

BIOWORLD® TODAY

FRIDAY
AUGUST 27, 2010

THE DAILY BIOTECHNOLOGY NEWSPAPER

VOLUME 21, No. 166
PAGE 1 OF 7

Plexxikon Drug Shows Stunning 81 Percent Response in Melanoma

By Donna Young
Washington Editor

In a space that's given many drug developers grief, Plexxikon Inc. had reason to be overjoyed this week, reporting a stunning 81 percent of metastatic melanoma patients with the BRAF V600E mutation had tumor shrinkage of at least 30 percent after receiving twice-daily dosages of PLX4032 (RG7204), a highly selective kinase inhibitor.

Indeed, two patients experienced a complete response, while 24 had partial responses, with all but two patients in the Berkeley, Calif.-based biotech's single-agent Phase I extension cohort showing some tumor regression after taking the experimental drug, which already is in Phase II and III testing.

"So [these] data would be impressive on any benchmark that you can measure it against," said Plexxikon President Kathy Glaub. But as a single agent, "this is extraordinary," she

See Plexxikon, Page 3

Cypress is on a Roll, Licensing Two More CNS-Targeted Assets

Catherine Hollingsworth
Staff Writer

Cypress Bioscience Inc. has in-licensed two early stage assets, the Staccato nicotine drug delivery technology from Alexza Pharmaceuticals Inc. in a potential \$6 million deal and rights to the Phase I autism drug candidate carbetocin from Marina Biotech Inc. for a potential \$27.75 million.

Both represent opportunities for Cypress to expand its reach into the central nervous system area.

Michael Hufford, vice president of clinical development at Cypress, said the two assets met the company's main criteria for such transactions, to fill an unmet need, to be well characterized candidates with the potential to be first-in-class and to reach value-creating milestones within two years.

The two assets "wonderfully fit each of those" criteria,

See Cypress, Page 4

Look on the Bright Side

Risky Genes Were Selected For In 'Recent' Evolutionary History

By Anette Breindl
Science Editor

The bright side of diseases such as rheumatoid arthritis and Type I diabetes is not intuitively obvious. But a new study suggests there must be one: In a genomewide analysis, scientists found that risk-conferring alleles for both diseases have been evolutionarily selected for in recent human history.

The work, senior author Atul Butte told *BioWorld Today*, represents the "joining of two fields: evolutionary biology and medicine."

Butte, who is an assistant professor of pediatric cancer biology at Stanford University, and his team used a two-step process to study risk-associated single nucleotide polymorphisms (SNPs) for seven complex diseases that have "only recently emerged in the human genome."

See Genes, Page 5

New Co News

Apexigen Exploits Unique Rabbit Physiology to Make Antibodies

By Catherine Shaffer
BioWorld Today Contributing Writer

Newly incorporated Apexigen Inc. will develop and commercialize rabbit monoclonal antibody technology developed by Epitomics Inc. under the premise that rabbit antibodies have a number of advantages over antibodies grown in mice or with phage display technology.

Rabbits use a different mechanism to generate antibodies than mice or humans. "They can generate higher affinity antibodies," Apexigen President and CEO Xioadong Yang told *BioWorld Today*. He explained that like humans and mice, the rabbit uses a recombination of different variable regions to produce a monoclonal antibody. However, unlike mice and humans, rabbits use a gene conversion mechanism

See Apexigen, Page 6

INSIDE:

CLINIC ROUNDUP: ANTIGENICS, BIOHEART, CARDIOXYL, CERULEAN, CHELSEA2
OTHER NEWS TO NOTE: CEPHALON, LFB, MOMENTA, SHIRE, XCELLEREX.....7

AHC Media LLC

Clinic Roundup

- **Antigenics Inc.**, of Lexington, Mass., said that London-based GlaxoSmithKline's plc.'s herpes zoster (shingles) vaccine candidate, which contains Antigenics' QS-21 Stimulon adjuvant as a key component, has commenced Phase III clinical trials for the prevention of shingles. GSK plans to study more than 30,000 patients globally for the debilitating condition which currently has limited treatment and prevention options available.

- **Bioheart Inc.**, of Sunrise, Fla., reported three-month follow-up data with stem cell therapy on the first two congestive heart failure patients showing that the first improved his walking distance on the six-minute walk test from 315 meters to 420 meters and had improved left ventricular ejection fraction (LVEF) from 32 percent to 38 percent. The second patient improved his walking distance from 450 meters to 492 meters and had improved LVEF from 40 percent to 55 percent. Bioheart's therapy involves the use of stem cells derived from the patient's own adipose tissue that are separated and later injected into the heart using the MyoCath needle injection catheter.

