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ENDOGENOUS REGULATOR MAY DO IT ALL

Durect to NASH-ville and beyond? 'Lucky' firm with metabolic NCE still in drug-delivery game

By Randy Osborne, Staff Writer

Durect Corp., better known as a drug delivery firm, disclosed a successful phase I trial with DUR-928, described as an endogenous small-molecule new chemical entity that could work in metabolic diseases such as nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH), as well as acute kidney injury.

"We've been working on this for three and a half years," CEO James Brown told *BioWorld Today*. "We didn't come out sooner than this because we wanted to make sure we filed the patents to protect ourselves. Everybody and their brother are in this

See Durect, page 3

NIH budget bump dependent on the future of sequestration

By Mari Serebrov, Regulatory Editor

Recognizing the NIH's role in driving biomedical advances and the economy, a House appropriations subcommittee seemed supportive Tuesday of a $1 billion bump in NIH funding – provided Congress does away with the threat of sequestration.

"We all support biomedical research,"

See NIH, page 4

CALBIO 2015

IPO pace likely to slow in 2015, says VC, banker

By Michael Fitzhugh, Staff Writer

SAN FRANCISCO – In the wake of last year's hot IPO market, this year's climate is likely to be significantly cooler, giving way to between 25 and 30 U.S. biopharma IPOs, projected venture captialist Brent Ahrens and banker Jennifer Jarrett during a "crystal ball"

See CalBio 2015, page 5

DEALS AND M&A

Eddingpharm flexes CDV muscle in $169M Amarin deal for Vascepa

By Shannon Ellis, Staff Writer

SHANGHAI – Making a strong move to enter China's cardiovascular (CDV) market, Shanghai-based Eddingpharm Co. Ltd. inked a deal with Amarin Corp. plc, of Dublin, to bring Vascepa to

See Eddingpharm, page 6

EUROPE

Information gaps persist in EMA drug assessments, IQWiG study claims

By Cormac Sheridan, Staff Writer

DUBLIN – A newly published analysis from Germany's main health technology assessment agency, the Institute for Quality and Efficiency in Health Care (Institut für Qualität und

See IQWiG, page 7

IN THIS ISSUE

REGULATORY

Taimed's ibalizumab wins FDA breakthrough status in HIV; BLA coming soon

By Cornelia Zou, Staff Writer

HONG KONG – Known already as the first China-manufactured biologic used in U.S. trials, HIV candidate ibalizumab (TMB-355) won FDA breakthrough therapy designation, which could

See Taimed, page 8

DEALS AND M&A

Blueprint Medicines to work with Alexion on rare genetic disease

By Peter Winter, BioWorld Insight Editor

Blueprint Medicines Corp. will bank $15 million as an up-front payment from Cheshire, Conn.-based Alexion Pharmaceuticals Inc. as a kick-off to their strategic collaboration that will center on

See Blueprint, page 9

REGULATORY FRONT

The Government Accountability Office (GAO) Tuesday issued a report critical of how Health and Human Services (HHS) is disseminating comparative-effectiveness research (CER) findings. While HHS's Assistant Secretary for Planning and Evaluation has coordinated among various agencies to fund projects to build CER data capacity, its approach lacks key elements – such as defined objectives, milestones and time frames – that are necessary to ensure effectiveness, GAO found. Additionally, HHS' Agency for Healthcare Research and Quality (AHRQ) has not clearly defined how to disseminate CER information to certain stakeholders specified in the Affordable Care Act (ACA), nor has it established time frames to implement marketing plans and distribute informational tools. Instead of creating the public CER database required by the ACA, AHRQ plans to create a webpage with links to existing databases that could be used to search for CER, but it hasn't documented an implementation plan with time frames and strategies to address potential limitations of the webpage, the GAO said.

Sens. Chris Coons (D-Del.), Dick Durbin (D-Ill) and Mazie Hirono (D-Hawaii) introduced the STRONG Patents Act Tuesday to protect individual inventors and research-intensive companies from frivolous patent lawsuits and to level the playing field between small inventors and large companies. The act would empower the Federal Trade Commission to target firms that send start-ups abusive demand letters rather than invent anything themselves, ensure that pleading standards for patent-infringement cases match the standards for all other forms of civil actions, eliminate fee diversion from the Patent and Trademark Office (PTO), ensure balance in post-grant proceedings at the PTO and analyze the impact the U.S. patent system has on small businesses.

EARNINGS

Arena Pharmaceuticals Inc., of San Diego, disclosed in fourth quarter earnings that partner **Eisai Inc.**, of Woodcliff Lake, N.J., reported net product sales of obesity drug Belviq (lorcaserin) totaling $10 million for the quarter. Arena reported about $3.8 million in Belviq revenue, including $3.2 million from the 31.5 percent royalty due from Eisai on net product sales and $600,000 related to redemptioms of the 15-day free voucher and product samples. Net loss for the quarter was $32.1 million, or 15 cents per shares. Consensus estimates had predicted a loss of 12 cents per share. For the full year, Arena reported revenues totaling $37 million and posted a net loss of $60.5 million, or 28 cents per share. As of Dec. 31, the firm had cash and equivalents totaling $163.2 million, though it added about $100.7 million in a stock sale earlier this year. Shares of Arena (NASDAQ:ARNA) closed Tuesday at $4.04, down 24 cents.

Salix Pharmaceuticals Ltd., of Raleigh, N.C., reported total net product revenues for the fourth quarter of $13 million, compared to $238 million for the fourth quarter of 2013. Non-GAAP net loss for the quarter was $167 million, or $2.61 per share, far greater than the expected 25-cent-per-share loss predicted by analysts. Salix attributed the loss of revenue in the quarter to its previously announced plan to accelerate the reduction of wholesaler inventory levels. The company reported that prescriptions remained strong in the fourth quarter compared to the same three months in 2013. For the full year, net product revenues totaled about $1.1 billion. Non-GAAP net loss for 2014 was $142 million, or $1.85 per share. Earlier this year, Salix agreed to be acquired by **Valeant Pharmaceuticals International Inc.**, of Laval, Quebec, in a deal valued at about $10.1 billion. (See *BioWorld Today*, Nov. 10, 2014, and Feb. 24, 2015.)

