years because of our research into PV-10 as an investigational treatment for melanoma. In fact, we began our phase 1 study of PV-10 in 2005 at the Sydney Melanoma Unit in North Sydney and the Newcastle Melanoma Unit in Waratah, both in New South Wales. Since then, we

have also worked with the Princess Alexandra Hospital in Brisbane, Queensland, the Royal Adelaide Hospital in Adelaide, South Australia, and the Peter MacCallum Cancer Centre in Melbourne, Victoria."

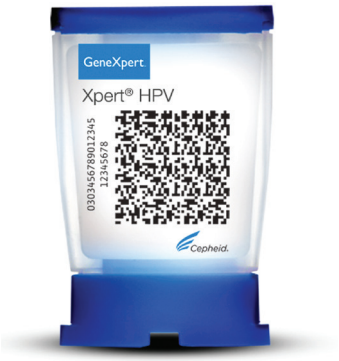
Culpepper concluded, "With a subsidiary in Australia, we are bringing our corporate structure in line with our scientific work. Our research and development program has been international from the very beginning, and now, Provectus is an international company. The new unit should make it easier to work with the Australian regulatory authorities, and having an office in the region may facilitate our work in Asian markets as Sydney is just two hours ahead of Beijing, Honk Kong and Singapore. If and when PV-10 receives approval in Australia and other nations in the region, we will have pre-positioned ourselves to develop a sales and marketing force."

For further information visit: www.provectusbio.com

Cepheid announces results of validation study for use of Xpert HPV In primary cervical cancer screening

Cepheid announced the publication of a validation study assessing the use of Xpert HPV (Human Papillomavirus) as a front-line cervical screening test in certain countries outside the United States. "Performance of a cartridge based assay for the detection of clinically significant HPV infection – lessons from VALGENT (Validation of HPV Genotyping Tests)" has been published on the *Journal of Clinical Microbiology* website, concluding that "the clinical performance and reproducibility of Xpert is comparable to well established HPV assays and fulfils the criteria for use in primary cervical cancer screening."

"In two years, we have seen at least four



European countries – including England – initiate plans to move to front-line HPV testing as a screen for cervical cancer," said John Bishop, Cepheid's Chairman and Chief Executive Officer. "As shown in large European studies, HPV as a front-line screening test is demonstrably more effective than cytology in identifying women at risk for cervical pre-cancer or cancer."

"Xpert HPV has performance highly comparable to established and validated assays, and can now be added to the list of tests validated for primary cervical cancer screening," said Jack Cuzick, PhD, FRS, Head of the Centre for Cancer Prevention. "It is an easy to use test that reports individual high risk HPV results in less than one hour."

For further information visit: www.cepheid.com

Mount Vernon Cancer Centre puts patient comfort at the forefront of its breast oncology service

Mount Vernon Cancer Centre, part of East and North Hertfordshire NHS Trust, has recently upgraded its range of breast boards to improve patient comfort and optimise clinical efficiency. The centre's Radiotherapy Department, which treats over 4,200 patients a year, has already received positive feedback following the purchase of 11 MacroMedics® BreastBoard LX™ units from Oncology Systems Limited (OSL). The easily adjustable and lightweight boards will enable reproducible day-to-day patient setup, creating time efficiencies when used in conjunction with CT and linear accelerator systems.

"Our previous breast boards were becoming outdated so we sought to replace them with a modern alternative that would support departmental efficiencies, states Oliver Shoffren, Superintendent Radiographer at Mount Vernon Cancer Centre. We trialled a number of boards looking at criteria such as weight, storage and size for manageability, the design for patient comfort and the cost-effectiveness. The MacroMedics BreastBoard LX came out on top, and the service provided by Oncology Systems Limited helped to ensure a smooth transition from old to new."

For more information on the BreastBoard LX, see the Oncology Systems Limited website or E: enquiry@osl.uk.com

Picture caption: Left to right: Mark Kpatakpa, Student at University of Hertfordshire; Elaine Dancer, Superintendent Radiographer; Leila Begum, Senior Radiographer; Oliver Shoffren, Superintendent Radiographer at Mount Vernon Cancer Centre and Serafine O'Brien, Territory Manager at Oncology Systems Limited.

Almac publish second validation of Stage II colon Cancer Recurrence Assay in the Journal of Clinical Oncology

Almac Group's Diagnostics business unit announced the publication of the second validation study of their stage II colon cancer recurrence signature ColDx in the Journal of Clinical Oncology (JCO).