- **Cardioxyl Pharmaceuticals Inc.**, of Chapel Hill, N.C., started a Phase IIa trial of lead candidate CXL-1020, a nitroxyl donor, in patients with acute decompensated heart failure. The three-cohort study will enroll 54 to 66 cardiac patients and is designed to further define a suitable clinical dosage. Hemodynamic parameters will be evaluated during intravenous infusion of CXL-1020 at several dose levels, and investigators will assess hemodynamics using invasive and noninvasive techniques, including both echocardiography and direct Swan-Ganz catheter-based measures of heart pressures and function.

- **Cerulean Pharma Inc.**, of Cambridge, UK, reported results of a Phase I clinical study of CRLX101 (formerly IT-101), Cerulean's lead clinical development candidate, and preclinical data on Cerulean's development candidate, CRLX288, at the American Chemical Society National Meeting & Exposition, ongoing in Boston. The Phase I study

Stock Movers

08/26/10

Company	Stock	Change
Nasdaq Biotechnology	-\$12.36	-1.50%
ArQule	+\$0.45	+10.20%
Antisoma	+\$0.50	+9.09%
Idenix Pharmaceuticals	-\$0.30	-5.57%
Isis Pharmaceuticals	-\$0.37	-4.51%
Marina Biotech	+\$0.23	+8.53%
Neurocrine Biosciences	-\$0.38	-6.53%
Somaxon Pharmaceuticals	+\$0.26	+5.99%

(Biotechs showing significant stock changes Thursday)

demonstrated that CRLX101 was well-tolerated as a first-in-class nanopharmaceutical. A key finding from the study was that several patients with advanced and progressive cancer achieved stable disease and continued on CRLX101 therapy for over six months. CRLX101 is currently in Phase IIa clinical development. Separately, the company also presented preclinical findings on CRLX288, a docetaxel nanopharmaceutical. The presentation highlighted animal data that suggest Cerulean's nanopharmaceutical platform has the potential to improve efficacy and mitigate side effects of a highly efficacious, broadly prescribed chemotherapy.

- **Chelsea Therapeutics International Ltd.**, of Charlotte, N.C., said the FDA approved its protocol for a Phase II trial of CH-4051 in rheumatoid arthritis. The 250-patient study is designed to test the drug head-to-head against methotrexate, with the primary efficacy analysis determined using the hybrid American College of Rheumatology score. Patient screening is expected to start next month, with treatment initiating in October. Chelsea intends to conduct an unblinded interim analysis after about 50 percent of patients in the two lower dose groups complete treatment. Full study results are anticipated in mid-2012.

BioWorld® Today (ISSN# 1541-0595) is published every business day by AHC Media LLC, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305 U.S.A. Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. BioWorld® and BioWorld® Today are trademarks of AHC Media LLC, a Thompson Publishing Group company. Copyright © 2009 AHC Media LLC. All Rights Reserved. No part of this publication may be reproduced without the written consent of AHC Media LLC. (GST Registration Number R128870672).

ATLANTA NEWSROOM: Managing Editor: **Lynn Yoffee**. Assistant Managing Editor: **Jennifer Boggs**. Senior Staff Writer: **Karen Pihl-Carey**. Senior Production Editor: **Ann Duncan**. Staff Writer: **Catherine Hollingsworth**.

WASHINGTON BUREAU: Washington Editor: **Donna Young**.

WEST COAST BUREAU: Staff Writer: **Trista Morrison**.

EAST COAST BUREAU: Science Editor: **Anette Breindl**.

BUSINESS OFFICE: Senior Vice President/Group Publisher: **Donald R. Johnston**. Director of Product Management: **Jane Cazzorla**. Marketing Coordinator: **Sonia Blanco**. Account Representatives: **Bob Sobel, Chris Wiley, Scott Robinson**.

DISPLAY ADVERTISING: For ad rates and information, please call **Stephen Vance** at (404) 262-5511 or email him at stephen.vance@ahcmedia.com.

REPRINTS: For photocopy rights or reprints, call our reprints department at (404) 262-5479.

PRESS MATERIALS: Send all press releases and related information to newsdesk@bioworld.com.