STOCK MOVERS 3/3/2015

Company	Stock in $	Change in %
Nasdaq Biotechnology	-$19.55	-0.55%
Intercept Pharmaceuticals	+$21.82	+9.67%
Orexigen Therapeutics Inc.	+$1.85	+31.95%
Sucampo Pharmaceuticals	+$1.37	+10.07%

Biotechs showing significant stock changes Tuesday

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Durect

Continued from page 1

area, and we didn't want one of the big guys to come in and try to scoop us."

Matthew Hogan, chief financial officer, said the move "should not be interpreted as backing off from our existing, ongoing programs, which are mostly based in drug delivery. This is just a new opportunity that surfaced through this relationship with one of our key scientists."

Shares (NASDAQ:DRRX) of the Cupertino, Calif.-based firm closed Tuesday up 21.4 percent, or 22 cents, at $1.25.

Durect has preclinical data from a half-dozen animal models that suggest the compound plays a key regulatory role in lipid homeostasis, inflammatory responses and cell survival. "We're pursuing two different avenues of development here," Brown said. Investigating oral prospects, "we just finished the first phase I and we'll be starting a multidose phase I in the not too distant future." The other route is injectable. "We're able to keep cells alive and reduce inflammation," Brown said. "By virtue of that, we've seen some really striking data in three different acute-use models."

The drug development aspect of the business shouldn't surprise anyone, Brown said. "A lot of people here came from biotech and pharma companies in general," with the average age of 51. "We've got a lot of veterans here," he said, and the phase I effort grew out of talks between one of Durect's scientists and a colleague "who was actually a former professor of hers," a specialist in cholesterol metabolism who has been working in the field for 20 years. "We won't be able to give you the subtleties of how it's done," he said. "It's very cool science, but it's not obvious."

For now, the company is describing the class as one of "epigenomic small molecules that regulate expression of a host of different genes," Brown said. "We're disclosing some aspects of it all. We know which genes we inhibit and that kind of thing. We've got very compelling, very good data on this." Although other firms have NASH programs, "we're the only ones looking at an endogenous molecule," he noted.

Among the headline-makers in the NASH space lately is Foster City, Calif.-based Gilead Sciences Inc., which in January bought privately held Phenex Pharmaceuticals AG's early stage farnesoid X receptor program for up to $470 million. Gilead committed to pay Ludwigshafen, Germany-based Phenex an undisclosed up-front payment plus additional development milestones worth up to $470 million. The companies were mum on whether Gilead would develop the program's phase II molecule PX-102, phase I candidate PX-104 or PX-103, a preclinical backup. (See *BioWorld Today*, Jan. 7, 2015.)

One to watch in NASH is Intercept Pharmaceuticals Inc., which won FDA breakthrough designation for its obeticholic acid, putting U.S. regulators on record about the disease – its dangers and the need for new therapies. Mark Pruzanski, president and CEO of New York-based Intercept, told investors at the J.P. Morgan Healthcare Conference in January that his firm is "in the driver's seat as we head into phase III, which we're planning to initiate within the first half of this year." He predicted "the first opportunity for approval will be an interim endpoint at probably around the 72-week time point in the phase III [trial] as a basis for accelerated approval, en route to confirming clinical benefit for full approval." (See *BioWorld Today*, Feb. 2, 2015.)

ORPHAN AND NON-ORPHAN

For Durect, DUR-928 drew much interest during the conference call on earnings Monday, when Brown told analysts the candidate represents "the most exciting molecule I've had the opportunity to work on, and I've been in the industry for more than 30 years. Some of the biggest names in the industry have spent a lot of money trying to find a molecule that does only part of what DUR-928 does naturally," he said, adding that the drug "inhibits cholesterol synthesis more broadly than statins. It inhibits triglyceride synthesis. DUR-928 inhibits bile acid and fatty acid synthesis, like the bile acid analogues that are FXR agonists. DUR-928 inhibits lipid absorption and transportation via microsomal triglyceride transfer protein, like lomitapide [Juxtapid, Aegerion Pharmaceuticals Inc.]," down-regulating PCSK9 as well.

Further detailing the biomedical activity, Brown said the drug affects 240 genes. It's a PPAR-gamma agonist, too. Twenty-four genes associated with apoptosis and cell survival are down-regulated.

"Phase II [trials] we expect to begin in 2016 in one or more patient populations – for acute organ injury, which is an orphan indication, with the injectable formulation, and on the chronic front, an orphan chronic indication with the oral formulation, as well a chronic indication that is not orphan, such as NAFLD and NASH," Brown said.

Durect's Epigenomic Regulator Program, from which DUR-928 emerged, involves a collaborative effort between the firm and the Department of Internal Medicine at Virginia Commonwealth University (VCU), the VCU Medical Center and the McGuire VA Medical Center.

The scientist behind the discovery is Shunlin Ren, associate professor of internal medicine at the VCU Medical Center and a recipient of multiple NIH grants for metabolic disease research.

After hearing of his research from the in-house scientist, "I think within less than 48 hours I was on a plane to meet him, and we did the [exclusive in-licensing] deal pretty quickly thereafter," Brown said. "You don't see too many things like this coming along. To have an endogenous molecule that has this breadth of capability – I think we're just scratching the surface with it. Quite frankly, we were lucky. A lot of times if you look at major discoveries, that's what happens. You've got to get lucky." //

NIH

Continued from page 1

Rep. Tom Cole (R-Okla.), chairman of the Labor, Health and Human Services, and Education Subcommittee, said in opening the hearing on the NIH fiscal 2016 budget.

But, he added, sequestration is the law of the land. Unless Congress comes up with a bipartisan solution to the spending caps that trigger the automatic cut in discretionary funding, the NIH and other federal agencies will see tight budgets again next year.

"Sequestration is bad policy for any budget. It is especially cruel when lives are at stake," said Rep. Rosa DeLauro (D-Conn.), as she called for full funding of the NIH. DeLauro re-introduced the Accelerating Biomedical Research Act in January to shield the NIH from future sequestrations by automatically adjusting the agency's spending caps upward to match any funding increase. (See *BioWorld Today*, Jan. 29, 2015.)

