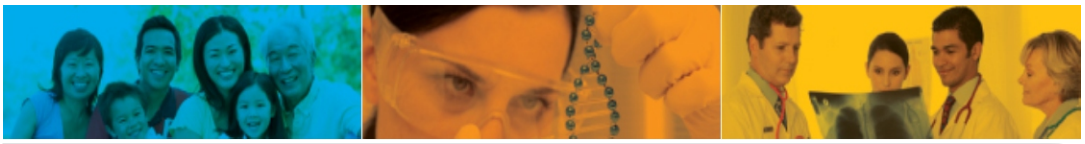

Clinical Research Update Volume - 6, June 2012

LAMBDA

CONTENTS

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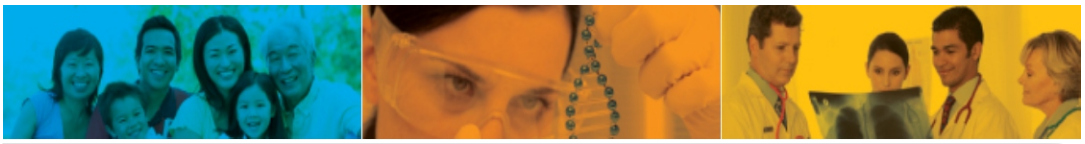

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GLOBAL NEWS

1.1. World Health Assembly Endorses New Plan To Increase Global Access to Vaccines

May 28, 2012

- At the Sixty-fifth World Health Assembly, Ministers of Health from 194 countries endorsed a landmark Global Vaccine Action Plan (GVAP), a roadmap, to prevent millions of deaths by 2020 through more equitable access to existing vaccines for people in all communities.

1.2. Thioridazine Successfully Kills Cancer Stem Cells in the Human

May 28, 2012

- A team of scientists at McMaster University has discovered a drug, thioridazine, successfully kills cancer stem cells in the human while avoiding the toxic side-effects of conventional cancer treatments.
- The next step is to test Thioridazine in clinical trials, focusing on patients with acute myeloid leukemia whose disease has relapsed after chemotherapy.

1.3. Biomarker Predicts Response to Cancer Treatment

May 22, 2012

- VIB researcher, Diether Lambrechts, associated with KU Leuven has discovered a biomarker that might potentially predict which patients will benefit more from treatment with bevacizumab (Avastin). If validated. This discovery could be an important step towards personalized medicine and patient-tailored use of this important cancer drug.
- If this biomarker would be clinically validated, it could be used to distinguish patients that would benefit from the drug from those that would not, and spare them a futile therapy with possible side effects.

DOMESTIC NEWS

2.1. Abbott, Syngene to Open First Nutrition R&D Center in India

May 04, 2012

- Abbott, a health care company, collaborated with Syngene, an Indian CRO and subsidiary of Biocon, to establish Abbott Nutrition R&D Center in the country. The facility will be based in Biocon Park in Bangalore and is expected to open in June 2012.
- The new R&D center will focus on the development of nutrition products for maternal and child nutrition and diabetes care.

2.2. Cipla's 'PRICE CUT'

May 09, 2012

- Cipla, one of India's leading pharmaceutical companies, announced a price cut of its drug, sorafenib, used for the treatment of liver and kidney cancers last week. The company claims its price of sorafenib will be Rs.6840 for a month's supply now. The company's announcement of the price cut of the cancer drug comes after the granting of compulsory license for the manufacture and sale of sorafenib by Patent Controller of India last March to Hyderabad based Natco.

2.3. Abbott's FDA Move Could Block Indian Biosimilar Drug Cos

May 07, 2012

- Innovator firm, Abbott Labs, has moved the US Food and Drug Administration (USFDA) and has urged it to block a lion's share of the existing biologicals market from generic versions or biosimilars as they are commonly known. Abbott has urged FDA not to grant licences to any biosimilars, the applications for which were received before March 23, 2010. The move, if approved by the USFDA, could dampen the prospects of Indian drugmakers eyeing the US market. Companies likely to be affected include Dr Reddy's, Biocon, Bharat Biotech, Serum Institute of India, Wockhardt, Lupin, Cipla and Glenmark.

REGULATORY UPDATES

3.1. Lenalidomide and Risk of New Cancers Ongoing safety review of multiple Myeloma Drug

May 07, 2012

- US FDA is informing the public of an increased risk of second primary malignancies (new types of cancer) in patients with newly-diagnosed multiple myeloma who received Revlimid (lenalidomide).
- Clinical trials conducted after Revlimid was approved showed that newly-diagnosed patients treated with Revlimid had an increased risk of developing second primary malignancies compared to similar patients who received a placebo. Specifically, these trials showed there was an increased risk of developing acute myelogenous leukemia, myelodysplastic syndromes, and Hodgkin lymphoma.
- This safety information has been added to the Warnings and Precautions section of the Revlimid drug label and the Patient Medication Guide is also being updated to inform patients about this risk.

3.2. Venus Remedies Bags another Patent Grant from South Africa

May 21, 2012

- Venus Remedies Limited, a research based global pharmaceutical company, has received its first patent for a novel antibiotic combination of carbapenem and aminoglycoside. Pioneering into antibacterial portfolio, Venus has added another international patent from CIPRO (Companies and Intellectual Property Registration Office), South Africa to its basket for the antibiotic combination designed to result in a pharmaceutical low dose. Overall, Venus is enjoying a total tally of more than 80 patents for its innovative research products across the globe.