SUBSCRIBER INFORMATION

Please call **(800) 688-2421** to subscribe or if you have fax transmission problems. Outside U.S. and Canada, call **(404) 262-5476**. Our customer service hours are 8:30 a.m. to 6:00 p.m. EST.

Lynn Yoffee, **(404) 262-5408**

Jennifer Boggs, **(404) 262-5427**

Anette Breindl, **(518) 595-4041**

Trista Morrison, **(858) 901-4785**

Donna Young, **(301) 216-2433**

Catherine Hollingsworth, **(301) 576-0667**

Senior Vice President/Group Publisher:

Donald R. Johnston, **(404) 262-5439**

Internet: <http://www.bioworld.com>

AHC Media LLC

Plexxikon

Continued from page 1

told *BioWorld Today*.

Plexxikon's new data, which were published in the August 26, 2010, issue of *The New England Journal of Medicine*, join recently reported positive results from Bristol-Myer Squibb Co. in providing hope for new therapies for patients with melanoma, the most serious type of skin cancer and one of the most deadly forms of cancer.

At the annual meeting in June of the American Society of Clinical Oncology (ASCO), BMS reported that patients given its investigational drug ipilimumab plus glycoprotein 100, a peptide vaccine, showed a median survival of 10 months, compared with 6.4 months for patients receiving the vaccine alone. Ipilimumab improved survival at one year compared with gp100, 46 percent vs. 25 percent, and 24 percent vs. 14 percent at two years. (See *BioWorld Today*, June 8, 2010.)

BMS' Phase III data reported at ASCO were published last week in *NEJM*. The company has filed a biologics license application with the FDA and just last week received fast-track status for ipilimumab, which BMS obtained last year through its \$2.4 billion acquisition of Medarex Inc. (See *BioWorld Today*, Aug. 26, 2009.)

But Plexxikon insists that its Phase I trial of PLX4032 represents the first evidence that a treatment that targets activating BRAF mutations can induce significant tumor regressions in patients.

"We are really the first to validate this target clinically," Glaub said. "There certainly are other companies with BRAF inhibitors that have come before us or coming after us, but ours probably is the first highly selective BRAF inhibitor, and we showed that you really need that very high selectivity to inhibit the target sufficient to show tumor regression."

In the past, she said, BRAF inhibitors "probably haven't been clean enough, selective enough, and that has resulted in off-target toxicities before you could get to a dose that was sufficiently potent on the target."

Although Plexxikon's data reported this week were Phase I, PLX4032 currently is in Phase II and III pivotal studies, which are being funded and executed by the company's partner, Roche AG, under a 2006 deal, Glaub said. (See *BioWorld Today*, Oct. 5, 2006.)

The Phase II BRIM2 study, which got under way in September, is testing PLX4032, also known as RG7204, in 132 second-line melanoma patients, with enrollment recently completed. The primary endpoint for the trial is best overall response. (See *BioWorld Today*, Sept. 30, 2009.)

Glaub said the companies anticipate a readout from the Phase II study later this year and expect to present data from the trial at a major medical conference before the end of the year.

The randomized, open-label Phase III BRIM3 trial, which started in December, plans to enroll about 700 patients, with enrollment expected to be completed by early next year. That trial, which has a primary endpoint of overall survival,

is comparing the efficacy, safety and tolerability of PLX4032 960 mg twice daily with dacarbazine 1,000mg/m² every three weeks in previously untreated patients with metastatic melanoma who test positive for the BRAF mutation.

While it is "highly unusual" to have parallel Phase II and III studies, Glaub contended that the data generated in Plexxikon's Phase I studies "provided much more information about the drug than what you are usually able to get out of a Phase I study.

"We actually saw significant indications of efficacy," she said. "And we certainly had an idea of safety. So there was a high degree of confidence to start both of these pivotal studies."

She noted that Roche and Plexxikon have had "quite a bit of interaction" with the FDA and European Medicines Agency on both trial designs, with regulators providing suggestions along the way.

"You always get some information from the health authorities as you discuss with them and fine tune your design, certainly a bit," she said.

If PLX4032's data continue to look positive, Plexxikon and Roche "certainly will take all actions to accelerate" the filing of approval applications "as quickly as possible," Glaub said.

Roche and Plexxikon also are developing a companion diagnostic for PLX4032, she noted.