The starting point for the subcommittee hearing was the president's 2016 budget request, which calls for $31.311 billion in NIH funding. That's a $1 billion or 3.3 percent increase from the enacted fiscal 2015 level. The bump includes $200 million for the Precision Medicine Initiative and an additional $100 million for antimicrobial research. (See *BioWorld Today*, Feb. 2, 2015, and Feb. 3, 2015.)

The president's request "highlights investments in innovative research that will advance fundamental knowledge and speed the development of new therapies, diagnostics and preventive measures to improve public health," NIH Director Francis Collins said in his written testimony.

It also will enhance the NIH's ability to support research and training of the scientific work force. With that budget, the NIH expects to support 10,303 new and competing research project grants in fiscal 2016, up from 9,076 this year. "The budget request allocates resources to areas of the most extraordinary promise for biomedical research, while maintaining the flexibility to pursue unplanned scientific opportunities and address unforeseen health needs," Collins said.

Noting the imbalance in research spending by disease, a few lawmakers questioned how the NIH allocates its funding. For instance, Rep. Andy Harris (R-Md.) pointed out that the NIH spends 100 times less per death caused by heart disease than HIV.

The NIH is constantly reallocating its resources, Collins responded, with the one constant being that everything is underfunded. If research funds were allocated based solely on the number of patients per disease, there would be no funding for rare diseases, he added. Yet research on rare diseases can impact what is known about more common diseases. Collins also explained that some diseases, such as Alzheimer's, have a larger societal burden than others.

Jon Lorsch, director of the National Institute of General Medical Sciences, said a new pilot program is under way to improve the efficiency and flexibility of NIH funding.

PLAYING CATCH-UP

Even with the bump in funding the president has requested, the NIH still has a ways to go to make up for a string of lean budget years. Since 2013, the agency has lost 22 percent of its purchasing power, Collins said. Meanwhile, other countries are increasing their biomedical research spending.

China, for example, increased its funding for biomedical research by $9 billion from 2007 to 2012. And China is filing more patents in the biomedical sector than the U.S. If those trends continue, the U.S. will relinquish its international lead in biomedical development within a few years. "We can turn this around," Collins said. But it will require a steady path forward that keeps research spending ahead of inflation.

Supporting the budget request, Rep. Nita Lowey (D-N.Y.) said, "The United States must keep pace with the rest of the world" when it comes to funding medical research.

However, Harris noted that most of the growth in China is occurring in the private sector. To compare biomedical research in the U.S. with other countries requires looking at a bigger picture than just NIH funding, he said. Government policy, such as the proposed Trans-Pacific Partnership trade agreement, can hurt U.S. biomedical patents and the industry as a whole, he added.

Cole raised another concern – the need for a healthy pipeline of young researchers. He recognized that if young scientists don't get the funding opportunities they need for their research, they're likely to get discouraged and leave the field.

Collins agreed, saying that issue wakes him up at night more than any other. The loss of young researchers today will affect the future and could deprive the world of new therapies tomorrow.

The NIH is developing new funding programs to attract and retain promising researchers in the biomedical field, but the bottom line still comes down to having adequate funding in the first place. **//**

FINANCINGS

Coronado Biosciences Inc., of Burlington, Mass., closed a private placement of a promissory note for $10 million. Net proceeds will be used to acquire medical technologies and products as well as create subsidiaries in which it can advance technologies and products.

Curis Inc., of Lexington, Mass., said it closed its public offering, selling 25.1 million shares at $2.75 apiece, including the exercise in full by underwriters to purchase an additional 3.3 million shares. Curis received net proceeds of about $64.7 million. Funds will be used for preclinical and clinical work on product candidates, including CUDC-907 and any candidates for which the firm exercises its option to exclusively in-license from **Aurigene Discovery Technologies Ltd.**, of Bangalore, India, as well as for general working capital and capital expenditures. (See *BioWorld Today*, Jan. 22, 2015.)

CalBio 2015

Continued from page 1

panel at the CalBio 2015 conference, a gathering of California industry mavens organized by BayBio and Biocom, the state's biggest life sciences trade associations.

"The bottom's not going to fall out. It's just going to slow down," said Ahrens, a general partner at Canaan Partners. Though he expects 2015's IPO crop to be healthy relative to other years, 2014 was "too hot," he said. "It's a multiround game." The current environment has been positive for companies that have had the chance to file confidentially through the Jumpstart Our Business Startups (JOBS) Act, go on a nondeal roadshow and reach crossover investors who have been increasingly active it the biotech space, he said.

Jarrett, managing director of health care investment banking at Citigroup, turned to the year's track record so far to project 30 U.S. biopharma IPOs this year. Comparing the six biopharma IPOs launched through February of this year to the 17 offerings that had launched through February 2014, the pace clearly has slowed, though she predicted, citing discussions with clients, that the second half of this year will be busier.

The backlog of offerings at big banks is probably the lowest its been since the window opened a few years ago, Jarrett said, but that doesn't mean momentum has faded. With worries that their big chance to dive into the public markets might pass, small companies are increasingly being pushed by their venture investors to consider accerelating their timetables for a potential offering, by either launching an offering ahead of clinical data or filing privately through the JOBS Act so that they're ready to quickly go public once they have data.

With most of the companies that have clinical data already public, she said, those hopefuls remaining mostly are in the preclinical stage or are entering phase I. "At some point, we're just going to run out of companies to go public," she said. "I think the bar's going to rise in terms of what investors are looking for in an IPO profile and will start to demand a little more data than some of the companies that we've seen go public."

Jarret also suggested a possible deflation could be ahead for certain issues. Questioning the consensus estimate that one of last year's IPO darlings, Juno Therapeutics Inc., will reach a market cap of $5.8 billion by the end of 2015, Jarret said she expects its $4.2 billion valuation to drop to $3.5 billion instead. "I think there are current segments within the biotech market that are on the frothy side, and that can't, from a valuation perspective, really be justified based on current fundamentals." (See *BioWorld Today*, Dec. 22, 2014.)

With little expectation of significantly new data on the company's programs, a growing number of competitors and the public company responsibility to report adverse events as they happen, she said there's more downside risk for both Juno and others in the chimeric antigen receptor T-cell therapy space.

