BIOTECH NEWS Joint BIA/ABPI taskforce on TGN1412

A joint taskforce has been set up by the Biolndustry Association (BIA) and the Association of the British Pharmaceutical Industry (ABPI) in the UK to provide industry input to the expert working group set up to learn from the TGN1412 clinical trial adverse events that occurred earlier this year.

The taskforce is co-chaired by Dr David Chiswell and Sir Colin Dollery, with its membership consisting of bioscience and pharmaceutical industry experts in fields such as immunology, biopharmaceutical development and clinical trials. It will offer input in the areas to be considered by Professor Gordon Duff's expert group, which is reviewing early-stage clinical trial design with specific reference to biological molecules with novel modes of action; new agents with a highly species-specific action; and new drugs directed towards immune system targets.

Aisling Burnand, chief executive of the BIA, commented: "As a responsible industry we have brought together this group of world-class individuals with significant experience in the clinical development of innovative medicines. We look forward to sharing this expertise with Professor Duff and his group to ensure the highest possible standards of patient and volunteer safety."

Dr Richard Barker, director general of the ABPI added: "Safety is at the forefront of all that we do, and it is imperative to examine carefully every aspect of the clinical development of ground-breaking medicines that work in a novel way related to that at the centre of this incident. We must do everything possible to prevent such an event ever again occurring without unnecessarily complicating a well-established procedure for testing the broad range of new medicines."

EU marketing authorisation for biosimilar human growth hormone

Cambridge Laboratories has received marketing authorisation for the European Union from the European Medicines Agency's Committee on Medicinal Products for Human Use (CHMP) for its biosimilar medicinal product, Valtropin®. The product is a recombinant human growth hormone for the treatment of growth deficiency in children, for which Cambridge Laboratories owns the UK rights. Valtropin was licensed from Biopartners, the private Swiss biopharmaceuticals company that owns the global rights to the product and is one of the first biosimilar products to be granted EU marketing authorisation.

AstraZeneca invests \$100 million in R&D in China

AstraZeneca is to invest \$100 million in R&D in China over the next three years, focusing on the benefit and value of innovative medicines for Chinese patients. The prime focus of the programme will be the establishment of the AstraZeneca Innovation Centre China. The company has initiated a comprehensive search for an appropriate location for the Innovation Centre, which will be operational by the end of 2009. The Centre will focus on translational science by developing knowledge about Chinese patients, biomarkers and genetics. The initial therapeutic area for the Innovation Centre will be cancer, which is a major cause of death in China.

In addition, AstraZeneca will expand its clinical research

capabilities and is looking this year to increase the number of scientific collaborations with local Chinese organisations. AstraZeneca recently signed a deal worth \$14 million with Wuxi Pharmatech for Compound Collection Synthesis and has an existing collaboration with Shanghai Jiao Tong University on the genetics of schizophrenia.

"With China's rapid economic growth and increasing demand for better health care, China has become one of the most important emerging markets for AstraZeneca and will be important to our future success," said David Brennan, CEO of AstraZeneca PLC. "We fully support China's national focus on innovation by substantially increasing our R&D investment, both in



AstraZeneca's Brennan: fully supporting Chinese focus on innovation.

financial terms and in terms of scientific collaboration.

"AstraZeneca welcomes and supports the Chinese government's continuing policy to recognise investment in knowledge transfer and R&D innovation by strengthening IP protection, and ensuring timely market access for Chinese patients to innovative products, at prices which recognise the value of innovation."

Phico Therapeutics and Angel Biotechnology process scale-up contract

Biopharmaceutical contract manufacturer Angel Biotechnology Holdings plc and Phico Therapeutics Ltd, an early-stage biotech company developing a novel antibacterial platform technology, have signed process scale-up and GMP contracts under which Angel will evaluate and scale up processes utilising Phico's novel methodology to manufacture Phico's therapeutic antibiotic products.

The technology utilises a broad-spectrum antibiotic protein coupled with a delivery system that can be programmed to target any selected harmful bacteria. Products currently in

development are aimed at Staphylococcus aureus, including MRSA, and Clostridium difficile. The developmental programme is expected will lead to the GMP manufacturing of Phico's first product, which is designed to eliminate nasal carriage of Staphylococcus aureus, including MRSA.

BioFine USA conference programme nears completion

The inaugural BioFine USA event takes place at the Town and Country Resort & Convention Center, San Diego, USA on September 7-8, 2006. This new networking event for companies offering products and services to the life sciences sector features two conferences in conjunction with the exhibition, and will attract key executives from pharma, biopharma and biotech companies. The two conferences are MedChem USA, organised by Scientific Update, and

Biotech for Small-Molecule Therapeutics, organised by avakado Conferences. There are also workshops on Drug Metabolism and hERG. The programme for the Biotech for Small-Molecule Therapeutics conference is almost complete, and includes presentions from Cylene Pharmaceuticals; TargeGen, Inc; Immusol, Inc; La Jolla Pharmaceutical Company; AndroScience Corporation; Merck Research Laboratories; Pharmatek Laboratories, Inc;



BioCatalytics, Inc; Ingenza Ltd, Hovione and Excelsyn. Companies wishing to present a paper should contact Tom Mulligan on Tel: +44-1403-220755. Email: tom@sp2.uk.com

Attendees can use
Eventscope software to prearrange meetings with
delegates, exhibitors and
visitors attending BioFine
USA. For further
information and FREE
visitor registration visit the
website
www.biofineusa.com