"We are anticipating that we will be able to launch not only the drug, but the diagnostic test at the same time," Glaub said. "If you have a specific target for the cancer and you want to indicate that your drug is a targeted therapy you are going to have to validate that with a test. This is the way the regulatory agencies are going."

Glaub said her company is "very fortunate to be part of this great story that is unfolding and very pleased to be able to deliver this medicine, hopefully, to patients some day soon."

Plexxikon also is investigating PLX4032 in colorectal cancer, with results of a Phase I study reported at ASCO.

She noted that Plexxikon has a number of other drugs in development, including PLX3397, a highly selective kinase inhibitor that targets macrophages, osteoclasts and mast cells. ■

Other News To Note

• **AgeneBio Inc.**, of Indianapolis, received a \$240,000 grant from the Alzheimer's Drug Discovery Foundation to develop a new class of small molecules aimed at treating amnesic mild cognitive impairment, a neurological condition that often progresses to Alzheimer's. AgeneBio is developing neural stabilizer therapies designed to selectively normalize the excess neural activity, improve memory and slow the progression to AD. The firm currently is testing a compound in Phase II trials.

Cypress

Continued from page 1

Hufford told *BioWorld Today*.

Both Alexza and Marina Biotech have other programs in their respective portfolios that are more advanced than the assets licensed to Cypress. Bothell, Washington-based Marina Biotech said it is focused on its RNAi drug discovery platform, while Mountain View, Calif.-based Alexza said it had more Staccato-based product candidates than it could afford to develop on its own.

Alexza's lead program, Staccato loxapine (AZ-004) for agitation in schizophrenia or bipolar disorder, is under FDA review with an agency action date set for Oct. 11. Its insomnia drug candidate, Staccato zaleplon (AZ-007), is headed for Phase II testing. Marina Biotech has a clinical candidate for familial adenomatous polyposis (a precancerous syndrome) and two preclinical programs in hepatocellular carcinoma and bladder cancer.

Cypress expects to spend about \$4 million this year and another \$7 million next year on additional development work for the Staccato nicotine technology, Sabrina Johnson, chief financial officer at Cypress, told *BioWorld Today*.

The San Diego-based firm hopes to meet with the FDA to clarify toxicology requirements for the nicotine delivery system. And the goal is to take that product candidate into Phase I trials in late 2011.

The nicotine delivery device could allow smokers to self-administer and possibly titrate the dose to treat cravings. About 80 percent of smokers who try to quit on their own relapse in a month, and only 3 percent will remain abstinent at six months.

As part of the deal with Alexza, Cypress will pay \$5 million up front to acquire the worldwide license for the Staccato nicotine technology. Upon completion of certain preclinical and clinical milestones relating to the technology, Cypress will be obligated to pay to an additional technology transfer payment of \$1 million.

Alexza will have a carried interest of 10 percent (subject to adjustment in certain circumstances) in the net proceeds of any sale or license by Cypress of the Staccato nicotine assets.

Under the deal with Marina, Cypress will pay \$750,000 up front and potential milestone payments of up to \$27 million in exchange for carbetocin. Cypress will be responsible for all future development and IP related expenses. In addition, Cypress will pay Marina Biotech royalties on commercial sales.

J. Michael French, president and CEO of Marina Biotech, said that "the sale of our carbetocin assets to Cypress is another example of our efforts to monetize the legacy assets of our predecessor company."

Nastech Pharmaceutical Co., the predecessor company of Marina Biotech (formerly known as MDRNA Inc.), completed two Phase I dose-escalation studies in healthy volunteers to evaluate the pharmacokinetics, bioavailability and safety of carbetocin nasal spray.

The next carbetocin study is expected to cost an

estimated \$1.5 million, Johnson said.

Carbetocin is a long-acting analog of oxytocin, a naturally produced hormone that may benefit individuals with autism. The drug currently is used to induce labor in pregnant women. Studies have suggested that oxytocin may play a role in the treatment of autism.

Thus far, autism has been a challenging area for drug developers, and few drugs are in autism trials.

Seaside Therapeutics LLC recently reported positive results from a Phase II study of STX209 in patients with Fragile X syndrome, the most common inherited form of mental impairment and the most common known cause of autism.

Curemark LLC is further along with its Phase III drug candidate CM-AT, which targets protein digestion disorders associated with autism.

The currently available drug treatments for autistic children are aimed at relieving related problems such as agitation or aggression.