Laurent Fischer, chairman and CEO of Tobira Therapeutics Inc., was decidedly more optimistic, suggesting that the year's theme will be "innovation rewarded." After filing an S-1 in June 2014 targeting a $69 million raise, the company changed gears, opting in the middle of the January's J.P. Morgan Healthcare Conference to join the market through a reverse merger with Regado Biosciences Inc. The combination of "momentum for innovation and success" and overabundance of capital relative to the number of companies available to invest in may drive more IPOs in 2015 than in a normal year, he said.

Despite Fischer's positivity on the financing front, he said uncertainties around the future leadership of the FDA in the wake of Commissioner Margaret Hamburg's planned retirement and potential challenges to the Affordable Care Act could darken the not-so-distant future. "Things like that which we can't control are always what worries me," he said. (See *BioWorld Today*, Feb. 6, 2015.)

At the session's end, moderator and Canale Communications Inc. President Carin Canale-Theakston turned to the panel's audience for an applause-based assessment of who to name as best prognosticator. The winner, Jarret, walked away with a hefty crystal ball engraved with a title that would make any banker proud: Chief Futurist. //

FINANCINGS

Lion Biotechnologies Inc., of Los Angeles, said it closed its public offering of 9.2 million shares priced at $8 apiece, including 1.2 million shares sold to cover overallotments. Gross proceeds are expected to total about $73.6 million and will be used for the development of product candidates, including a planned phase II trial in metastatic melanoma, and for other general corporate and working capital purposes.

Pulmokine Inc., of Rensselaer, N.Y., said it entered an investment agreement with Broadview Ventures for $1 million. Proceeds will be used to advance the firm's lead candidate, PK10571, an inhaled PDGF receptor inhibitor, into phase I trials in patients with pulmonary arterial hypertension.

Tesaro Inc., of Waltham, Mass., said it commenced a public offering of $150 million of common stock, though the number of shares and the per-share price have not yet been disclosed. The company plans to grant underwriters an option to purchase up to an additional $22.5 million to cover overallotments. Proceeds will be used for general corporate purposes. Citigroup, Leerink Partners and Deutsche Bank Securities are acting as joint book-running managers, with BMO Capital Markets, Baird and Mizuho acting as co-managers. Shares of Tesaro (NASDAQ:TSRO) closed Tuesday at $52.37, down $1.88.

Vascular Pharmaceuticals Inc. (VPI), of Chapel Hill, N.C., said it increased its series A financing with the addition of a $9 million expansion round, bringing the total series A to $25 million. Lead investor Lumira Capital and one unnamed investor were joined by existing investors Intersouth Partners and MPM Capital. Proceeds will be used to fund the ongoing phase II trials of VPI-2690B, a monoclonal antibody designed to bind to a molecular target within the alphaVbeta3 receptor, for the treatment of diabetic nephropathy. Beni Rovinski, of Lumira, will join VPI's board.

Eddingpharm

Continued from page 1

Greater China. Amarin will receive a nonrefundable $15 million up-front payment, while the total deal is valued at $169 million in milestones and tiered sales royalties.

Vascepa (icosapent ethyl) was approved by the FDA in 2012 to reduce triglyceride levels in adults with severe hypertriglyceridemia (≥500 mg/dL) as adjunct to diet. The deal rights acquired by Eddingpharm extend to Vascepa indications both commercialized and under development in several Amarin trials: Marine, Anchor and the ongoing outcomes study, Reduce-it.

Eddingpharm, a Chinese biotech that brings global products to China, has had success developing and commercializing respiratory, antibiotic, oncology and clinical nutrition products. It is well accustomed to getting products through China's regulatory obstacle course and will seek an imported drug license for Vascepa.

The deal with Amarin comes after Eddingpharm's first foray into CDV in late December with Cardiome Pharma Corp., a $3 million deal for Cardiome's atrial fibrillation drug, Brinavess (vernakalant). (See *BioWorld Asia*, Dec. 24, 2014.)

"We are fortunate to have the first relationship with Cardiome, and we are making a bigger transaction to get access to Vascepa, which we think will be a very important anchor product to our upcoming cardiovascular business unit," Xiaoming Zou, chief business officer at Eddingpharm, told *BioWorld Today*.

A highly purified eicosapentaenoic acid (EPA) omega-3 supplement that is derived from fish oil, Vascepa is much more concentrated than over-the-counter pills and requires a prescription. Currently, there are no other prescription omega-3 products available in China.

"The key point [is that] it is not the omega-3 that will do the job," explained Zou. "You need the high-quality EPA that has the reducing effect on triglycerides. Amarin's Vascepa is really the first product to achieve this level of purity and has the clinical data behind it to show that it is effectively reducing triglycerides without elevating LDL [low-density lipoprotein, otherwise known as bad cholesterol] and other issues."

But it has not all been smooth sailing for Amarin. In October 2013, the FDA withdrew a special protocol assessment (SPA) agreement for Amarin's Anchor trial and denied broader marketing approval for Vascepa until the results were in from a much larger outcomes study, Reduce-it. The company's stock (NASDAQ:AMRN) took a 60 percent hit on that news. (See *BioWorld Today*, Oct. 18, 2013.)

Undeterred by the setback, Amarin has been recruiting patients for its 8,000-person, double-blind, placebo-controlled Reduce-it study that started in 2011. The study seeks to show that taking a pure, EPA-only omega-3 drug on top of existing statin therapy can provide a significant reduction in cardiovascular events. The $15 million up-front payment from Eddingpharm likely will help to further fund the trial.

The study is the first of its kind and promises to definitively demonstrate taking a fish oil pill really works. If it does, Amarin might find itself sitting on an opportunity worth several billion.

According to the Amarin website, by November 2014, 7,100 patients had been enrolled with 60 percent of the patients in the global study coming from Western countries. The study is expected to be complete in 2017, with results published in 2018.

"Those results will really add a lot more weight to the benefit of managing triglycerides to help to reduce cardiovascular events," Zou said. "We are very excited about the study and think it is worthwhile for us to start all the necessary registration steps in China, and ultimately we will go into the prevention indication and pursue that, too."

