

Message

From: Pharma Information Center [Pharma.InfoCenter@covidien.com]
Sent: 6/1/2012 12:38:11 AM
To: Pharma Information Center [Pharma.InfoCenter@covidien.com]
Subject: Pharma/Pain Priority News Brief - (5/31/12) - Pharma InfoCenter

Please email Dennis Eliceiri<mailto:dennis.eliceiri> directly of the Pharma InfoCenter<http://na-teamsites/pharmainfocenter> with any requests, questions or suggestions of other Covidien employees to add to the distribution list

[Pharma/Pain Priority News Brief]

<http://www.covidien.com>[Covidien]<http://www.covidien.com/><http://www.covidien.com>

Thursday - May 31, 2012

[http://nb.headlinespot.com/images/tabwhite.gif]

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Today's Categories:

R&D: Pain/Opioids | Generic Drugs | BUSINESS: Partnerships & Alliances | Company News | Trends | People
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R&D

PAIN/OPIOIDS [7-

days<http://nb.headlinespot.com/news_search.htm?advanced=0&brief=covidienpharma&category=a%3A1%3A%7Bi%3A0%3Bs%3A12%3A%22Pain%2FOpioids%22%3B%7D&all_stories=on&n_days=7&page=1> | 30-
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Prescription drug abuse can be stemmed with innovation, not restriction

<http://nb.headlinespot.com/newsbrief.php?brief=covidienpharma&date=20120531#NO-C1-S0>

Writing for Forbes, Gergana Koleva reported on the challenge of balancing the needs of patients with chronic pain and policymakers' efforts to rein in America's growing prescription drug crisis. She also discussed an opinion piece published online in The New England Journal of Medicine, which offers a vision of an "ideal" software for curbing prescription drug overuse. First, the software would track and save patient prescriptions over time, and it would also allow pharmacists to log in using a unique code issued by the Drug Enforcement Administration. This code would also serve as an identification number against forged or stolen prescriptions. Koleva noted that the imagined effect of this drug monitoring program would extend to other areas that necessitate timely medical information as well, such as law enforcement and medical examiners.

Forbes (5/30/12), [document] Read the
article<http://www.nejm.org/doi/full/10.1056/NEJMp1204493?query=featured_home> (5/30/12),

Flexion Phase II data for FX005 gives clinical PoC in arthritis
pain<http://alert.scripintelligence.com/c/123cJL0lFhFKb81o2BeFscZmT0>

Flexion Therapeutics reported topline data from a Phase II proof-of-concept study that showed that its lead anti-inflammatory drug candidate FX005 was well-tolerated, provided sustained pain relief and improved joint function for patients with moderate...

Scrip (5/31/2012) Please contact Dennis for the full-text and additional information

GW Pharmaceuticals initiates third Phase III cancer pain trial

GW Pharmaceuticals plc, an R&D company developing cannabinoid pharmaceuticals, has announced the initiation of a third Phase III Sativex clinical trial in the treatment of pain in patients with advanced cancer, who experience inadequate analgesia during optimized chronic opioid therapy.

GW's cancer pain clinical program is being wholly funded by Otsuka Pharmaceutical Co. Ltd, which has licensed the US commercialization rights to this product. The trials are designed to obtain approval in this indication from the FDA in the US, and these data will also be used by GW for future regulatory applications in this indication in Europe and around the world.

GW has previously announced the start of two pivotal Phase III cancer pain studies, both of which are proceeding on track and are expected to complete recruitment around the end of 2013. Regulatory filings are intended to be made upon completion of these two studies. This newly commenced third Phase III trial is a supportive study intended to provide, as needed, supplementary data to that generated in the first two studies.

The third Phase III trial differs in design from the first two studies, employing an enriched study design akin to that which was successfully employed in the MS spasticity trials program. The study involves exposing patients to Sativex in a single blind phase of two weeks duration (Phase A), following which responders will be randomized either to stay on Sativex or switch to placebo in a double blind phase for a five week treatment period (Phase B). The primary efficacy analysis will be the mean change from baseline in Phase B as measured using a 0-10 Numeric Rating Scale (NRS). The study will aim to recruit 540 patients into Phase A and target 216 patients to enter Phase B.

Prior to commencing the Phase III programme, GW completed two Phase II studies with positive results including over 500 patients in total.