Risperdal (risperidone), for example, is FDA-approved to treat symptomatic irritability (aggression, deliberate self-injury and temper tantrums) in autistic children. In addition, antipsychotics such as Zyprexa (olanzapine) are prescribed off-label for aggression and other behavioral disturbances in children, including those with autism.

These latest licensing deals follow on the heels of Cypress's recent deal with Israeli biotech BioLineRx, in which it paid \$30 million up front and potentially \$335 million in milestones for the exclusive North American development and commercialization rights to the CYP-1020 antipsychotic compound. Cypress investors, including activist shareholder Ramius Value and Opportunity Advisors LLC viewed the transaction as a bad move. (See *BioWorld Today*, June 22, 2010, and July 20, 2010.)

New York-based Ramius, which owns nearly 10 percent of Cypress, is seeking to take over the company, initially offering to buy the rest of the company shares that it does not already own for \$4 per share, an offer that Cypress rejected.

However, this week, Ramius requested a meeting with members of the board and reiterated its wish to acquire Cypress, including the possibility of raising the value in the event that Ramius is granted limited due diligence and the company agreed to negotiate in good faith. ■

ADVERTISE HERE

... and reach high-level biotech professionals every day!

For advertising opportunities in *BioWorld Today*, please contact Stephen Vance at (404) 262-5511 or stephen.vance@ahcmedia.com

Genes

Continued from page 1

Recent in this case means within 50,000-100,000 years. "Not within recorded history," Butte specified, "but after the divergence from chimps."

In the first step, they tested whether such SNPs had been subjected to selection pressure within the past 50,000-100,000 years. If alleles had been under selection pressure, the scientists went on to test whether it was the risk-conferring or the protective allele that was being selected for.

In their analysis, which is published in the Aug. 17, 2010, edition of *PLoS ONE*, the team found that both risk-conferring alleles for rheumatoid arthritis and Type 1 diabetes had been strongly selected for within the time period they were looking at.

The authors also found that several SNPs for Type II diabetes, coronary artery disease and bipolar disorder were selected for symmetrically, meaning there was selection pressure for both some risk-conferring and some protective alleles. And last, humanity appears to be evolving away from a tendency to Crohn's disease.

That an allele that puts a person at increased risk of disease could be selected for seems counterintuitive at first glance.

But examples of disease-causing alleles are well known. The gene that causes sickle-cell disease in two copies protects against malaria in one; the cystic fibrosis gene appears to be protective against cholera.

Alleles may have been protective before the advent of modern medicine and overly plentiful food. "What if we were in a world where no human got enough calories?" Butte said. Type II diabetes would not be a problem. In fact, packing on the pounds at maximum speed in times of plenty would be an advantage.

And some of the risky alleles appear to lead to stronger immune responses – a big advantage in the days when encountering nasty infections was a sure thing, and living long enough to develop rheumatoid arthritis was lucky.

To do their analysis, Butte and his team looked at SNPs that were "moderately" associated with disease risk. In practice, this means they used a higher cutoff for the value of *p* than GWA studies usually do. Such an approach brings with it a greater chance of false positives – that is, findings that reach statistical significance due to chance, not because there is a true underlying association between gene and risk.

Butte acknowledged that relaxing the criterion for what effects should be considered real, rather than due to a statistical fluke, brings risks with it. But, he said, "We're using the same threshold across all different diseases, and we see a clear-cut difference across the diseases." In fact, the study also suggests that some of the "missing

heritability" that has puzzled genome researchers may be found in the no-man's-land of effects that are real, but not strong enough to be distinguishable from false positives.

Butte and his team want to apply their approach to other diseases. In particular, his team is now looking at different cancer genes. The work does not point, in any obvious way, to therapeutic approaches, but if risk-conferring SNPs are indeed there for a reason, Butte believes they might have prognostic value, albeit possibly a grim one: "My gut feeling is that some of those are going to be the most difficult to treat." ■

Clinic Roundup

• **FibroGen Inc.**, of San Francisco, reported results of a two-year clinical study demonstrating that surgical implantation of biosynthetic corneas formulated with the company's recombinant human type III collagen restored vision and promoted nerve regeneration (restoring sensitivity) in patients who had corneal damage and significant vision loss. The results of this Phase I, investigator-sponsored study were published in *Science Translational Medicine*.