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Clinical Statistics for Nonstatisticians Training Course

Renaissance Amsterdam Hotel, THE NETHERLANDS

EudraVigilance Training Course (EV)

August 23-25, ID 06518 November 8-10, ID 06523 September 13-15, ID 06519 December 13-15, ID 06525 October 4-6, ID 06521

EMEA, London, UK

For local EV training courses, please contact tatjana.topalovic@diaeurope.org

EudraVigilance Medicinal Product Dictionary (EVMPD)

Aug 22, ID 06517 October 3, ID 06520 December 12, ID 06524 EMEA, London, UK

European Regulatory Affairs Training Course

Renaissance Amsterdam Hotel, THE NETHERLANDS

Medical Approach in Diagnosis and Management of ADRs Training Course

Hotel Sofitel Paris Forum Rive Gauche, FRANCE

Clinical Trial Directive

September 28-29, ID 06110 Scandic Hotel Copenhagen, DENMARK

Pharma Legislation

September 28-29, ID 06111
Scandic Hotel Copenhagen, DENMARK

Statistical Methodology in Clinical R&D Conference and Exhibition

October 4-6, ID 06102
Heidelberg Marriott Hotel, GERMANY

Practical GCP Compliance Auditing of Trials & Systems Training Course

Hotel Copthorne Tara, London, UNITED KINGDOM

Clinical Statistics for Nonstatisticians Training Course

Prague Renaissance Hotel, CZECH REPUBLIC

US Regulatory Affairs Training Course October 23-26, ID 06526

Hotel Crowne Plaza, Amsterdam, THE NETHERLANDS

Pharmacovigilance / Risk Management Conference and Exhibition

November 2-3, ID 06113

Hotel Sofitel Paris Forum Rive Gauche, FRANCE

Multi-Track Conference and Exhibition: "The Changing World of Clinical Trials" 16th Annual European Clinical Data Management European eClinical

European Clinical Research Conference

Congress Centre Basel, SWITZERLAND

7th Middle East Regulatory Conference (MERC)

November 14-16, ID 06104
JW Marriott Hotel, Dubai, UNITED ARAB EMIRATES

European Regulatory Affairs Training Course

November 27-28, ID 06505
Renaissance Paris Hotel La Défense, FRANCE

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Pharmacovigilance Training Course November 27-Dec 1, ID 06537

Renaissance Paris Hotel La Défense, FRANCE

Cardiac Safety Conference

December 4-5, ID 06116 Maritim Hotel, Berlin, GERMANY

Electronic Document Management (EDM)

December 4-5, ID 06114 Maritim Hotel, Berlin, GERMANY

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BIOTECH NEWS Sigma-Aldrich and Rosetta Inpharmatics establish siRNA design partnership

Sigma-Aldrich has entered into an exclusive arrangement to access Rosetta Inpharmatics' bioinformatics design tools for siRNA research and development purposes. The licence agreement will provide RNAi researchers with cuttingedge siRNA design technology for enhanced performance through improved specificity and silencing. Sigma- Aldrich plans to utilise the design technology to launch human and model organism siRNA whole genome libraries, to deliver siRNA panels targeted to specific gene families, and to provide access to single-target pre-designed siRNAs through an enhanced web interface on Sigma-Aldrich's website. Researchers will have access to products that will be manufactured worldwide by the Sigma Genosys and Proligo operations.

Applied Biosystems and SAIC-Frederick collaborate on cancer biomarkers research

Applied Biosystems has entered into a collaboration with the Core Genotyping Facility, SAIC-Frederick, Inc on a series of biomarker studies for cancer research. The US National Cancer Institute-funded Core Genotyping Facility will use Applied Biosystems' entire TaqMan® Drug Metabolism Genotyping Assay collection to examine genetic variations in the HapMap and SNP500Cancer samples in order to validate additional cancer biomarkers.

In support of the NCI, the Core
Genotyping Facility is using more than
2,400 TaqMan Drug Metabolism
Genotyping Assays to generate the
genotypes for samples from the
International HapMap Project and from the
NCI's SNP500Cancer standard sample
panel. In addition, select assays with
significant correlation from data analysis
will be used to genotype individuals who
participated in a pharmacogenetic study at
the NCI evaluating treatment for nonHodgkin lymphoma.

"The objective of this study is to better understand the genetic differences associated with individual responses to cancer treatment," said Dennis A. Gilbert, PhD, chief scientific officer of Applied Biosystems. "Because our TaqMan Drug Metabolism Genotyping Assays were developed using extensive computational analysis in combination with assay optimisation and validation that identified novel and well-known gene variants, we believe they represent the most complete set of drug metabolism assays available to the scientific research community."

Clariant sells Pharmaceutical Fine Chemicals to TowerBrook Capital Partners

Clariant has announced the sale of its Pharmaceutical Fine Chemicals unit to TowerBrook Capital Partners, LP for a transaction value of about SFr110 million. The company said the sale marks a further step in its strategy to focus its portfolio on core activities. TowerBrook Capital Partners, LP is a private equity firm with more than \$2.5 billion under management. The firm has offices in London and New York and focuses on making investments in European and North American companies.

