

IZB to complete new building in September

We present a round-up of recent news from IZB companies including a report on IZB's own expansion plans with a new building scheduled for completion in September of this year.

Since 1995, The Innovation and Startup Centers for Biotechnology (IZB), based in Planegg-Martinsried and Freising-Weihestephan near Munich, Germany, has offered young biotech start-ups an optimal building infrastructure at two top locations for biotechnology in Europe. The goal of the Centers is to promote the commercialisation of medical products and services. In IZB Martinsried the focus is on medical biotechnology. The main emphasis of IZB Weihestephan is on new methods for drug development and production, environmental science and the agriculture and food sector. IZB offers premium premises and equipped labs specially designed for the needs of young biotech start-up companies.

IZB is set to complete its new building 'West 2' with a further 3,200 sq m of facilities in September this year. The space is now fully booked by IZB firms that needed room for expansion, namely Menlosystems and Bio-M Cluster Development GmbH.

Also from September 2010, the training of biotechnical assistants (BTAs) from the Dr. Erwin Elhardt School of Chemistry will be transferred to the new IZB building, where modern laboratories with state-of-the-art equipment, tailor-made for this training, are available. A major advantage of this development is that practical and theoretical instruction can be given in close proximity to the numerous life science companies located at the Center.

The Dr. Erwin Elhardt School of Chemistry, located in IZB's training centre for chemistry, biology and the environment, is the oldest private school in Munich with more than 120 years of experience in the area of scientific and technology training. State-approved chemical-technical assistants (CTAs), biotechnical assistants (BTAs) and chemical technicians are trained at the School.

IZB has now grown to a total of 25,000 sq m of lab and office space for young biotech start-ups! With the new building, IZB has new scope for establishing new start-ups on its premises and to meet requirements of new IZB firms for more space.

LEUKOCARE relocates to Martinsried

The latest company to relocate its



IZB Martinsried West 2 building: completion due in September

headquarters and R&D facilities to the IZB in Martinsried near Munich, Germany is LEUKOCARE, a privately owned, product-focused, clinical-stage biotechnology company founded in 2003. LEUKOCARE develops innovative life science technologies in the fields of biopharmaceuticals, drug device combination products, biochemical research products and diagnostic assays.

LEUKOCARE's Stabilizing and Protecting Solution (SPS) allows the extension of the shelf life of biologics in a dehydrated state and the retention of functionality during sterilisation by gamma-, beta-radiation or ethylene oxide. The company's technologies thus enable the design of a new range of products that would not be amenable otherwise, reduce costs, simplify production, and ease regulatory issues.

LEUKOCARE also has expertise in functionalising a wide variety of surfaces including implant surfaces, wound dressings, patches, stents, catheters, columns for *ex-vivo* blood treatment and others. The company offers collaborative research and development services with biological and chemical lab capacity to partners related to its core competences. Its portfolio of patented technologies is available for purchase, licensing or collaborative product development customising the SPS technologies to the requirements of partners.

In order to ensure both consistent high

quality of its products and services and to comply with ISO standards, LEUKOCARE implemented a Quality Management System and is certified according to DIN EN ISO 9001:2008 and DIN EN ISO 13485:2003.

Helmholtz Zentrum München and SIRION BIOTECH collaboration

Helmholtz Zentrum München has launched a new co-operative project with SIRION BIOTECH GmbH in Martinsried to develop new therapeutic approaches against lymphoid tumours. With a two-year grant of about €500,000 from the Federal Ministry for Economics and Technology, the two partners will seek to further develop lentiviral vector systems to better understand the disease mechanisms of this cancer form and to devise new treatments.

The future of gene therapy approaches in cancer treatment is especially dependent on the quality of the vectors involved in the regulation of gene expression in the tumour cells. Lentiviruses are a very promising vector system for this, as they even reach difficult-to-access cell types such as the hematopoietic cells in the blood-forming system.

In this new research co-operation, Helmholtz Zentrum München and SIRION BIOTECH will look to optimise the use of lentiviruses as gene vectors for hematopoietic

cells. Over the long term this may result in an important step forward in the therapy of malignant lymphomas.