Tipping the Market Scales with Biotech Regimens

OBESITY REPORT

BIOWORLD®

This brand new report from *BioWorld Today*, and co-published with *Medical Device Daily*, shows how a burgeoning disease, a strong public awareness, committed government endeavors and a lack of new drug and device approvals have created the perfect "unmet need" recipe for opportunity.

Order this new report today from *BioWorld*—it's just \$299 plus \$17.95 in S&H.

 **Call**
1-800-688-2421 or 1-404-262-5476

 **Visit**
www.bioworld.com/bioobesity

Apexigen

Continued from page 1

that results in high affinity antibodies.

The Burlingame, Calif., company acquired exclusive rights to develop and commercialize humanized rabbit monoclonal antibodies along with sufficient funding and support to carry it through early preclinical development.

Why rabbits? They can produce a greater diversity of antibodies, including antibodies to tricky antigens such as phosphorylated proteins or carbohydrates that are not immunogenic in mouse. However, for many years production of monoclonal antibodies in rabbits eluded scientists who would have liked to take advantage of this feature.

It was not until 1995 that Katherine Knight of Loyola University in Chicago created a cell line that could produce rabbit monoclonal antibodies. This was accomplished by breeding a double transgenic rabbit that developed a myeloma-like tumor.

From the tumor, she isolated a plasmacytoma cell line, 240E-1. Fusion of 240E-1 with rabbit lymphocytes resulted in a hybridoma that could produce the coveted rabbit monoclonal antibody, or RabMAb. Knight published those results in the *Proceedings of the National Academy of Sciences* in 1995.

Those early RabMAbs were not very stable. Burlingame, Ca.-based Epitomics refined a method based on Knight's original work and developed it into a product catalog of more than 1,600 monoclonal rabbit antibodies, a custom antibody service, and an in vitro diagnostics platform.

Apexigen will move forward with a therapeutic pipeline including programs developing RabMAbs against VEGF (vascular endothelial growth factor) and TNF-alpha. The choice of these targets is strategic, setting Apexigen's RabMAb's up against some of the most sought-after targets. Avastin (bevacizumab, Genentech Inc./Roche AG) is a humanized, monoclonal IgG-1 antibody against VEGF and Enbrel (etanercept, Amgen Inc. and Wyeth Pharmaceuticals Inc.) is an anti-TNF-alpha antibody.

In addition to advancing its pipeline, the company will also cultivate partnerships to produce antibodies for other biotech and pharma companies. Apexigen already has relationships with two Chinese pharma companies: Sincere Pharma Chemicals, of Yang Chen, China, and Shenyang Sunshine Pharmaceutical Co. Ltd. (3S Bio), also of Shenyang.

While Apexigen is acquiring rights to develop the RabMAbs as therapeutic antibodies, along with Epitomics humanizing technology, Epitomics will retain rights to the RabMAbs for diagnostics, research services and reagents.

Apexigen inherited its Chinese connections from Epitomics, which owns a subsidiary company located in Hangzhou, China. "We have a plan . . . to license out some of the China rights of some of the product candidates to some big Chinese companies," Yang said, citing the Chinese government's interest in biotherapeutics as added incentive to partner with companies in China.

The company also inherits an agreement with Amorfis Life Sciences Ltd. to develop antibodies against a variety of

cancer targets. (See *BioWorld Today*, May 12, 2010.)

Yang expects such partnerships to provide significant financial support to the company when its seed funding from Epitomics runs out. In order to support future partnerships in developing therapeutic humanized RabMAbs, the company will undertake proof-of-concept studies, showing that the antibodies can be effective, and that Apexigen can produce them to GMP standards.

The crowded field of monoclonal antibody companies divides roughly into those that own platforms and those that license that technology from the first group. Apexigen aspires to be a provider of "best-in-class" antibodies by exploiting the unique rabbit physiology.

There are many contenders for best-in-class title including San Diego-based BioAtla LLC and Wynnwood, Pa.-based Immunome Inc.

BioAtla and San Diego, Calif.-based Femta Pharmaceuticals Inc. have a similar relationship and occupy a parallel niche to Epitomics and Apexigen. Sharing a platform technology in antibody evolution and rapid humanization of antibodies, BioAtla exists as a service company while Femta is pursuing therapeutic targets and partnerships. (See *BioWorld Today*, Jan. 25, 2010.)

Meanwhile, Immunome seeks to distinguish itself by offering superior native human monoclonal antibodies. (See *BioWorld Today*, May 25, 2010.)