The Pharmaceutical Fine Chemicals unit manufactures

building blocks, regulatory starting materials, intermediates and active pharmaceutical ingredients (APIs) for both the innovative and the generic pharmaceutical industry. The new autonomous entity will be one of the world's largest businesses based solely on pharmaceutical fine chemicals, with 2005 sales of around SFr210 million and employing about 800 people. It will operate all manufacturing sites of Clariant Pharmaceutical Fine Chemicals and will be headquartered in Frankfurt am Main, Germany.

Jan Secher, Clariant's chief executive, said: "The Pharmaceutical Fine Chemicals business sharpened its strategy and improved its efficiency, enabling it to become one of the industry's leading suppliers. As an independent entity supported by a committed investor, it has an excellent opportunity to perform well in the future.

another important step in focusing our business portfolio on innovative applications with value-increasing service components."

On the Clariant side, this is

Activotec completes funding round

UK chemistry and biochemistry services company Activotec has completed a major funding round which it says will enable it to accelerate its growth. The company has its trading base in Cambridge and an R&D and production facility in Southampton, and was founded in 2002 as a spin-out from the University of Southampton. Activotec provides high-technology products and services for chemistry and biochemistry applications including a range of products and services for



Activotec: new funding for chemistry and biochemistry services.

peptide and protein synthesis. The funding was raised through a syndicate mainly composed of private investors. Activotec chief executive, Chris Littlewood, commented: "The funds will be invested in further research and

development while expanding our current business. This will assist us in our dual strategy of creating and licensing technology to drug developers while also quickly growing our custom peptide and synthesiser sales."

EU marketing authorisation for biosimilar human growth hormone

Biopartners has received marketing authorisation for the European Union from the European Commission for its biosimilar medicinal product Valtropin, a recombinant human growth hormone used for the treatment of human growth deficiency in children and Turner's Syndrome. This product is only the second biosimilar to receive EU marketing authorisation. Biopartners, jointly with LG Life Sciences, has

co-developed a number of biopharmaceutical products including Valtropin and a sustained release formulation of Valtropin. The company inlicensed Valtropin from LG Life Sciences and has commercialisation rights for the product in Europe, Japan and other parts of Asia. Biopartners is currently developing a sustained release version of Valtropin which is currently in Phase III clinical trials.

"We are delighted to have gained EU marketing authorisation for Valtropin," said Jean-Noël Treilles, CEO of Biopartners. "As the first product in our broad and advanced pipeline to gain authorisation, this marks a major milestone for Biopartners.

"We aim to make Valtropin available to health care professionals and patients through our distributors before the end of the year."

3

Thermo Electron and Fisher Scientific in reverse merger deal

Thermo Electron Corporation and Fisher Scientific International Inc have agreed to combine the two companies in a tax-free, stock-for-stock exchange. The new company will be named Thermo Fisher Scientific Inc and is expected to have 2007 revenues of more than \$9 billion. Thermo and Fisher have complementary technology in instrumentation, life science consumables, software and

services. Under the terms of the agreement, Fisher shareholders will receive two shares of Thermo common stock for each share of Fisher common stock they own. Upon completion of the transaction, Thermo's shareholders would own about 39 per cent of the combined company, and Fisher shareholders would own approximately 61 percent. The transaction will be treated as a reverse merger with Thermo as the acquirer.

Marijn E. Dekkers, president and chief executive officer of Thermo, will become president and chief executive officer of the combined company, and Paul M. Meister, vice chairman of the board for Fisher, will become chairman of the board of the combined company. Following the close of the transaction, Paul M. Montrone, chairman and chief executive

officer of Fisher, will be stepping aside in support of the new management team. He will be concentrating on launching new business opportunities and will remain an adviser to the company. Jim P. Manzi, chairman of the board of Thermo, will serve on the board of directors of the combined company. Thermo Fisher Scientific's board of directors will be comprised of eight members, with five nominated by Thermo and three nominated by Fisher.

Sigma-Aldrich establishes RNAi Partnership Program to advance functional genomics

Sigma-Aldrich, a leader in RNAi and functional genomics, and a member of The RNAi Consortium (TRC), has established a worldwide RNAi Partnership Program with select academic institutions to advance functional genomics research. Scientists from participating organisations will benefit from access to a broad portfolio of intellectual property, early access to emerging new technologies, and special partnership pricing on Sigma's range of functional genomics and RNAi products.

Researchers at participating institutions will have early access to new technologies that are developed through Sigma-Aldrich's collaborations with TRC, Oxford BioMedica and Benitec. The partnership programme will also facilitate collaborations with scientists at Sigma-Aldrich to validate current and emerging RNAi technologies.

Programme participants will also benefit from a dedicated support team on Sigma's functional genomics product portfolio. This extensive product offering includes the Lentivirus-based MISSION™ TRC shRNA libraries, targeting more than 15,000 human and mouse genes, activated lentiviral particles, custom siRNA, and qPCR reagents.