Zou said the positive results from the large-scale, completed Japanese Jellis study of 18,000 people, funded by Mochida Pharmaceutical Co. Ltd., of Tokyo, although not placebo-controlled and using a drug slightly less pure than Amarin's, is another reason to be hopeful about Vascepa's prospects in Chinese patients.

Eddingpharm will import the drug manufactured by Amarin, requiring that it follow a particular regulatory path according to China's rules. For the indication already approved by the FDA, the company said it plans to file for clinical trial approval in a few months, but expects the approval to take the industry norm of about a year.

SOONER-THAN-EXPECTED APPROVAL?

Given all the existing data collected by Amarin, Eddingpharm's China trial in Chinese patients will go quickly, expected to be complete in eight to 12 weeks. Eddingpharm plans to launch in Hong Kong first, benefiting from less regulatory red tape than the mainland. The firm will have the chance to collect data in Chinese patients, which will be a boon for its discussions with the CFDA.

The drug is expected to be on the market in China in about four years. And there's a chance it could be even sooner.

There are signs "the CFDA is listening to industry feedback and expediting the process [for FDA-approved drugs]. We hope we will benefit and the whole industry and patients will benefit," said Zou. "But based on the current status, we will work together with the CDE and CFDA to present the patient need to get to market."

In terms of the partnership, Zou said that although Amarin had initiated the formal process to find a partner for China, Eddingpharm had long been following the development of Amarin.

In the end, many companies were competing for Vascepa but Eddingpharm won the bidding war.

"Our agreement with Eddingpharm reflects the culmination of a competitive process and represents a significant step toward commercializing Vascepa in a major market outside the United States," said John F. Thero, president and CEO of Amarin.

See Eddingpharm, page 7

IQWiG

Continued from page 1

Wirtschaftlichkeit im Gesundheitswesen, IQWiG), concluded that the benefit assessment process Germany introduced for new drugs in 2011 has narrowed the information gap on new medicines and provided a fuller understanding of their benefits and risks than that available from other regulatory and academic sources.

The study, although it involves a limited sample, adds to the growing body of literature on clinical trial data transparency and puts down a marker for the EMA. That agency's new data transparency policy became effective on Jan. 1, but as it applies only to clinical data it receives after that date, proactive publication of clinical data on approved drugs – and of clinical study reports, in particular – will only start as the approvals start to flow next year.

The EMA has already clashed with the European Ombudsman – and indeed with IQWiG – over its overly restrictive interpretation of what constitutes commercially confidential information. (See *BioWorld Today*, Feb. 17, 2015, and May 27, 2014.)

Lead author Beate Wieseler and colleagues suggested that the AMNOG approach, which involves the publication of complete clinical study reports, including the study protocol and the analysis plan, anonymized individual patient data, the registry report and all relevant papers, could form the basis of an international model for publication of clinical studies.

The IQWiG study, compared the completeness of drug information supplied under the mandatory benefit assessment process – introduced under Germany's pharmaceuticals market reform act (Arzneimittelmarktneuordnungsgesetz, AMNOG) – with that contained in the European public assessment reports (EPARs), published by the EMA, in academic papers and in public registries.

The analysis applied to dossiers submitted to IQWiG between Jan. 1, 2011, and Feb. 28, 2013. It excluded dossiers on orphan drugs, as the Federal Joint Committee (Gemeinsamer Bundesausschuss, GB), the main decisionmaking body overseeing Germany's statutory health insurance system, assesses those directly.

The study authors deemed 15 of the 27 available dossiers as being eligible for inclusion. The 15 dossier assessments contained 28 individual assessments, covering 15 total study populations and another 13 approved subpopulations, that is, patient subgroups for whom the relevant drug was explicitly approved.

An EPAR was available for each drug, while journal publications were available for 14 of the 15 drugs. Eleven of the 15 available registry reports in ClinicalTrials.gov contained results. The "completeness" of a given information source was assessed on the basis of 19 criteria, eight of which referred to methods and 11 of which referred to results, including patients' baseline characteristics and relevant outcomes.

The documents obtained via the AMNOG process had the highest level of completeness, according to the study, with about 90 percent of both methods and results completely reported. For non-AMNOG documents, the rate was 75 percent for methods and 52 percent for results, the study reported. It found that journal publications contained more complete information than EPARs, while registry reports contained the least.

The gap between AMNOG documents and other sources was far wider when the analysis was confined to approved patient subpopulations, particularly where information on results was concerned. Seventy-one percent of the AMNOG documents were regarded as being complete, whereas just 11 percent of the other types of documents were. For patient-relevant outcomes, the respective figures were 70 percent and 5 percent.

"Our findings show that, at the time of market entry of a new drug, a substantial amount of information needed for assessment of the corresponding clinical studies and for understanding of the drug's benefits and harms is missing in publicly available European public assessment reports, journal publications and registry reports," the authors stated. "In many of these cases, non-AMNOG documents, including European public assessment reports, reported no results data at all."

Although the EMA's transparency policy became effective almost two years after the end of the period under analysis, that does not make the findings redundant, the authors argued. Although the EMA will make clinical study reports and other relevant data publicly available, "it is unclear to what extent the documents will be redacted, and the terms of use have been criticized," they stated.

The paper, titled "Information on new drugs at market entry: retrospective analysis of health technology assessment reports versus regulatory reports, journal publications, and registry reports," appeared in the Feb. 26, 2015, issue of the *British Medical Journal*. //

Eddingpharm

Continued from page 6

Eddingpharm is relatively small company with only 700 employees. Not surprisingly, it found itself up against companies with much larger CDV sales forces, but according to Zou, it is precisely Eddingpharm's status as a midsize company that makes it a good fit to work with Amarin, another midsize biotech.

"We really try to be a partner of choice in China. We are not a large company, we have no bureaucracy; it's myself, the CEO and the whole management team is very involved in any key transaction. We can provide a lot of attention and also a lot of resources," Zou said.

"Hopefully, they feel our culture is more appealing, more attractive to them, given our open, cooperative, partnering business model in comparison to some of our competitors," he added. "But on the whole business side, we did spend some efforts to convince them even though we are not dedicated to CV . . . they can be rest assured that Vascepa will be [an] anchor product for this business unit." //

Taimed

Continued from page 1

substantially accelerate the product's launch.

