

# Merck Launches New **BIOLOGICS DIVISION**

Merck has formed a new biologics division, Merck BioVentures, which capitalizes on the company's expertise in the manufacture of biologics, as well as proprietary technologies that streamline the production of protein-based therapies.

The new division employs the company's proprietary glycoengineering technology to become a leading provider of both follow-on and novel bio-

Follow-on biologics represent a significant market opportunity due to the extensive patent expirations of leading biologics scheduled to occur

The company's first follow-on biologic program, MK-2578 for anemia, is in clinical development, and the company plans to launch MK-2578 in 2012. In addition, Merck anticipates having at least five follow-on biologic candidates in late-stage development by 2012.

The formation of Merck BioVentures was enabled by Merck's acquisition of GlycoFi in 2006. GlycoFi developed a breakthrough technology for manufacturing proteins in specialized yeast cells instead of mammalian cells.

Scientists at GlycoFi genetically engineered the yeast to attach sugars to proteins in a manner that closely mimics the process that occurs in the human body, but unlike mammalian cells, the engineered yeast cells allow for greater control of how sugars are attached to the glycoproteins.

"Merck BioVentures is uniquely positioned for success as a result of the humanized GlycoFi yeast platform, which has the potential to provide us with a competitive advantage at a time when the patents on many marketed biologic therapeutics are set to expire," says Peter Kim, Ph.D., executive VP and president of Merck Research Laboratories.

## Women's Health Company Adds CNS DIVISION

The new division's focus is on developing treatments for depression, anxiety disorders, eating disorders, and neuropathic pain specific to women.

FemmePharma Global Healthcare has established a new division that focuses on central nervous system (CNS) disorders

Since its founding in 1996, FemmePharma has focused on women's gynecological health issues, including urinary incontinence and fibrocystic breast disease. With the addition of FemmePharma Mental Healthcare, Central Nervous System, this

focus is expanding to the development of treatments for depression, including postpartum depression, anxiety disorders, eating disorders, and neuropathic pain specific to women.

"We know that women respond differently than men to medications for depression, for example," notes FemmePharma President and CEO Gerianne Tringali DiPiano, referring to a study published in 2006 in the Journal of Affective Disorders."Understanding and developing treatments that respond to women's unique health challenges is FemmePharma's mission, so our expansion into CNS disorders in women represents a natural progression."

Ms. DiPiano says the economic downturn and resulting pharmaceutical industry pullback represents a concern for her personally while providing an exciting opportunity for her company.



MSL360° has announced a line of consulting solutions aimed at maximizing the value of medical affairs initiatives for pharmaceutical, biotechnology, specialty pharmaceutical, diagnostic, and medicaldevice companies.

MSL360° is offering partners a broad range of both strategic and tactical consulting services, including preparation for all phases of new product launches, contracting with independent medical science liaison teams, expansion of existing MSL teams, and medical-affairs program creation and management.

In addition, according to Deb Kientop, president and CEO, the company is providing tools and services that enable improved efficiency and compliance, such as guidance on best industry practices and government and corporate regulations, strategies for benchmarking against peers and establishing appropriate team goals, assistance with selection and customization of specialty MSL software, recruitment of key opinion leaders, execution of scientific advisory meetings, and support for managed care and national accounts management.

The gap in developing

treatments unique to women is widening

even though there are significant unmet needs, says Gerianne

Tringali DiPiano of

FemmePharma.

# U.K. Government and Pharma Industry Forge **PRICING AGREEMENT FOR 2009**

The U.K. Department of Health and the pharmaceutical industry have agreed to a flexible drug-pricing plan intended to ensure that more patients benefit from a wider range of drug treatments more quickly and at a fair price to the National Health Service (NHS)

year based on the proportion of savings from generic substitution.

A more flexible approach to pricing is in everyone's interest, says Alan Johnson, the U.K. Secretary of State for Health.