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EVENTS

(Events organisers' contact details on page 12)

June 21-23, 2006 APIs EUROPE

Spazio Villa Erba, Como, Italy Organiser: CPA

June 26-27, 2006 Clinical Trials in Cancer

Holiday Inn Bloomsbury, London, UK Organiser: SMi

July 17-19, 2006 Organic Process Research and Development

Vancouver, Canada Organiser: Scientific Update

August 26-27, 2006 Microwave-Assisted Organic Synthesis

Budapest, Hungary Organiser: Karl-Franzens University, Graz and Eotvos Lorand University, Budapest

September 7-8, 2006 *BioFine USA*

Town and Country Resort & Convention Center, San Diego, USA Organiser: avakado

September 7-8, 2006 Biotech for Small-Molecule Therapeutics

Town and Country Resort & Convention Center, San Diego, USA Organiser: avakado

September 7-8, 2006 MedChem USA

Town and Country Resort & Convention Center, San Diego, USA Organiser: Scientific Update

September 17-21, 2006 Society for Biomolecular Sciences Annual Conference and Exhibition

Washington Convention & Trade Center, Seattle, Washington, USA Organiser: Society for Biomolecular Sciences

October 3-5, 2006 CPhI Worldwide

Paris-Nord Villepinte, Paris, France Organiser: CMP Information

October 5-6, 2006 cGMP: Current Good Manufacturing Practices

The Loews Philadelphia Hotel, Philadelphia, IISA

Organiser: Cambridge Healthtech Insitute

More events on page 12

Gene Logic and Organon collaborate on new pharma applications

Gene Logic Inc and Organon have entered into a drug repositioning agreement to seek alternative development paths for multiple drug candidates for which Organon previously discontinued clinical development. Gene Logic will investigate new therapeutic uses for the compounds and upon discovery of potential new therapeutic utility for a

drug candidate both companies will become equal owners and may decide to jointly develop and commercialise the product. Gene Logic will receive a success-based milestone payment for each therapeutic candidate that Organon chooses to enter into clinical development.

David Nicholson, executive

vice president of global research & development at Organon commented: "We believe Gene Logic's programme has the potential to find new value in our previously deprioritised drug candidates. Organon continues to seek new technologies to increase our drug research output. This technology is an opportunity to address that."

Diatos acquires cancer product from Gilead Sciences

Diatos SA, a biopharmaceutical company focusing on the research, development and commercialisation of targeted anti-cancer therapies, has formed an exclusive licensing agreement with Gilead Sciences, Inc for the worldwide development and commercialisation rights to cancer product DaunoXome. The product is a marketed liposomal formulation of

daunorubicin, which has been approved for AIDS/HIV-related Kaposi's sarcoma and is sold by Gilead in more than 20 countries.

DaunoXome has also been evaluated in clinical studies for potential efficacy and safety in acute myeloid leukemia (AML). It is a widely used chemotherapeutic agent, principally in hematological malignancies. Gilead will receive upfront and milestone

payments of up to \$4.7 million, based on regulatory approval of new indications, and royalties on net sales. On the basis of data derived from DaunoXome's commercial use and from clinical studies in acute leukemic diseases, Diatos will seek approval from European regulatory authorities for the use of DaunoXome in acute leukemia. Diatos intends to continue to market DaunoXome for treatment of Kaposi's sarcoma in Europe and Brazil.

sanofi-aventis and partners in hepatotoxicity project

Aureus Pharma and ChemAxon have been awarded a European Eureka project along with pharmaceutical partner sanofi-aventis and academic partner Budapest University of Technology and Economics to build a new knowledge base related to hepatotoxicity. The KnowTox® project is also aimed at building a knowledge base of related predictive tools to extend the value of the system.

Drug-induced hepatotoxicity or liver damage/disease is a major concern during the drug

development process. Toxicity knowledge exists but data is scattered in numerous sources and cannot easily be accessed simultaneously. Having access to a knowledge database containing detailed biological and chemical data and associated analysis applications will lead to better use of available knowledge and time- and cost-saving during drug development.

In the project Aureus Pharma will provide its expertise in building chemical biology knowledge databases and sanofi-aventis will provide toxicological experts to validate the products. Software solution provider ChemAxon and **Budapest University of** Technology and Economics, which has expertise in chemical reaction modeling, will extend their software tools to deal with reactions and substrates involved in the metabolism of compounds and also develop predictive tools for hepatotoxicity. It is expected that the KnowTox Knowledge database and predictive tools will be commercially available upon completion of the project.

Vaccine technology patent for Allergy Therapeutics

Specialist pharmaceutical company Allergy Therapeutics plc has been granted a broad technology patent for the combination of MPL® with tyrosine and an antigen by the European Patent Office.

The patent covers 24

countries in Europe. The patent covers vaccine therapy for any bacterial or viral disease and uses an antigen derived from the target organism.

The technology may therefore be employed in the

anti-infective field, as a prophylactic or preventative vaccine. The patent also covers the use of this advanced adjuvant system in cancer immunotherapy in addition to bacterial and viral immunotherapy.



JUNE 2006 www.sp2.uk.com

Degussa presents chiral chemistry award



Professor Thorsten Bach: receives Degussa's chiral chemistry award.

Professor Thorsten Bach of the Technical University of Munich is this year's recipient of the Degussa Award for Chirality in Chemistry. Established in 2004, the Award recognises innovative work in chiral chemistry performed by a young chemist. Professor Bach has contributed widely to the chemistry of chiral molecules and has pioneered several new synthetic methods. The international jury, who together with Degussa scientists decided the recipient of the award, recognised the work he has done in the use of chiral catalysts, particularly in photochemical reactions. His work has led to new routes to molecules that are of interest to pharmaceutical companies. Bach studied at the University

of Heidelberg and received his PhD from the University of Marburg. After post-doctoral studies at Harvard University, he started his independent research at the University of Münster in 1992. He became Professor of Chemistry at the University of Marburg in 1997 and moved to his present position at the Technical University of Munich in 2000. The award has a value of €5,000 and was presented to Professor Bach at the Modern Synthetic Methods and Chiral Europe 2006 conference organised by Scientific Update and this year sponsored by Degussa Exclusive Synthesis & Catalysts.