Apexigen currently runs a very lean operation with only three employees, sharing facilities and resources with parent company Epitomics. ■

The BioWorld® Biofuels Report 2009

Lane-Changing Trends and Fork-in-the-Road Dynamics

Published in BioWorld's intuitive and objective editorial style, this informative and analytical report delivers data, news and analysis designed to stimulate and facilitate your reasoned executive agenda.

How To Order:

Call:

1-800-688-2421 or 1-404-262-5476

Online:

www.bioworld.com/biofuels

E-mail:

orders@bioworld.com

Mention priority code S10400-EM/7789

Other News To Note

- **Cephalon Inc.**, of Frazer, Pa., said Frank Baldino Jr., the firm's chairman and CEO, will take a temporary medical leave of absence. The company's chief operating officer, J. Kevin Buchi, will assume Baldino's responsibilities during the absence.

- **LFB Biotechnologies SA**, of Les Ulis, France, said LFB-R603, a chimeric monoclonal antibody directed at CD20, received orphan drug status in chronic lymphocytic leukemia from the FDA. That designation provides regulatory assistance and would guarantee seven years of marketing exclusivity upon approval. LFB-R603 is in a Phase I/II trial in Europe, where it also has orphan designation.

- **Momenta Pharmaceuticals Inc.**, of Cambridge, Mass., said Paris-based **Sanofi-Aventis SA**'s request for a preliminary injunction directing the FDA to suspend and

withdraw approval of the abbreviated new drug application for enoxaparin sodium injection, a generic version of Sanofi's Lovenox, was denied in U.S. District Court. Sanofi has the option to appeal the ruling. Momenta and partner Sandoz, the generic unit of Basel, Switzerland-based **Novartis AG**, gained approval of the generic drug last month. (See *BioWorld Today*, July 26, 2010.)

- **Shire plc**, of Basingstoke, UK, said the European Commission granted marketing approval for Vpriv (velaglucerase alfa), a human cell line-derived enzyme replacement therapy, for the long-term treatment of Type I Gaucher disease. Vpriv has been designated an orphan medicine. The ERT gained FDA approval earlier this year. (See *BioWorld Today*, March 1, 2010.)

- **Xcellerex Inc.**, of Marlborough, Mass., signed a memorandum of understanding with SK Chemicals Co. Ltd., of South Korea, for an alliance to develop and commercialize SK-developed vaccines with Xcellerex's FlexFactory biomanufacturing platform. Specific terms will be defined in the coming months.

BioWorld and BioAbility's Biotechnology and Medical Device VC Directory: U.S., Canadian, European, and Asia Pacific Venture Capital Firms and Contacts

Giving you access to VC portfolios and a comprehensive list of relevant subsidiary sites, this new market report is a must-have! It includes a listing of the partners' names, locations, site phone numbers and many e-mail addresses. Coverage includes VCs located in the U.S., Canada, Europe, Israel, and Asia Pacific.

- ▷ 952 VC firms are profiled at 1,595 locations.
- ▷ 757 in the U.S., 67 in Canada, 460 in Europe, 278 in Asia Pacific and 33 in Israel.
- ▷ 2,884 individuals are included (e-mails are listed for many).

For More Information:

Call: 1-800-688-2421 or 1-404-262-5476

Online: Go to www.bioworld.com

E-mail: orders@bioworld.com

BioWorld® BioTech SuperBook: Vital Signs & The 2010 State of the Industry

From the most respected news source in the industry—BioWorld Today, comes the most in-depth industry analysis. This **475-page report** brings you the defining moments from the year—and shows you the future from all angles.

Exclusive updated sections include:

Analysis

perspectives and predictions by industry experts from Wall Street, Washington, and academia.

Corporate Deals

details of collaborations and agreements among biotech companies, universities, and others.

Product Development

products in development, to be approved in the U.S. and overseas, and licensing.

The View from Europe

trends, predictions, and predicaments facing Europe's biotechnology community.

Financial Data

a year's worth of data on IPOs, performance, venture capital, grants, and more!

We've beefed up the Annual Report with sector analyses, revenue projections, a timeline and more to augment the value you traditionally received. We've taken nothing out of the information that has made this a market summary best-seller for years, but we have added data and analysis that will surely increase its value to the reader.

How To Order:

Call: 1-800-688-2421

or 1-404-262-5476

Online: Go to

www.bioworld.com/superbook

E-mail: orders@bioworld.com

Mention priority code S10406-

EM/11651