Taiwanese drugmaker Taimed Biologics Inc. will soon submit a biologics license application for ibalizumab, with Chinese R&D services giant Wuxi Pharmatech (Cayman) Inc. providing additional clinical supply manufacture and process validation. If approved, ibalizumab will be the first China-manufactured biologic product to be launched in the U.S. market.

"This designation significantly helps accelerate the launching of TMB-355. We were already in the fast lane for an approval; with this designation, we're moving even faster to a product launch," Taimed's financial controller Jack Chen told *BioWorld Today*. "We'll have a talk with the U.S. FDA next week and discuss about a clearer timeline."

Ibalizumab is a humanized monoclonal antibody. It belongs to an emerging class of HIV therapies known as viral entry inhibitors and has completed a phase IIb trial and will soon move on to phase III. Clinical trial supplies of ibalizumab were manufactured by Wuxi's biologics manufacturing facilities in China.

The FDA designates as breakthrough therapies drugs that are developed to treat serious or life-threatening conditions and that may demonstrate substantially higher efficacy than existing treatments.

"We're launching all our HIV drugs in the U.S. first, then Europe and then maybe China . . . because the U.S. and Europe take up almost 80 percent of the market," said Chen. "The FDA thinks this HIV therapy is just what they need in the country, so they're providing maximum administrative support and guidance to get this drug developed and launched as soon as possible."

After gaining approval for use in U.S. trials, ibalizumab also received orphan drug designation from last October. (See *BioWorld Today*, May 8, 2014.)

Headquartered in Shanghai, Wuxi is a leading open-access R&D capability and technology company that works with pharmaceutical, biotech and medical device companies with operations in both China and the U.S.

Wuxi signed a contract manufacturing agreement with Taimed for the manufacture of ibalizumab in August 2012 and also is providing support for global phase II and phase III trials. Wuxi will use both its biologics manufacturing facilities in China and its biologics testing facilities in the U.S. for the manufacture of ibalizumab.

"This is the fourth Wuxi-manufactured product to be so designated, reflecting the high quality of the molecules that we choose to work on," said Ge Li, chairman and CEO of Wuxi. "We will give Taimed our full support as they advance this promising product candidate through regulatory review."

In addition to TMB-355, Taimed has started working on an improved version of the drug, called TMB-360. The second-generation compound is being developed as part of a cooperative program between Taimed and Rockefeller University.

TMB-360 is in preclinical studies and the manufacturing of clinical supplies has been contracted out to Eirgenix Inc. The drug is designed to be more advanced in terms of breadth, potency and in pharmacokinetic profile compared to TMB-355. Chen said the company is planning to file an investigational new drug application for TMB-360 at the end of 2015.

"We haven't made any partnership plans for its mass production," he said. "At this early stage of the development, we're only working with Eirgenix for the trials."

TMB-607, an HIV-1 protease inhibitor, is another HIV therapy Taimed is developing. Originally developed by Canadian biopharmaceutical company Ambrilia Biopharma Inc., the compound was acquired by Taimed via a global licensing agreement in March 2011.

TMB-571 is the only non-HIV drug in Taimed's pipeline. It is a preclinical small-molecule inhibitor of influenza virus neuraminidase in-licensed from Academia Sinica, Taiwan's top academic institution for scientific research. TMB-571 has shown significant in vitro activity and has been shown to have higher potency against wild-type neuraminidases, both H1N1 and H5N1 viruses. //

OTHER NEWS TO NOTE

Actelion Ltd., of Allschwil, Switzerland, said the FDA accepted the new drug application seeking approval of Uptravi (selexipag), a selective, oral prostacyclin IP receptor agonist, in pulmonary arterial hypertension. Actelion submitted the application Dec. 22 and expects the review process to take about 12 months.

Atheronova Inc., of Irvine, Calif., said it and subsidiary Atheronova Operations Inc. filed voluntary petitions under Chapter 11 of the U.S. Bankruptcy Code on March 2. The company will evaluate all options, including a Bankruptcy Court-supervised asset sale process, for all or substantially all of its assets to a party who could potentially be interested in continuing the company's clinical programs.

Cohbar Inc., of Pasadena, Calif., said research published in the March 3, 2015, issue of *Cell Metabolism* described MOTS-c, a new mitochondrial-derived peptide hormone that prevents obesity caused by a high-fat diet and stimulates the metabolism in the same way as exercise. Cohbar has an exclusive, worldwide license for the development of MOTS-c into therapeutics.

Blueprint

Continued from page 1

an undisclosed activated kinase target, which is the cause of a rare genetic disease. Blueprint brings to the table its specialized kinase-focused drug discovery platform to identify and optimize drug candidates and will conduct the research, with Alexion responsible for the development and commercialization of promising drug candidates.

In addition to the up-front payment, Blueprint will be reimbursed for all research expenses and will be eligible to receive more than $250 million in milestone payments as well royalty payments related to successful product commercialization.

As its name suggests, Blueprint aims to understand the blueprint of cancer and to craft highly selective therapies employing its kinase-specific chemical library that offers the potential to target specific gene mutations to treat cancer.

In November 2014, the company attracted $50 million in a series C financing round to help drive its first two compounds for genetically defined cancers into the clinic. (See *BioWorld Today*, Nov.15, 2014.)

One of those is BLU-285, a selective inhibitor of KIT exon 17 mutants, in development initially for aggressive systemic mastocytosis (ASM) and a subset of patients with gastrointestinal stromal tumors. The genomic mutation associated with ASM, KIT D816V, is believed to occur in about 95 percent of ASM patients. The firm is planning to initiate clinical trials with BLU-285 this year.

The second compound is BLU-554, a selective inhibitor of FGFR4, that Blueprint plans to test in a subset of patients with hepatocellular carcinoma.

Although Blueprint's main focus is on oncology it does have a program in the rare disease space and so its collaboration with rare diseases specialist Alexion makes it the "ideal partner for this target," noted Jeffrey Albers, CEO of Blueprint Medicines. It allows the company to focus on oncology, while it leverages its platform in additional therapeutic areas, he added.