CIA NEWS

CIA welcomes UK government momentum on energy

The CIA has welcomed a series of UK government announcements recognising the significance of security of energy supply and related price concerns in the country. Support from the Prime Minister, Tony Blair, for the renewal of the UK's nuclear generation capacity was especially welcomed; in an earlier announcement, the Secretary of State for Trade and Industry, Alistair Darling, appealed to planning authorities to be more mindful of the urgent national interest when considering applications for new gas storage facilities. He also announced the creation of a Business Energy Forum to address urgent concerns for the next

Stephen Elliott, Chief Executive at the CIA, commented:

"Secure, competitively priced energy supplies are vital to the future of chemical manufacturing in this country and we see nuclear energy as an essential component of a diversified, low-carbon energy supply mix for the long term future."

Turning to the more immediate issue of gas storage he added:

"As the UK's natural resources decline we are becoming more reliant on other sources of gas to meet our national needs. The CIA welcomes the considerable investment being undertaken to enable new supplies to reach our shores. However, last winter taught us that this import capacity is not always fully utilised. It is therefore essential that the UK rapidly increases its gas storage capabilities to ensure all demand, both domestic and industrial, can be met even when import flows to the UK are restricted."

The CIA has also welcomed the decision by the electricity and gas markets regulator Ofgem to implement energywatch's network code modification to release close to near real time flow information.

The CIA said it agreed with Ofgem that a central foundation of any competitive market is information provision, and that the implementation of this modification represented an important development in the IIK market

Alan Eastwood, Head of Competitiveness and Utilities at the CIA, said:

"We recognise the leading role the UK, Ofgem and North Sea producers have taken within Europe in data provision and we believe that this modification represents an important step for the UK along the road to transparency. We now look to Ofgem to ensure that the light is turned on in Europe."

MorphoSys and Schering-Plough in R&D agreement

MorphoSys AG has signed an initial two-year licence agreement with Schering-Plough Corporation for the use of MorphoSys's HuCAL GOLD® technology in the research and development of human therapeutic antibodies. MorphoSys has granted access to its proprietary antibody library to Schering-Plough for use in its drug discovery programmes at one research site. The contract also provides

Schering-Plough with the option to develop HuCAL-derived therapeutic antibodies against up to ten disease-related targets. During the initial two-year term of the agreement, which also provides Schering-Plough with the option of an extension of up to three more years, MorphoSys's HuCAL GOLD® antibody library will be installed at Schering-Plough's research site in Palo Alto, California, the location of

Schering-Plough Biopharma. "The agreement signed today is our twelfth with a top 20 pharmaceutical company," commented Dr Simon Moroney, chief executive officer of MorphoSys. "This deal marks further progress in the successful execution of our strategy to strengthen the pipeline of therapeutic antibodies based on our proprietary technology through strategic deals with quality partners."

Optima Procurement Solutions launches on-line pharma outsourcing service

Optima Procurement Solutions has launched its OptimaCRO on-line resource for the pharmaceutical, fine chemical and biotechnology industries, designed as a single point of reference for biopharmaceutical outsourcing on a global scale.

The dedicated and secure portal enables worldwide procurement of services for the industry.

Biopharmaceutical clients can control either global 'sealed bid' events, or a reverse auction system, and can drastically improve efficiency and cost-savings in securing their outsourcing needs. Companies will have free access to information provided by contract research organisations (CROs), identifying those that can best serve their needs in Europe, the Americas or Asia.

Dr Steve Allin, outsourcing advisor to OPS, and a founder of UK-based research services company Charnwood Molecular Ltd, commented:

"With OptimaCRO, our biopharma partners can develop their own unique list of preferred CRO suppliers that will have on-line access to individual project descriptions offered for tender, thereby opening up a project to only a handful of CROs, or potentially to the entire global CRO community. We can protect the identity of our biopharma client, so that bids received for projects will be blind and therefore an open and fair reflection of the current market. Alternatively, rather than an acting as a global marketplace, we can customise our unique software to form a bespoke, in-house system for individual companies, should that be preferred."

See www.optimacro.com

www.sp2.uk.com

EVENTS

November 16-17, 2006 NanoBiotech World Congress Boston, USA

Organiser: Select Conferences

December 1-3, 2006 CPhI India

Bombay Exhibition Centre Organiser: CMP information

Organisers' contact details

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SMi Conferences

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Merck & Co to acquire GlycoFi

Merck & Co, Inc is to acquire GlycoFi, Inc, a biotechnology company specialising in yeast glycoengineering and optimisation of biologic drug molecules. Glycoengineering provides the ability to make proteins such as monoclonal antibodies with pre-specified and defined human carbohydrate side chains. The ability to make such proteins in yeast has advantages of

speed, cost and quality over current methods of producing monoclonal antibodies and other protein therapeutic agents.

Merck will acquire 100 per cent of the equity of GlycoFi, which will become a whollyowned subsidiary of Merck & Co, Inc. The all-cash transaction is valued at about \$400 million and is expected to close in the second quarter of 2006, subject to customary closing conditions and clearance under the Hart-Scott-Rodino Anti-Trust Improvements Act. GlycoFi, which was founded in 2000, is based in Lebanon, New Hampshire, USA and has about 55 employees. Merck and GlycoFi have been partners since late 2005, when they established a strategic alliance and research collaboration to develop novel biologic candidates.