Dr Stephen Wright, GW's R&D Director, said, "We are pleased to have commenced this planned third Phase III study evaluating the efficacy and safety of Sativex as a potential treatment for cancer pain. This clinical development programme, being performed in partnership with Otsuka, is the largest ever undertaken by GW. With significant numbers of patients with advanced cancer around the world suffering pain in spite of treatment with opioid therapy, Sativex has the potential to meet a very significant unmet need."

Datamonitor Pharmaceutical & HealthWire (5/30/2012)

Channel-tuning neuropathy<<http://www.nature.com/scibx/journal/v5/n22/full/scibx.2012.564.html>>

International researchers have shown that a methylglyoxal-scavenging peptide treated painful diabetic neuropathy in mice by preventing structural changes to a sodium channel in peripheral neurons. The team is seeking venture capital to spin out the findings into a new company.

Terry Snutch, CSO of Zalucus Inc., concurred. "It is a nice piece of work with a new and interesting angle on how Nav1.8 could contribute to painful diabetic neuropathy. It also adds to the growing base of evidence that Nav1.8 is involved in neuropathic pain in general."

Later this year Zalucus expects to take its lead compound, Z160, an oral N-type calcium channel blocker, into Phase IIa testing to treat neuropathic pain that is not related to diabetes. The company also has Z123212 (Z212), a small molecule that blocks the Nav1.7 (SCN9A) and Nav1.8 sodium channels, and other undisclosed sodium channel blockers in preclinical development to treat chronic inflammatory and neuropathic pain.

The only two drugs approved to treat pain associated with diabetic neuropathy are Lyrica pregabalin and Cymbalta duloxetine. The former has side effects such as edema, weight gain, concentration and attention deficits and suicidal thoughts. The latter carries a black box warning for suicidal thoughts and behavior, and has other side effects such as hepatotoxicity and increased blood glucose in patients with diabetes.

Pfizer Inc. and Eisai Co. Ltd. market the γ -aminobutyric acid receptor (GABA_A) agonist Lyrica to treat neuropathic pain, epilepsy and generalized anxiety disorder (GAD). Eli Lilly and Co. and Shionogi & Co. Ltd. market the selective serotonin and norepinephrine reuptake inhibitor (SSNRI) Cymbalta to treat diabetic peripheral neuropathic pain (DPNP), other types of chronic pain, anxiety and depression.

SciBx<<http://www.nature.com/scibx/journal/v5/n22/full/scibx.2012.564.html>> (5/31/2012) Please contact Dennis for the full-text

PLX Pharma Proposes "GI-Safer" OTC Aspirin In New Drug

Application<<http://click.elsevierbi.net/?qs=8f7a4768cd5f3594fc1ff60737f0ccbb1496db4fc389c40f8253ed9033d1784>>

The firm files a rare new drug application for an OTC product, a formulation of aspirin and phosphatidylcholine designed to be more tolerable to the gastrointestinal tract. The involvement of OTC veterans Peter Mann and Michael Valentino on PLX's board suggests strong market potential.

"The Pink Sheet" DAILY May 30,

2012<<http://click.elsevierbi.net/?qs=8f7a4768cd5f3594921732740858a49e0735dfc855c9b4db10423e46b582b74d>>

Please contact Dennis for the full-text and additional information

GENERIC DRUGS [7-

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Actavis launches generic equivalent of Adalat CC extended-release tablets
<<http://nb.headlinespot.com/newsbrief.php?brief=covidienpharma&date=20120531#N0-C3-S0>>

Actavis said Wednesday it received FDA approval of a generic version of Bayer's hypertension and angina drug Adalat CC (nifedipine) extended-release tablets, 90 mg. Actavis already sells the drug in 30-mg and 60-mg tablets. According to IMS Health, Adalat CC had sales of about \$23 million for the year ending Dec. 31, 2011.

PR Newswire (5/30/12)

Bayshore Pharmaceuticals announces pending ANDA acquisition from unnamed U.S. generics company
<<http://nb.headlinespot.com/newsbrief.php?brief=covidienpharma&date=20120531#N0-C3-S1>>

Bayshore Pharmaceuticals announced Wednesday the acquisition of a pending abbreviated new drug application by way of an asset purchase agreement with an unnamed, large U.S.-based generic pharma company. Bayshore said the product, which is expected to gain full FDA approval within the next quarter, has reported U.S. sales of about \$12 million over the previous 12-month period based on industry sales data. Terms of the deal were not disclosed. Bayshore develops and manufactures off-patent solid oral dose, semi-solid, ophthalmic and injectable products.