Although the specific genetic disease that will be the focus of the collaboration remains under wraps at this time, Blueprint's research will apply its kinase-focused drug discovery platform to identify and optimize drug candidates prior to the filing of an investigational new drug application with the FDA.

Shares of Alexion (NASDAQ:ALXN) closed Tuesday at $182.51, down $2.11. //

OTHER NEWS TO NOTE

Denovo Biopharma LLC, of San Diego, said it exclusively licensed pomaglumetad methionil, a late-stage mGlu2/3 receptor agonist, from **Eli Lilly and Co.**, of Indianapolis, gaining all rights to develop, manufacture and commercialize the drug globally, including transfer of all intellectual property and other rights, data and information. Lilly has an option to reacquire pomaglumetad upon a successful clinical trial, for predetermined undisclosed financial terms. Pomaglumetad (formerly LY2140023), which was primarily developed and tested in schizophrenia, including in phase II and phase III trials, missed its primary endpoint in phase III though predefined subpopulation analyses found a subset of patients who showed significantly improved outcomes. Denovo will use its platform to identify genetic biomarkers as a companion diagnostic to screen for appropriate patient subsets in future clinical trials and eventual commercialization.

OTHER NEWS TO NOTE

ISA Pharmaceuticals BV, of Leiden, the Netherlands, said its fully owned subsidiary, ISA Therapeutics BV, closed an R&D agreement with Tokyo-based **Shin Nippon Biomedical Laboratories Ltd.** (SNBL) to explore a new nasal delivery for ISA's cervical cancer immunotherapeutic. ISA's Synthetic Long Peptide immunotherapeutic ISA101 will be administered via SNBL's nasal drug delivery technology. Both parties expect to obtain basic research data on a potential antigen-specific immune response. Terms were not disclosed.

Islet Sciences Inc., of Raleigh, N.C., said it entered a license agreement with Brighthaven Ventures (BHV) for exclusive rights to develop and commercialize SGLT2 inhibitor remogliflozin etabonate, which is in phase IIb development in type 2 diabetes and non-alcoholic steatohepatitis. Under the terms, Islet gets exclusive global rights to remogliflozin outside of Japan, Korea, Taiwan, China and Latin America in exchange for an up-front fee of $5 million and up to $35.1 million in pre-regulatory approval milestones and up to $76.75 million in post-regulatory approval milestones. Royalties under the license agreement are due on net sales in the territory during the term of the agreement. The license will only become effective upon Islet raising a minimum of $10 million and paying BHV the up-front fee by May 31.

Oncolytics Biotech Inc., of Calgary, Alberta, said the FDA granted orphan designation to Reolysin for the treatment of primary peritoneal cancers. The oncolytic virus-based drug previously received orphan designation in ovarian cancer and cancers of the fallopian tube.

Probiodrug AG, of Halle, Germany, said a paper published in *Acta Neuropathologica* details the role of glutaminyl cyclases (QCs) in Alzheimer's disease pathology, with findings showing that besides QC, as shown earlier, its sister enzyme, isoQC, also contributes to amyloid beta pathology and neuroinflammation. Data from a transgenic animal model showed co-expression of isoQC with its substrate, the chemokine CCL2, which is increased upon stimulation by pGlu-Abeta in brain astrocytes, supporting earlier data obtained by the company.

Regenicin Inc., of Little Falls, N.J., said it received the final payment to conclude the asset purchase agreement with **Amarantus Bioscience Holdings Inc.**, of San Francisco. Under the terms, Amarantus made the final payments due to Reginicin in the amount of $2.3 million, along with a payment of $200,000 to Reginicin's senior secured creditor.

IN THE CLINIC

Aquinox Pharmaceuticals Inc., of Vancouver, British Columbia, reached its target enrollment in the phase II LEADERSHIP trial of AQX-1125 for the treatment of bladder pain syndrome/interstitial cystitis, investigating the ability of the drug to reduce pain in female patients. The primary endpoint is the difference in the change from baseline in mean daily bladder pain scores based on an 11-point numerical rating scale at six weeks recorded by daily, electronic diaries for patients administered AQX-1125 as compared to placebo. Top-line data are expected around midyear. The drug is a small-molecule activator of SHIP1, which is a regulating component of the PI3K cellular signaling pathway.

Benitec Biopharma Ltd., of Sydney, Australia, said the data safety monitoring board recommended that its phase I/IIa trial for TT-034 continue to proceed after finding no drug-related adverse events upon reviewing the data from the third patient, who was the first patient in cohort 2. TT-034 is a ddRNAi-based therapeutic, designed to treat and potentially cure hepatitis C virus with a single administration by targeting the hepatitis C viral RNA at three separate, highly conserved sites.

IN THE CLINIC

Biota Pharmaceuticals Inc., of Atlanta, commenced dosing of patients in its phase IIb SPIRITUS trial of the capsid binder vapendavir. The goal of the study is to enroll about 150 laboratory-confirmed human rhinovirus-infected patients with moderate to severe asthma from the U.S. and multiple European countries over the next 12 months and to report top-line data in mid-2016.

Cerulean Pharma Inc., of Cambridge, Mass., signed a clinical research agreement with the Gynecologic Oncology Group (GOG) Foundation to conduct an open-label phase Ib trial of its lead product candidate, CRLX101, in combination with weekly paclitaxel in patients with relapsed ovarian cancer. Cerulean and GOG have commenced start-up procedures and expect to enroll the first patient in the second quarter of 2015.

Epizyme Inc., of Cambridge, Mass., said updated data from the ongoing phase I dose-escalation study of EPZ-6438 (referred to as E7438 by Epizyme's partner **Eisai Co. Ltd.**, of Tokyo) were presented at the 13th International Congress on Targeted Anticancer Therapies in Paris. EPZ-6438, a first-in-class, oral EZH2 inhibitor, is being investigated in patients with advanced B-cell non-Hodgkin lymphomas (NHL) and solid tumors. Mainly reviewed were the EPZ-6438 dose-escalation data that were previously presented at the EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in November 2014. Following that presentation, the response in one patient with an INI1-deficient malignant rhabdoid tumor that previously been classified and reported as a partial response was re-classified t oa complete response. Four of the 10 evaluable patients with NHL reported on in November continue on study, with time on study ranging from 29 weeks to 59 weeks, as of Jan. 23. (See *BioWorld Today*, March 11, 2011.)