Designer microorganisms for steroid drug production



Biotechnology company BRAIN AG and Berlin, Germany based pharmaceutical corporation Schering AG have established an agreement to co-operate on the improvement of a production process for steroid drugs. Using molecular biology

methods, a microbial production strain will be optimised to reduce the amount of side products and to increase the amount of the desired steroid intermediate. The goal is the optimised fermentation of steroid drugs using improved production strains fed with plant raw materials. Optimised microbial biotransformation processes are expected to increase product yields and to supersede time-consuming and complex product processing.

"The identification and

development of customised microorganisms hallmarks the growing importance of white biotechnology for efficient production processes," commented Dr Jürgen Eck, head of research at BRAIN AG. "With our molecular biology technology platform we can selectively modify and improve the genomes of established production strains in order to exclude yield-limiting genes. Through the use of these 'designer bugs' more efficient transformations of steroidal intermediates will be achieved".

Cyprotex launches in vitro ADME data guide

Cyprotex has launched an educational guide to the interpretation of in vitro ADME data, Everything You Needed to Know About ADME, But Were Too Afraid to Ask. The guide is an on-line instructive tool that has been developed to assist drug discovery teams in selecting compounds for the later stages of the discovery

Constructed using an easyto-follow handbook format, the guide includes commonly used

methods, useful tips and frequently asked questions, all of which aim to help researchers obtain full value from their ADME and pharmacokinetic data. Attached to each ADME assay featured within the guide is a reading list to provide the user with a further source of valuable information.

Dr Darwin Cheney, Cyprotex's chief scientific officer, commented: "The intention of the guide is to provide a resource for scientists who may be unfamiliar with commonly used in vitro ADME assays and how best to use the data obtained from such assays. At Cyprotex, we believe in sharing our knowledge and expertise with our clients so that they are better able to make informed decisions and we hope this guide will aid researchers when selecting potential drug candidates."

To access the guide, visit: www.cyprotex.com/products/ publications_library.htm

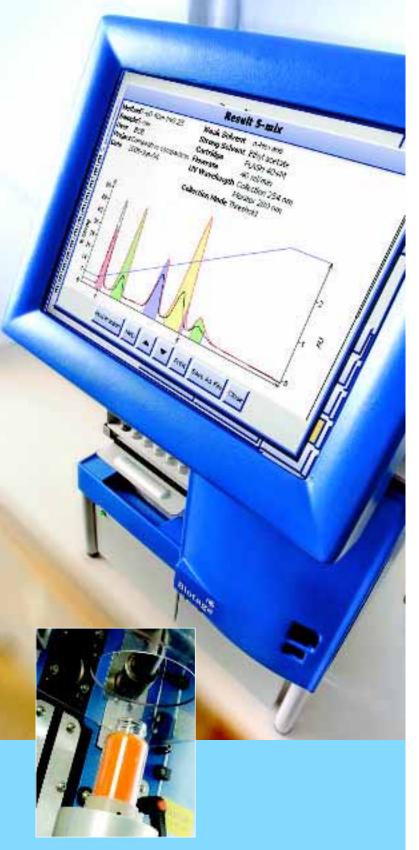
HaptoGuard and University of Calgary in licence agreement

HaptoGuard, Inc has signed a worldwide exclusive licence agreement with UTI Limited Partnership, the University of Calgary's technology transfer and commercialisation center, to acquire rights to a family of compounds developed by

Thomas G. Back, PhD, Professor of Chemistry, University of Calgary. This new class of compounds has the potential to treat patients with cardiovascular disease. HaptoGuard obtains exclusive worldwide rights to develop,

manufacture and market products from a library of compounds characterised as glutathione peroxidase mimetics. The company will be responsible for worldwide product development programmes.

JUNE 2006



NEW V-10 Evaporator

Vortex and vacuum evaporation systemQuickly and safely dry dissolved compounds

- Unique 3-way drying (4ox faster)
- No risk of compound bumping or overheating
- No sample transfer or reformatting issues drys directly into the vial
- Compatible with liquid handling robots and HPLC sample loops
- Compact footprint

Smart, Reliable Purification Workhorse

... the latest in FLASH technology from the experts in flash chromatography

Get 4x the power with the new Swedish-engineered Biotage SP4 system. Operating at pressures up to 100 psi, this system is the fastest automated flash chromatography system on the market. Purify sample loads from milligrams (FLASH 12+, 4.5 g silica) to tens of grams (FLASH 75™, 800g silica) using only one system. New Touch Logic Control™ is a touch screen interface with custom designed intuitive software that offers unique features such as TLC-to-gradient and Auto-continue sample protection. Expanded fraction capacity collects up to 5.8 L with a minimum of 24 fractions per run.





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SOCMA NEWS

Performance Track - EPA to increase incentives

The US EPA has published a notice and request for comment on actions by the agency to increase incentives for Performance Track facilities. The actions being taken by the EPA are in response to a report that provided it with recommendations on how to enhance incentives to participate. Three workgroups formed by the EPA and the Environmental Council of States (ECOS) provided recommendations on incentives, integration of the performance-based programmes into the EPA and state budget planning, and outreach and recruiting for the programme. The incentives include expedited permitting on the state and federal level, enhanced recognition, and simplifying existing flexibility to make it more accessible to P-Track facilities.