PR Web (5/30/12), [Reference] Generic Drug Reference

Commentary: Abbott's pipeline is crucial in advance of 2016 patent cliff
<<http://nb.headlinespot.com/newsbrief.php?brief=covidienpharma&date=20120531#N0-C3-S2>>

Forbes reported that Abbott Laboratories' best-selling rheumatoid arthritis drug Humira (adalimumab) and HIV drug Kaletra (lopinavir/ritonavir) are both set to lose patent exclusivity in 2016. According to estimates by Trefis, Humira's market share is likely to gradually decline as generic competition penetrates the market, with revenue significantly affected by the beginning of 2017. Trefis predicted that Kaletra's market share will continue its gradual decline through 2015, and then drop sharply after its patent expiry in June 2016.

[blog]Forbes (5/30/12), [Spotlight] Abbott Laboratories Spotlight

BUSINESS

PARTNERSHIPS & ALLIANCES [7-
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Phylogica hits new milestone in Pfizer project
<<http://nb.headlinespot.com/newsbrief.php?brief=covidienpharma&date=20120531#N0-C16-S0>>

Phylogica reached a new research milestone regarding its peptide drug discovery collaboration with Pfizer. The company will receive its second milestone payment from Pfizer as part of their collaboration and license agreement, which is worth up to \$134.5 million. The companies did not disclose details of the milestone or the size of the payment. The first milestone was reached in December 2011, at which time Phylogica identified several novel peptides that fit Pfizer's evaluation criteria.

Australian Life Scientist (5/31/12), Finance News Network (5/31/12), [Spotlight] Pfizer Spotlight

COMPANY NEWS [7-

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Teva stock moves from Nasdaq to NYSE

<<http://nb.headlinespot.com/newsbrief.php?brief=covidienpharma&date=20120531#N0-C18-S0>>

Phillip Frost, chairman of the board for Teva Pharmaceutical Industries, and company President and CEO Jeremy Levin rang the opening bell at the New York Stock Exchange with a group of Teva employees Wednesday. The group marked the company's transfer from the Nasdaq to the NYSE. "We are pleased to partner with the NYSE and begin using their state-of-the-art trading platform and market research," Frost said.

Philadelphia Business Journal (free reg. req'd) (5/30/12), Business Wire (5/30/12), [Spotlight] Teva Pharmaceutical Spotlight

Fresenius Kabi Oncology drops 20 percent as delisting hopes dim

<<http://nb.headlinespot.com/newsbrief.php?brief=covidienpharma&date=20120531#N0-C18-S1>>

The Business Standard reported that Fresenius Kabi Oncology Limited's stock dipped 20 percent, to 108 rupees per share, after its promoter - Singapore-based Fresenius Kabi Oncology - notified the company of an intention to undertake an offer for sale. Fresenius Kabi Oncology said in a filing that the offer would include the sale of up to 23.73 million shares, or about 15 percent of the total share capital of the company, in one or more tranches. The Business Standard said Fresenius Kabi Oncology, in which the promoter holds a 90 percent stake, is one of the delisting candidates.

Business Standard (5/31/12)

BioMarin announces public offering of common stock

<<http://nb.headlinespot.com/newsbrief.php?brief=covidienpharma&date=20120531#N0-C18-S2>>

BioMarin Pharmaceutical said it is offering to sell 6.5 million shares of its common stock in an underwritten public offering. The company also said underwriters will have a 30-day option to buy an additional 650,000 shares of common stock.

GlobeNewswire (5/30/12), [document] Read the SEC filing (5/30/12)

TRENDS [7-

days<http://nb.headlinespot.com/news_search.htm?advanced=0&brief=covidienpharma&category=a%3A1%3A%7Bi%3A0%3Bs%3A6%3A%22Trends%22%3B%7D&all_stories=on&n_days=7&page=1> | 30-
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Report: Health care costs to rise 7.5 percent in 2013

<<http://nb.headlinespot.com/newsbrief.php?brief=covidienpharma&date=20120531#N0-C19-S0>>

According to a report by PricewaterhouseCoopers, health care costs are expected to increase 7.5 percent in 2013 while premiums for large employer-sponsored health plans may increase by only 5.5 percent, resulting from company wellness programs and plans that impose higher insurance costs on employees. According to the report, slower medical growth is anticipated, resulting from issues such as increased use of generic drugs, the consolidation of hospitals and physician practices, insurance industry pressure on hospital expenses, price transparency, and a growing variety of primary care options such as workplace and retail health clinics.