The publication entitled 'Association Between Results of a Gene Expression Signature Assay and Recurrence-Free Interval in Patients With Stage II Colon Cancer in Cancer and Leukemia Group B 9581 (Alliance)' demonstrates that the ColDx assay is a significant, independent predictor of Recurrence-Free Interval (RFI) in stage II colon cancer therefore indicating it's potential utility with the traditional clinical markers of risk to refine patient prognosis.

The study was performed in conjunction with the Alliance for Clinical Trials in Oncology. This large, independent clinical validation study utilised data from 393 stage II colon cancer patients enrolled in the phase III CALGB (Alliance) 9581 clinical trial to assess the ability of the prognostic, 634-probe gene expression signature (ColDx) to improve upon current methods of differentiating patients as higher versus lower risk of recurrence within five years post-surgery. The signature remained significant after adjustment for conventional prognostic risk factors, including micro-satellite instability (MSI), T-stage and number of nodes examined.

The ColDx assay has been out-licensed and is currently being marketed by Helomics® Corporation under the name GeneFx® Colon in the United States.

For further information visit:
www.almacgroup.com or
E: media@almacgroup.com

medac launches Spectrila®, a recombinant E.coli asparaginase for the treatment of acute lymphoblastic leukaemia

Spectrila® 10,000 U powder for concentrate for solution for infusion.

This innovative drug is bioequivalent to reference E.coli asparaginase and therefore a safe and effective replacement in treatment protocols. Produced in a state-of-the-art production process, Spectrila® was developed to have a low content of protein aggregates. Associated with a considerably lower rate of allergic reactions, it promises a high compliance rate. Spectrila® is licensed for use as part of antineoplastic combination therapy to treat acute lymphoblastic leukaemia (ALL) in infants and adolescents (from birth to 18 years) as well as in adults [1].

Spectrila® 10,000 U powder for concentrate for solution is administered once every three days by intravenous infusion. The dosage depends on the patient's age or body surface area respectively.

With the EU-wide approval and a newly developed manufacturing process, medac is able to ensure a long term supply in the UK with this established therapeutic agent.

For further information on Spectrila®,
contact medac GmbH,
T: +44 (0)1786 458086,
E: info@medac-uk.co.uk
W: www.medacuk.com

Reference

1. medac Gesellschaft für klinische Spezialpräparate mbH, Summary of product characteristics Spectrila 10,000 U powder for concentrate for solution for infusion, Wedel January 2016

Provectus Biopharmaceuticals receives patent alowance for use of Halogenated Xanthenes in pharmaceutical compositions and as medicaments

Provectus Biopharmaceuticals, Inc. have received a Notice of Allowance from the U.S. Patent and Trademark Office covering additional aspects of its process for synthesising halogenated xanthenes, the family of compound to which rose bengal belongs. The allowed claims cover use of certain halogenated xanthenes in pharmaceutical compositions and as medicaments.

Peter Culpepper, Interim CEO of Provectus, remarked, "This patent allowance speaks to the first and second pillars in our value proposition: our intellectual property and our control of the drug supply chain. We have a robust portfolio of patents related to the production of PV-10, and this allowance extends the value of that to potential future products that build on the work we've put into PV-10."

Culpepper added, "Earlier this year, we received U.S. Patent No. 9,273,022, which extends the scope of protection of the manufacturing process conferred by our September 2013 patent to include coverage of the use of alternative raw material in manufacturing halogenated xanthenes, including rose bengal, the active pharmaceutical ingredient (API) in PV-10. That patent, which is wholly owned by Provectus and conferring coverage to at least 2031, provides further protection around our proposed commercial process for manufacturing PV-10. Investigational drug product generated using this proprietary technology is being used in all ongoing clinical trials of PV-10, including the pivotal phase 3 trial in melanoma (NCT02288897)."

For further information visit:
www.provectusbio.com

Varian Medical Systems selected to supply first modern radiotherapy systems in Ethiopia

Cancer patients in Ethiopia will gain access to modern radiotherapy treatments for the first time with the announcement that Varian Medical Systems has been selected to supply advanced medical linear accelerators to six hospitals in the country. The Clinac™ iX treatment systems will be the first such devices offering treatments to cancer patients in a country of 93 million people.

The first phase of a cancer plan being rolled out by the Ethiopian government will see Varian supplying the treatment systems to Ethiopian university hospitals in the cities of Harar, Mek'ele, Jima, Hawasa, Gondar, and the capital Addis Ababa. The first of these projects is intended to start offering clinical treatments by the end of this year. The order for the six treatment machines was received by Varian in June.