Compliance Conference for Pharmaceutical Ingredient Suppliers

SOCMA's cGMP Compliance Conference for Pharmaceutical Ingredient Suppliers takes place from at the Four Points Sheraton Hotel in Washington, DC from October 4-5, 2006. The cGMP compliance conference is intended for compliance and regulatory managers of active pharmaceutical ingredients (APIs), intermediates and excipients manufacturers with job responsibilities covering areas such as quality systems management, regulatory affairs and plant operations.

Programme features include the Fundamentals of cGMP Workshop; ICH Q7a regulatory and legal review; the pharmaceutical ingredient suppliers industry colloquium; and the networking reception. There will also be a keynote address from an FDA representative. For more information contact Lynne Jones Bashton, email: jonesl@socma.com or Liz Egitto, email: eqittoe@socma.com

85th SOCMA Annual Dinner

SOCMA's 85th Annual Dinner will take place at the Marriott New York Marquis Hotel, New York City on December 11, 2006. The Annual Dinner attracts more than 600 members and the event features entertainment by a well-known comedian or other artist. For more information contact malene Ward, email: wardm@socma.com

Biacore launches Chinese operation

Biacore International AB has formally launched its own operation in China, and is taking over full business responsibility for its products in China. The company said the new organisation is designed to take Biacore's business to the next stage of its development in the rapidly growing market for life science instrumentation in China.

The Chinese operation will be headed by Peter Lee, the former regional sales manager for GE Healthcare in Southern China. He will lead a team of six people based in Shanghai which will be responsible for the sales, marketing, applications support and service of Biacore's systems in China. In the outlying areas of the country Biacore will be supported by a network of local dealers and distributors. The organisation will target customers in the life science research, pharmaceutical and biotechnology and food sectors.

Erik Walldén, Biacore's president and CEO commented:

"I am pleased to announce this important strategic development for Biacore, and at the same time I would like to thank GE Healthcare, our previous distributor, for a good

initial job of establishing Biacore's Chinese business. We believe that China has the potential to become a major market for our products and having our own organisation will be crucial in achieving our medium-term sales targets. Given the broad range of customers and applications that our systems address, it is crucial that we are in a position to market their key benefits directly to the customers that we target. Given his previous success with Biacore's products in China I am sure that Peter Lee and his team will be able to quickly build a much larger business for us in this key strategic market."

Evotec and Roche extend medicinal chemistry agreements

Evotec AG has completed two service contracts with Roche, one extending the global medicinal chemistry agreement signed in May 2004 for a further 12 months and the other extending the medicinal chemistry collaboration in oncology signed in October 2003 for an additional two years. In the global medicinal chemistry agreement a dedicated team of chemists from Evotec supports all of Roche's European and US research sites in the design and synthesis of high-quality

compounds for lead-finding and optimisation programmes. In the medicinal chemistry oncology collaboration, both companies aim to identify and develop a clinical lead candidate for a priority target within Roche's oncology research.

Rentschler and Maxygen in second manufacturing agreement

Rentschler Biotechnologie GmbH has signed a contract with Maxygen Holdings Ltd for the manufacture of a novel factor VIIa protein therapeutic. The announcement follows a recent agreement between Maxygen and Roche to codevelop and commercialise the protein for multiple clinical indications. In the first phase Rentschler will set up the GMP process and manufacture the drug to supply the clinical studies. Additionally, Maxygen and Roche have an option to retain Rentschler as contract manufacturer for late-stage clinical and commercial supplies. Factor VIIa is a natural protein with a pivotal role in blood coagulation and clotting. A recombinant factor VIIa product is approved in

the USA and Europe for the treatment of hemophilia. Maxygen's novel protein will be evaluated for its therapeutic potential in new indications such as severe bleeding in trauma and intracerebral haemorrhage (ICH). Analysts estimate that world wide sales of all factor VII products could exceed \$2 billion by 2012.

KNF Flodos pumps for scale-up of processes

Process chemists at
AstraZeneca in Sweden are
using the Stepdos® and
Liquiport® ranges of liquid
pumps from KNF Flodos for
the development of their
manufacturing processes. The
pumps allow good control of
very exothermic reactions. The
Stepdos range offers medium
size pumps of 30 or 80
ml/minute, made with Teflon

heads. Both Stepdos pumps are RS-232 compliant, and allow the use of software in automated experiments. Liquiport pumps are used as transfer pumps between larger reactors of 1 litre to 10 litres. They have Teflon or fluorinated plastic pump heads, so are chemically inert. For further information visit www.knf-flodos.ch



Pharmacopeia and Cephalon in therapeutics alliance

Pharmacopeia has formed a drug discovery, development and commercialisation alliance with Cephalon, Inc. The primary objective of the alliance is to identify active molecules and bring them forward to clinical proof of concept, yielding novel candidates for drug development in various

therapeutic areas. Cephalon will be responsible for identifying promising compounds. The companies will work collaboratively to advance the lead compounds to clinical candidates. Pharmacopeia will be principally responsible for medicinal chemistry and primary biology, while

Cephalon will provide further biology support as required. Upon nomination, if any, of clinical candidates, Cephalon will be primarily responsible for their development and commercialisation. Pharmacopeia retains an option to develop candidates from the collaboration, subject to Cephalon's agreement.