Reuters (5/31/12), Bloomberg (5/30/12), PR Newswire (5/31/12), [video] Go to the report website (5/31/12)

Academia increasingly going beyond basic research by setting up translational med centers
<<http://nb.headlinespot.com/newsbrief.php?brief=covidienpharma&date=20120531#N0-C19-S1>>

Genetic Engineering & Biotechnology News reported both the University of California at San Diego and the University of Florida are in the process of developing translational medicine centers. The Board of Regents of UCSD are expected to be formally presented with plans for a \$110 million research center designed to accelerate development of new treatments by the university and its industry partners. The UF's \$45 million Clinical and Translational Research Building is scheduled for completion in February 2013. Additionally, Ohio State University and Ohio University contributed a combined \$35 million this year toward a new venture fund to finance early stages of biopharma and other innovative technology ventures. The projects reflect an increasing interest by academia toward a more active role in bringing novel medicines to market. Todd Sherer, president of the Association of University Technology Managers, said universities are a source of new technology and often a source of patients for clinical trials.

Genetic Engineering & Biotechnology News (5/30/12)

Commentary: Should pharma grow or shrink?

<<http://nb.headlinespot.com/newsbrief.php?brief=covidienpharma&date=20120531#N0-C19-S2>>

A blog post by Daniel R. Hoffman that appeared in The Philadelphia Inquirer said the pharmaceutical industry's leading competitors appear fundamentally at odds about whether they should grow bigger, smaller, more diversified or more focused. Hoffman said managers at some Big Pharma firms, including Novartis, Pfizer and GlaxoSmithKline, hope to dispel the traditional view that niche classes cannot justify the high fixed overheads by showing they can create synergies across a number of small, niche franchises. A number of pharma strategists have made the case that the best prospects for achieving growth and margins lie in smaller drug classes such as dermatology, ophthalmology, dental and podiatric therapeutics. "Big, small, diversified and pure-play can each be a potential winner, but a successful outcome requires the ability to work effectively with a company's situation and its competitive environment," Hoffman said.

[blog]The Philadelphia Inquirer (free reg. req'd) (5/30/12)

Researchers say overdiagnosis poses significant threat to human health

<<http://nb.headlinespot.com/newsbrief.php?brief=covidienpharma&date=20120531#N0-C19-S3>>

Overdiagnosis causes significant harm to healthy people while wasting resources, according to an article in BMJ. Ray Moynihan of Bond University in Australia and colleagues cited a large Canadian study that found almost a third of people diagnosed with asthma may not have the condition, as well as a systematic review that suggested as many as one in three breast cancer cases detected through screenings may be overdiagnosed. The authors wrote that factors such as commercial and professional vested interests, legal incentives, cultural issues, and more-sensitive tests that detect tiny "abnormalities" are driving the trend. "Increasingly we've come to regard simply being 'at risk' of future disease as being a disease in its own right," Moynihan said.

MassDevice (5/31/12), French Tribune (5/31/12), Dartmouth-Hitchcock Medical Center (5/30/12)

PEOPLE [7-

days<http://nb.headlinespot.com/news_search.htm?advanced=0&brief=covidienpharma&category=a%3A1%3A%7Bi%3A0%3Bs%3A6%3A%22People%22%3B%7D&all_stories=on&n_days=7&page=1> | 30-
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Icahn to nominate directors in second effort at Forest Laboratories

<<http://nb.headlinespot.com/newsbrief.php?brief=covidienpharma&date=20120531#N0-C26-S0>>

After a failed attempt in 2011 to install directors on Forest Laboratories' board of directors, billionaire investor Carl Icahn intends to back another slate of directors at the drugmaker's next shareholder meeting. Currently, Icahn holds 9.92 percent of the company's shares, making him the company's second-largest shareholder, according to Thomson Reuters. Icahn's proposed slate of directors would not constitute a majority of the board, according to an SEC filing. Forest said Icahn has not provided the names of his proposed nominees to the company.

Bloomberg (5/30/12), Reuters (5/30/12), AP (5/30/12), Business Wire (5/30/12), [document] Read the SEC filing (5/30/12)

EVENTS [7-

days<http://nb.headlinespot.com/news_search.htm?advanced=0&brief=covidienpharma&category=a%3A1%3A%7Bi%3A0%3Bs%3A6%3A%22Events%22%3B%7D&all_stories=on&n_days=7&page=1> | 30-
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Teva presents at Sanford C. Bernstein Strategic Decisions Conference

<<http://nb.headlinespot.com/newsbrief.php?brief=covidienpharma&date=20120531#N0-C28-S0>>

Teva Pharmaceutical Industries announced its President and CEO Jeremy Levin presented at the Sanford C. Bernstein Strategic Decisions Conference in New York on Wednesday.