"We quite consciously decided on a cooperation partner from the biotech sector," said Professor Günther Wess, scientific-technical director of Helmholtz Zentrum München. "The symbiosis of our scientific expertise in the field of lentiviruses with the technical know-how of SIRION BIOTECH promises to yield valuable insights about the molecular disease mechanisms and the function of disease-relevant genes in blood cells."

Pieris initiates Phase 1 clinical trial for lead Anticalin compound

Pieris AG has initiated a Phase 1 clinical trial in cancer patients for its lead programme, PRS-050, an anti-VEGF Anticalin. The trial is an open-label, dose-escalating evaluation of the compound's safety and tolerability in patients with solid tumours. Conducted at three sites in Germany, the trial is now underway and patients from the first cohort have been dosed.

"Meeting our goal of initiating this trial in the first half of 2010 demonstrates Pieris' commitment to establishing the safety and the therapeutic relevance of the Anticalin drug class," stated Stephen Yoder, CEO of Pieris. "Further, the high potency observed in preclinical studies, together with the small size and the lack of an antibody Fc domain, show promise of an attractive combined efficacy and safety profile for PRS-050."

The trial is designed to test PRS-050 in about 40 patients, who will receive the compound and then be monitored for safety and tolerability. The patients recruited for the trial are cancer patients with advanced, recurrent or metastatic solid tumours, refractory to standard therapy.

Pieris AG is an independent biotechnology company advancing its proprietary Anticalin technology to create safer, more efficacious and more convenient protein therapeutics. Exclusive to Pieris, Anticalin-based drugs promise to address high unmet medical needs. The company's pipeline ranges from its lead clinical programme (anti-VEGF, oncology), to multiple Anticalins in preclinical development. Pieris plans to commercialise Anticalin therapeutics through strategic partnerships, involving both its proprietary pipeline and its *de novo* drug discovery capabilities. Its most recent partnership is with Allergan, Inc, focusing on novel treatments for eye diseases.

Pieris is a privately held company funded by biotechn-focused venture capital, including lead investors OrbiMed Advisors and Global Life Science Ventures.

4SC presents Q1 2010 results

Martinsried-based 4SC AG, a drug discovery and development company focused on autoimmune and cancer indications, has presented its financial results for the quarter ended March 31, 2010. Highlights for the period included the commencement of a Phase 2 study to assess the efficacy of resminostat in Hodgkin's lymphoma, as well as the start of two Phase 1 studies with the multi-kinase inhibitor 4SC-203 and the Eg5 Inhibitor 4SC-205. The company also selected colon cancer as the third indication for resminostat, and has initiated preparations for a Phase 1/2 study in combination with a standard chemotherapy (FOLFIRI-regimen).

In Q1 2010, 4SC generated revenue of €300,000 from research collaborations, down from €500,000 for the same period in 2009. Total operating expenses came to €5.6 million, compared with €4.4 million in the prior-year quarter. This rise is largely attributable to an increase in research and development costs of about one-third to €4.5 million, which in turn was primarily due to the continued development of 4SC's product pipeline and the doubling of the number of ongoing clinical studies from three in the first quarter of 2009 to six at present.

The decline in revenue coupled with higher expenses yielded an operating loss of €5.3 million for the period from January to March 2010, contrasting with a loss of €3.9 million in the prior-year period. As anticipated, the net loss for the period rose to €5.3 million, up from €3.7 million in the first quarter of 2009. However, earnings per share remained virtually unchanged on the prior-year figure of €-0.13. Funds totalled €31.0 million as at March 31, 2010.

4SC's portfolio currently comprises a total of four drugs in six clinical studies as well as two further drug candidates in preclinical development. Several of these drug products will reach key milestones in the short to medium term. Vidofludimus is due to report results for the Phase 2a study in inflammatory bowel disease (IBD) in the second half of 2010. Results from the Phase 2b study in rheumatoid arthritis are expected at the end of 2010. Phase 1 results for the compound 4SC-203 are also expected towards the end of 2010. The Phase 2 trials in HCC and HL with resminostat will continue to advance in 2010 and are expected to yield value-enhancing clinical results in 2011, as for 4SC-205. In addition, the launch of the colon cancer study with resminostat and the preparation of 4SC-202 for clinical development will enhance the sustainability of the company's product pipeline in the next twelve months.



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