Rapid equilibrium dialysis from Perbio Science

Perbio Science has introduced the RED Rapid Equilibrium Dialysis Device from Pierce. This new dialysis method in plasma protein binding determination is automationfriendly and is used for the analysis of multiple drug candidates. The device has a high membrane surface-tovolume ratio, reducing dialysis time. With short incubation times, the dialysis device inserts are pre-assembled, disposable and leak-proof. The 96-well plate format is compatible with automated handlers and the individual insert format also allows for partial plate use. A reusable Teflon base plate eliminates non-specific binding. Further information www.perbio.com

Vectura and Unilever Ventures spin out speciality pharma company

Vectura Group plc and Unilever Ventures Ltd have jointly established a new speciality pharmaceutical company, PharmaKodex Ltd, to develop a pipeline of pharmaceutical prescription and consumer health products utilising a range of proprietary oral and transdermal and enabling technologies from Vectura and Unilever. With its concentration on pulmonary technologies, Vectura transferred its oral and dermal technologies to a whollyowned Vectura subsidiary, PharmaKodex Ltd, in 2005. In addition, the Unilever Group companies have

licensed to PharmaKodex two enabling technologies for use in pharmaceutical products. PharmaKodex is developing a pipeline of improved medicinal products, focusing on re-purposing existing drugs for new indications or combinations, or to provide improved administration.

PFOPI F ON THE MOVE



Kevin Cox

Reflecting a new phase in its corporate development, biotechnology company Avecia has announced a new three-man Board for its parent, Avecia Holdings plc. The new Board members are chief executive officer & director Adrian Buckmaster, chief financial officer Duncan McLellan and executive director Dr Kevin Cox. Buckmaster joined Avecia in October 2005, having previously been CEO of the Automotive Products Group and Dobson Park Industries. Earlier in his career he was a director of the Dowty Group responsible for its Mining Machinery and Polymers Engineering businesses, before leading a buyout of the Mining Machinery business in 1989. Much of his experience has been in project-based businesses providing bespoke solutions to customers' requirements. An engineer by training, he studied at Cambridge University.

McLellan worked on the creation of Avecia, including the original financing of the launch, and was appointed group controller on Avecia's formation in mid-1999. He was previously financial controller of Zeneca Specialties. He joined the Pharmaceutical Division of ICI as a management accountant in 1983. He qualified as a Chartered Accountant in 1981, after gaining an Economics BA at Sheffield University.

Dr Cox has been president of the Avecia Biologics business unit since October 2005. Formerly Avecia's vice president, biotechnology, he held a series of senior positions in Avecia's predecessors Zeneca Specialties and ICI, including periods in Japan and the USA. He has over 10 years' experience in the biotechnology industry, leading Avecia's biotechnology-based businesses from their early stages of development through the subsequent period of high growth. He chairs the advisory committee of BioNow, a health care cluster initiative in the North-West of England. He has a Chemistry Degree from Sheffield University and a DPhil from Oxford.

Astex Therapeutics recently announced the appointment of **Leon Bushara** as its new chief executive officer. He joins Astex from Serono SA, where he is currently senior executive vice president of corporate and business development and a member of the Executive Management Board that has overseen the growth of

Serono into a global biotechnology leader, and Europe's largest biotechnology company, with a market capitalisation of over \$10 billion and worldwide revenues of about \$2.6 billion in the year 2005.

Elizabeth (Betty) Dragon, PhD has joined Sequenom as senior vice president of research and development. Dr Dragon has over 25 years of diagnostics R&D, management, and leadership experience, including product development and commercialisation planning and execution achievements during her tenure at Roche Molecular Systems from 1990 to 2006. Her most recent role at Roche was as senior vice president of global standardization and vice president of diagnostics development. She earned her PhD in Virology and Cell Biology from Albert Einstein College of Medicine of Yeshiva University.

Biopharmaceutical contract manufacturer Angel Biotechnology Holdings plc has appointed two new business development managers, Ian Hallett and Gary Oliff.
Hallett will be responsible for continuing to build Angel's North American customer base. He brings with him more than 20 years' experience in research and business development within the pharmaceutical and contract research industries, most recently with Cambrex Biosciences. Prior to that, he worked at Ouintiles where he was responsible for business development of the preclinical pharmacology and toxicology

services worldwide. He has a BSc in Biology from the University of Stirling and an MPhil in Cardiovascular Pharmacology from the University of Wales College of Medicine.

Oliff will be responsible for leading business development activities in Europe. He has more than 20 years' extensive experience in the medical, diagnostic, pharmaceutical, contract research and manufacturing industries. Most recently, he was European account manager for Biotechnology Services at Covance Laboratories Ltd and prior to that gained industry expertise at Excell Biotech Ltd and Q-One Biotech Ltd. He has a Degree in Biomedical Sciences from Glasgow Caledonian University.

AGI Therapeutics plc has appointed **David Young, PharmD, PhD,** as president of US
operations and executive member of the
Board of AGI. Dr Young, 53, joins AGI from
the GloboMax Division of ICON plc where he
was executive vice president with
responsibility for strategic drug development
efforts in the USA. Founded by Dr Young in
1997, GloboMax was acquired in 2003 by
ICON plc, a global provider of outsourced
development services to the
pharmaceutical, biotechnology and medical
device industries.

Prior to forming GloboMax, Dr Young was with the University of Maryland at Baltimore for 11 years where he was a tenured associate professor in the Department of Pharmaceutical Sciences and the managing director of the Clinical Research Unit.

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