Glycomimetics Inc., of Gaithersburg, Md., said results were published from a randomized, placebo-controlled phase II study evaluating the efficacy, safety and pharmacokinetics of rivipansel (GMI-1070) in patients with sickle cell disease hospitalized for a vaso-occlusive crisis. Study results were pre-published online by *Blood*. The article highlights rivipansel's potential to improve clinical outcomes in such sickle cell patients. Rivipansel is a selectin inhibitor, inhibiting E-selectin in particular.

Melior Pharmaceuticals Inc., of Exton, Pa., randomized the first patient into treatment arms of a phase II study aimed at evaluating the efficacy of MLR-1023 in type 2 diabetes. The four-week treatment protocol will enroll 120 subjects across 14 clinical sites in the U.S. and Korea. The study is a joint development effort between Melior and **Bukwang Pharmaceutical Co.**, of Seoul, South Korea. MLR-1023 is an oral insulin sensitizer said to improve glycemic control by directly and selectively activating the Lyn tyrosine kinase enzyme, which has been shown to modulate insulin-signaling pathways independently of PPAR-related interactions.

Myokardia Inc., of South San Francisco, started dosing in a phase I trial with MYK-461, described as the first-ever therapy designed to target the underlying cause of hypertrophic cardiomyopathy (HCM), the most common heritable cardiovascular disease. Patients with HCM are born with a mutation that causes overcontraction of the heart muscle cells, leading to thickening and stiffening of the heart muscle. MYK-461 has been designed to correct one of the most common molecular mechanisms causing HCM, the company said, and patients in the trial will be identified by genetic screening.

Orexigen Therapeutics Inc., of San Diego, disclosed in an 8-K filing that a planned 25 percent interim analysis from its ongoing LIGHT study, a trial requested by the FDA to evaluate cardiovascular outcomes for obesity drug Contrave (naltrexone/bupropion), showed a statistically significant cardiovascular benefit for Contrave vs. placebo. Orexigen used the new data to gain a new patent extending intellectual protection of the drug another seven years, to 2034, but analysts, while cautioning that the data are early, said the results could give Contrave an edge over its competitors in the obesity space. Piper Jaffray analysts wrote in a research note that they see the cardiovascular effect of Contrave "as surprisingly positive," with several implications, including the possibility of "driving competitive advantage in the U.S. market and enhancing probability of approvals ex-U.S." They also called the new patent "galvanizing." Shares of Orexigen (NASDAQ:OREX) jumped $1.85, or 32 percent, to close Tuesday at $7.64. (See *BioWorld Today*, Nov. 26, 2013, and Sept. 12, 2014.)

Soligenix Inc., of Princeton, N.J., received a positive recommendation from the data review committee to continue enrolling into the company's phase II study evaluating SGX942, an innate defense regulator as a treatment for oral mucositis in patients undergoing chemoradiation therapy for head and neck cancer. The committee recommended that enrollment include 20 more subjects randomized into either a single SGX942 dose group or the placebo group to allow for a more targeted assessment of the drug's potential effect and to inform final dose selection in that patient population. Soligenix described the drug as a new class of short, synthetic peptides that has a novel mechanism of action in that it has simultaneous anti-inflammatory and anti-infective activity.

PHARMA: OTHER NEWS TO NOTE

Actavis plc, of Dublin, said it closed its concurrent offerings of ordinary shares and mandatory convertible preferred shares for net proceeds of $4.1 billion and $4.9 billion, respectively. Actavis plans to use the proceeds, together with additional debt financing, including senior unsecured notes and borrowings under unsecured term loan facilities and an unsecured cash bridge loan facility, to finance a portion of its $66 billion acquisition of Irvine, Cali.-based **Allergan Inc.**, which includes a cash payment of $129.22 million. (See *BioWorld Today*, Nov. 18, 2014.)

PHARMA: OTHER NEWS TO NOTE

With sponsorship fromLondon-based **Astrazeneca plc**, the COPD Foundation unveiled an initiative designed to accelerate research and stimulate innovation for chronic obstructive pulmonary disease (COPD), a spectrum of inflammatory lung diseases that include chronic bronchitis and emphysema. Patients with COPD experience chronic respiratory symptoms such as difficulty breathing and coughing. The COPD360 program will enroll 125,000 patients to databases on an integrated research registry composed of the COPD Patient-Powered Research Network and physician registries. Once completed in the next three to five years, it will combine patient-reported outcomes, clinical data, electronic medical records and observational research into one of the largest COPD research networks ever assembled. Patients entered into the registry have agreed to share their health information and testimonies on how COPD has impacted their lives. The foundation said it hopes to uncover new opportunities for academic and industry researchers to identify new treatments. Astrazeneca provided $2.5 million for the COPD360 initiative.

Johnson & Johnson Innovation LLC, of San Francisco, part of Johnson & Johnson, said it opened JLABS @South San Francisco, a 30,000-square foot incubator that can accommodate up to 50 biotech, pharmaceutical, medical device, consumer and digital health start-ups. The first resident start-ups have been selected, including the winners of the Johnson & Johnson Innovation, JLABS Quick Fire Challenge, which was designed to recognize the most promising new, early stage innovation companies and award them with the use of a bench and access to the JLABS @SSF community.

Pfizer Inc., of New York, said the European Commission approved an expanded indication for the use of Prevenar 13 (pneumococcal polysaccharide conjugate vaccine [13-valent, adsorbed]) for the prevention of pneumonia caused by the 13 pneumococcal serotypes in the vaccine in adults 18 and older. The summary of product characteristics has also been updated to include efficacy data from Pfizer's landmark Community-Acquired Pneumonia Immunization Trial in Adults (CAPiTA), which demonstrated statistically significant reductions in first episodes of vaccine-type pneumococcal community-acquired pneumonia (CAP), including non-invasive/non-bacteremic CAP and invasive pneumococcal disease (IPD) in adults ages 65 and older.

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