Under the terms of the 2009 Pharmaceutical Price Regulation Scheme (PPRS), a 3.9% price cut for drugs sold to the NHS has been instituted as of February 2009, with a further 1.9% reduction scheduled for January 2010. Subject to discussion with the affected parties, the U.K. Department of Health also plans to introduce generic substitution beginning January 2010. In addition, there may be further price adjustments in January of each

For companies with sales of £25 pounds or less in 2007, the first £5 million in sales are exempt from the price cut. Also, as with the current PPRS, companies will have freedom of pricing for new products and be able to modulate prices, and an independent dispute resolution mechanism will be put in place.

"A more flexible approach to pricing is in everyone's interest," says the Rt. Hon. Alan Johnson, the U.K. Secretary of State for Health."It gets clinically and cost-effective drugs to more patients, providing cheaper options where clinically appropriate; delivers value for money for the NHS and the taxpayer; and creates a better market for the pharmaceutical industry while supporting research and innovation."



#### **AROUND THE GLOBE**



For more information, visit daiichi-sankyo.eu.

The nonprofit DRUG INFORMATION ASSOCIATION (DIA) has opened an office in Beijing. DIA's regional office in China expands its presence outside the United States to four countries, with existing offices in Tokyo; Basel, Switzerland; and Mumbai, India.

For more information, visit diahome.org.

MERCK SERONO, a division of Merck KGaA, is expanding its Merck Serono Biotech Center (MSBC) production site in Corsier-sur-Vevey, Switzerland. The MSBC facility currently produces the active ingredient for Merck Serono's multiple sclerosis treatment Rebif. The expansion is intended to enable the production of greater quantities of Erbitux, Merck Serono's monoclonal antibody

for the targeted treatment of colorectal and head and neck cancers.

For more information, visit merckserono.com.

Global biopharmaceutical services provider PAREXEL INTERNA-**TIONAL** has **opened an office in Lima**, **Peru**, to provide regulatory consulting and clinical research capabilities. With the addition of the Peru office, Parexel now has locations throughout five important biopharmaceutical centers in Latin America: Peru, Argentina, Brazil, Chile, and Mexico.

For more information, visit parexel.com.

Clinical research organization PRA INTERNATIONAL continues its global expansion with new offices in Munich and Mexico City. The Munich office is PRA's third location in Germany, joining the CRO's offices in Berlin and Mannheim, and will eventually grow to more than 50 employees over the next five years. The new Mexico City location provides proximity to the city's large population center, easy access to Mexico's Ministry of Health, and the ability to oversee trials in Central America.

For more information, visit prainternational.com.



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9th Investigator Initiated Trials February 5 - 6, 2009

InterContinental Miami, Miami, FL

• Managed Markets Insight & Marketing for the Pharmaceutical **Industry** 

February 9 - 10, 2009 Loews Philadelphia Hotel, Philadelphia, PA

4th Investigator Relationship Management

February 23 - 24, 2009 Baltimore Marriott at Inner Harbor at Camden Yards, Baltimore, MD

2nd Annual Latin America **Clinical Trials** 

February 23 - 24, 2009 InterContinental Miami, Miami, FL

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3rd Clinical Trial Billing & **Research Compliance** February 23 - 24, 2009

Baltimore Marriott at Inner Harbor at Camden Yards, Baltimore, MD

4th Data Monitoring Committees

February 23 - 24, 2009 Loews Philadelphia Hotel, Philadelphia, PA

■ The 3rd Pharmaceutical Search **Engine Marketing Strategies** Conference

February 24 - 25, 2009 Hyatt Regency, Princeton, NJ

2nd Annual Lean Sigma and **Kaizen for Life Sciences R&D** 

March 30 - 31, 2009 Park Hyatt Philadelphia at the Bellevue, Philadelphia, PA

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# DPM SETS NEW COURSE

Donahoe Purohit Miller has undergone a name change and rebranding campaign; the company is now known as Purohit Navigation. The name change reflects the agency's evolution and success in helping clients creatively navigate specialty brands to achieve their full potential.