The Clinac iX systems will be capable of delivering fast and precise RapidArc® treatments with image-guidance tools on each system. Each site will have an Eclipse™ system for treatment planning and 3 ARIA® oncology information management workstations, and each hospital will have two radiotherapy

bunkers to enable future expansion. Varian and Elsmed, one of its local representatives, are also working with the Ethiopian government to establish clinical education and training resources in the country.

For further information contact:
Neil Madle, Varian Medical Systems,
T: +44 7786 526068
E: neil.madle@varian.com
W: www.varian.com

Pioneering research aims to end misery of cancer-induced bone pain

Researchers at the University of Oxford have launched a pioneering project to tackle crippling bone pain suffered by thousands of cancer patients.

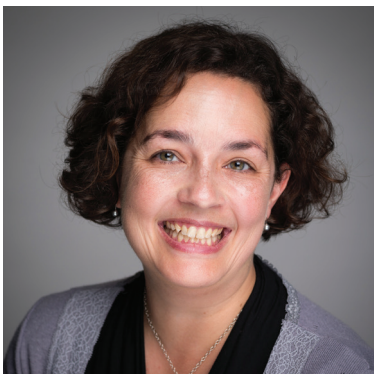
An estimated 30,000 people every year develop this cancer-induced pain linked to a destructive and hugely debilitating bone disease caused by their cancers.

It affects people with primary bone tumours, bone marrow cancers such as multiple myeloma and other forms, such as breast and prostate cancer, that commonly spread to bone.

Dr Claire Edwards, Associate Professor of Bone Oncology at the University of Oxford, is leading the research project, believed to be the first of its kind.

She said: "The major clinical feature of this cancer-induced bone disease is significant and life-altering bone pain but it's the thing that we understand least.

"We believe that tumour cells increase the expression of molecules that promote pain. Our goal is to identify and understand pain-related changes in patients with cancer-induced bone disease so that new approaches to target



Dr Claire Edwards Associate Professor of Bone Oncology at Oxford University

this pain can be developed."

The two-year Oxford project is being funded by Orthopaedic Research UK (ORUK), one of the country's leading charities working to improve the lives of people with bone and joint disease and injury.

For further information contact:
a.angadji@oruk.org or
visit www.oruk.org

Poster titled 'Intralesional Rose Bengal for Stage III and IV Melanoma' Congress scheduled to run October 7-11, 2016, Copenhagen, Denmark

Provectus Biopharmaceuticals, Inc. announced that the European Society for Medical Oncology's Scientific Committee has accepted an abstract for a poster presentation detailing the use of PV-10 as a treatment for stage III and IV melanoma as part of ESMO's 2016 Congress. The exact date and time of the presentation, titled 'Intralesional Rose Bengal for Stage III and IV Melanoma,' has yet to be decided. When the schedule is set, the details for this abstract, #3438, will be available at http://www.esmo.org/Conferences/ESMO-2016-Congress/Programme.

In addition, the abstract will also be published in the ESMO 2016 Congress Abstract Book, a supplement to the official ESMO journal, *Annals of Oncology*. ESMO has not yet announced the final publication number. The ESMO 2016 Congress will be held in Copenhagen, Denmark, from October 7-11, 2016.

For further information visit: www.provectusbio.com

PROVECTUS
BIOPHARMACEUTICALS, INC.

Provectus Biopharmaceuticals, Inc. receives patent from USPTO related to Rose Bengal Analogs

Provectus Biopharmaceuticals, Inc. has received a U.S. patent covering additional aspects of its process for synthesising halogenated xanthenes, the family of compound to which rose bengal belongs. The patent covers use of certain halogenated xanthenes in pharmaceutical compositions and as medicaments.

Eric Wachter, CTO of Provectus, noted, "U.S. Patent No. 9,422,260 covers claims that we announced in mid-July had been allowed by the U.S. Patent and Trademark Office. It covers subject matter included in the original, 'parent' case that led to issuance of U.S. Patent 8,530,675 in September 2013, covering our novel process for synthesising rose bengal and related analogs. This 'daughter' patent extends protection to use of a wide range of those analogs in or as therapeutic products, and provides complementary protection to that afforded by the parent patent."

Wachter added, "The daughter patent provides a significant potential commercial lifetime for these analogs. Along with U.S. Patent No. 9,273,022, issued earlier this year and also derived from the original parent case, the new patent expands our ability to control the supply chain for rose bengal and related analogs for use in PV-10, PH-10 and possible successor products."

For further information visit:
http://www.provectusbio.com/news/press-releases/provectus-pr-20160823-1

PROVECTUS
BIOPHARMACEUTICALS, INC.