Business Wire (5/30/12), [audio] Listen to the presentation (5/30/12), [Spotlight] Teva Pharmaceutical Spotlight

CALENDAR WATCH [7-

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Covidien to present at the Goldman Sachs Global Healthcare Conference

<<http://nb.headlinespot.com/newsbrief.php?brief=covidienpharma&date=20120531#N0-C29-S0>>

Covidien said its CEO Jose Almeida will present on June 7 at 8 a.m. PDT at the Goldman Sachs Global Healthcare Conference in Palos Verdes, Calif.

Business Wire (6/07/12), Listen to the presentation (6/07/12)

OTHER

U.S. GOVERNMENT [7-

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House approves user fee legislation, now must align its bill with Senate's version

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A bill reauthorizing and expanding the FDA's user fee programs passed the House in a 387 to 5 vote on Wednesday. The House must now reconcile the differences of its bill with that of the Senate, and though the two bills are similar, they have differences that are important to their sponsors, according to Modern Healthcare. Though both bills contain measures requiring drugmakers to notify the Department of Health and Human Services secretary at least six months before a drug is discontinued, the Senate bill featured a provision requiring the secretary to create a task force to improve the secretary's response to shortages and also create a plan to improve interagency coordination, while the House bill did not.

The Generic Pharmaceutical Association released a statement commending the House for approving the user fee proposals.

Reuters (5/30/12), Bloomberg (5/30/12), Modern Healthcare (free reg. req'd) (5/30/12), [blog] The Hill (5/30/12), MassDevice (5/30/12), Generic Pharmaceutical Association (5/30/12), [pdf] Read the House bill (5/09/12), [pdf] Read the Senate bill (5/31/12), [Reference] FDA Reference

Merck, Pfizer backed lawmakers in 2010 who oppose companies' products

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The Pharmaceutical Research and Manufacturers of America, with members including Johnson & Johnson, Pfizer, Bayer and Merck, donated approximately \$4.8 million in 2010 to Republican-leaning nonprofits that helped elect 23 lawmakers who subsequently voted to limit access to birth control and reduce federal funding for it. These companies earned approximately \$1.7 billion selling contraceptives, but they potentially are undermining their own products by supporting politicians who are looking to eliminate a revenue source for sales, according to Shelley Alpern, vice president of Trillium Asset Management.

Bloomberg (5/30/12)

U.S. aims to cut use of drugs on dementia patients

<<http://nb.headlinespot.com/newsbrief.php?brief=covidiénpharma&date=20120531#N0-C42-S2>>

On Wednesday, the Centers for Medicare & Medicaid Services announced a multiyear initiative to cut the unnecessary use of antipsychotic drugs in nursing home residents, noting that close to 40 percent of residents with dementia were given strong sedatives without having a condition to warrant the drugs' use. The regulator said it was looking to reduce the use of antipsychotic drugs by 15 percent in nursing homes by the end of 2012. The cutback will be helped by way of training on antipsychotic alternatives to settle an aggressive and agitated patient.

The Boston Globe (limited free access/reg. req'd) (5/31/12)

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Massachusetts may overturn its coupon ban

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The Massachusetts House and Senate approved amendments to the state budget that, if it becomes law in June, will allow consumers to use coupons to purchase prescription medicines. Gov. Deval Patrick indicated in his 2010 re-election campaign that he supported the measure, which the rest of the nation has also approved. A law from 1988 exists in the state that forbids any rebate for health care purchases.

[blog]Pharmalot (5/30/12), Boston Herald (5/29/12), State House News Service (5/29/12)

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Litigation as a drug safety risk index?

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The Institute for Safe Medicine Practices created a risk index that tallies a drug's serious domestic adverse events that are reported to the FDA in connection with lawsuits. In 2011, the nonprofit recorded 43,819 such filings made by drugmakers and coded as coming from lawyers, as opposed to doctors or consumers. The reports represented 19 percent of adverse events filed, not including nonserious and foreign reports. "Here are patients who alleged they have a serious injury, stepping forward and filing lawsuits... It's a vivid realization of safety concerns," said Thomas Moore, a senior scientist at ISMP.

[blog]Pharmalot (5/30/12)