Purohit Navigation is derived from a name that is well-known and respected in the pharmaceutical industry. The new branding capitalizes on one of the agency's differentiating factors: the ability to strategically and creatively help companies plot a successful course by providing integrated healthcare brand solutions.

In addition to the new name, the company has unveiled a new Website, purohitnavigation.com, and branding materials.

# Pfizer Unveils REGENERATIVE MEDICINE RESEARCH UNIT

Pfizer's latest independent research unit, Pfizer Regenerative Medicine, is building on recent scientific progress in understanding the biology of stem cells. Scientists at Pfizer Regenerative Medicine are exploring the use of stem cells to develop future treatments that may prevent disability, repair failing organs, and treat degenerative diseases, with the goal of delivering new medicinal products.

Pfizer Regenerative Medicine is led by Pfizer Chief Scientific Officer Ruth McKernan, Ph.D., and operates as one of Pfizer's new small, independent research units to help it foster a biotechnology culture and environment.

"While there is still a lot to understand about how stem cells can be used therapeutically, we believe it is one of the most promising areas of scientific research," Dr. McKernan says.

Pfizer Regenerative Medicine is co-located in the biotech hubs of Cambridge, United Kingdom, and Cambridge, Mass., and is expected to expand to employ around 70 researchers. The U.K. site is focused on neural and sensory disorders, while the U.S. site is concentrating on endocrine and cardiac research.

Corey Goodman, Ph.D., president of Pfizer's Biotherapeutics and Bioinnovation Center, adds, "The formation of this new unit represents another key step forward in Pfizer's commitment to be at the forefront of new approaches in biotherapeutics and bioinnovation and to expand our research efforts and expertise into emerging areas of biomedical science, like regenerative medicine, that have great potential for human health."



Purohit Navigation Executive Team (left to right): Marita Gomez, VP, Promotional Education & Public Relations; Monica Noce Kanarek, Executive VP, Creative; Anshal Purohit, VP, Strategy & New Business; Bill Fillipp, VP, Creative Director, Copy; Ahnal Purohit, Ph.D., President/CEO; Shana Robinson, Director Account Services; Jay Doniger, VP, Creative Director, Advertising; Ben Currie, Director, Emerging Technologies (not pictured: Kim Hogen, Controller).

#### MEDICAL PUBLICATIONS CERTIFICATION

### **Reinforces Credibility**

The International Society for Medical Publication Professionals (ISMPP) is implementing a certification program that offers professionals an opportunity to become credentialed in the practice of medical publication planning.

The newly established Certified Medical Publication Professional (CMPP) program is intended to help promote integrity and excellence in the profession by encouraging adherence to best practice standards across the industry. Publication planning is a relatively new profession with few defined common standards and established best practices. At

the same time, the profession is under significant and increasing scrutiny from a range of external stakeholders to ensure the highest levels of scientific and professional integrity.

Open to ISMPP members and nonmembers, CMPP applicants must have either a bachelor's degree from an accredited college or university or an equivalent credential and at least two years of demonstrated professional experience in the medical publications field; or a high school diploma or equivalent, and at least five years of demonstrated professional experience in the medical publications field.

#### Follow up

#### **FEMMEPHARMA GLOBAL HEALTHCARE**

**INC.** is devoted to developing drugs for diseases and disorders disproportionately affecting women. For more information, visit femmepharma.com.

# THE INTERNATIONAL SOCIETY FOR MEDICAL PUBLICATION PROFESSIONALS

(**ISMPP**) is a not-for-profit organization for medical publication professionals. For more information, visit ismpp.org.

MERCK & CO. INC. is a global

research-driven pharmaceutical company that discovers, develops, manufactures, and markets vaccines and medicines to address unmet medical needs. For more information, visit merck.com.

**MSL360°** is a full-service medical science liaison and medical affairs company. For more information, visit msl360.net.

**PFIZER INC.** is a global pharmaceutical company committed to helping people improve their health by discovering and developing medicines. For more information, visit pfizer.com.

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