3.3. US FDA May Impose Huge Drug User Fee on Generic Imports Soon

May 21, 2012

- The US FDA may introduce a Generic Drug User Fee Act (GDUFA) soon to curb import of cheap generic drugs into that country. The proposed Act empowers the US government to fix an exorbitant fee on the import of each generic product category coming from any overseas sources. The US currently imports about 80 per cent of APIs and 40 per cent of generics made in the overseas locations.

- The US Food and Drug Administration (FDA) recently completed and submitted its recommendations for the proposed Generic Drug User Fee Act (GDUFA) to the Congress. The proposed fees could range from $35,000 for API manufacturers to $150,000 for finished drug units.

DRUG IN DEVELOPMENT

4.1. Lundbeck Boosted by Phase III Antidepressant Data

May 15, 2012

- Lundbeck and partner Takeda Pharmaceutical Co are planning to file a new antidepressant in the coming months on the back of positive late-stage data from three recently-completed Phase III studies of Lu AA21004, for the treatment of adults with major depressive disorder using dosages from 10 to 20mg. The data from the three studies showed that the drug statistically significantly reduced depression symptoms in patients with MDD compared to placebo.

4.2. Elevation Pharma releases positive phase IIb results in COPD

May 17, 2012

- Elevation Pharmaceuticals, a San Diego-based company focused on the development of new aerosol therapies, has released positive results from a phase IIb study of EP-101 in patients with chronic obstructive pulmonary disease (COPD), a progressive disease of chronic bronchitis and emphysema.
- EP-101 is a proprietary inhalation solution formulation of glycopyrrolate, a long-acting muscarinic antagonist (LAMA), delivered by a proprietary investigational eFlow nebulizer device licensed from PARI Pharma GmbH.

4.3. Janssen's Nucynta Meets Primary Endpoint in Diabetic Peripheral Neuropathy Study

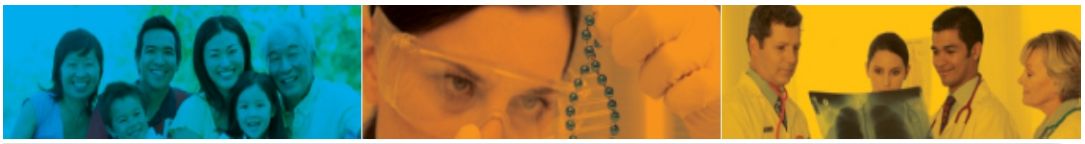
May 21, 2012

- Janssen Pharmaceuticals has issued results from an investigational phase III study suggesting Nucynta ER (tapentadol) extended-release tablets were significantly more effective than placebo in providing pain management among adults with chronic moderate to severe, painful diabetic peripheral neuropathy (DPN).

4.4. Phase 3 Trial of Nexavar in Patients with NSCLC Fails to Meet Primary Endpoint

May 23, 2012

- Bayer HealthCare Pharmaceuticals and Onyx Pharmaceuticals, Inc. have reported that the phase 3 trial evaluating Nexavar (sorafenib) tablets in patients with advanced relapsed or refractory non-squamous non-small cell lung cancer (NSCLC) whose disease progressed after two or three previous treatments, did not meet its primary endpoint of improving overall survival. An improvement in the secondary endpoint of progression-free survival (PFS) was observed.



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DRUG APPROVALS

5.1. US FDA Committee Recommends Approval of Pfizer's Tofacitinib May 11, 2012

- The FDA has provided an anticipated Prescription Drug User Fee Act (PDUFA) action date in August 2012. If approved by the FDA, tofacitinib would be the first new oral disease-modifying antirheumatic drug (or DMARD) for adult patients with moderately to severely active RA in more than 10 years and the first RA treatment in a new class of medicines known as Janus kinase (JAK) inhibitors.

5.2. Novo Nordisk gets US FDA Nod for Expanded Use of Levemir in Children with Type 1 Diabetes
May 23, 2012

- The US Food and Drug Administration (FDA) has approved Novo Nordisk's, a world leader in diabetes care, Levemir (insulin detemir [rDNA origin] injection) for use in children ages two to five years with type 1 diabetes. With the expansion of its paediatric indication, Levemir is now available for type 1 diabetes patients from age two through adulthood and adult patients with type 2 diabetes. The FDA approval now makes Levemir the first and only basal insulin analog for use in this young patient group.

5.3. Bayer Seeks US FDA Approval for Regorafenib to Treat Metastatic Colorectal Cancer
May 25, 2012

- Bayer HealthCare, a subsidiary of Bayer AG, has submitted a New Drug Application (NDA) to the US Food and Drug Administration (FDA) seeking approval for the oral multi-kinase inhibitor regorafenib for the treatment of patients with metastatic colorectal cancer (mCRC).
- Bayer has also submitted an application for European marketing authorization for regorafenib for the treatment of patients with mCRC.

MERGER AND ACQUISITIONS

6.1. Watson will Pay up to €4.5 billion for Actavis April 25, 2012

- Watson Pharmaceuticals, Inc. and Actavis Group today jointly announced that Watson has entered into a definitive agreement to acquire privately held Actavis for approximately €4.25 billion upfront. As a result of this acquisition, Watson will become the third largest global generics company with 2012 anticipated pro forma revenue of approximately $8 billion.

6.2 Novartis to acquire Fougera Pharmaceuticals May 04, 2012

- Switzerland-based Novartis has signed a definitive agreement to acquire specialty dermatology generics company Fougera Pharmaceuticals of Melville, N.Y., for $1.5 billion in cash.

6.3. Piramal Healthcare to Acquire Decision Resources Group — May 16, 2012

- Piramal Healthcare, an innovation led company, has agreed to acquire Decision Resources Group (DRG), a US based company in the healthcare information segment, for a consideration of approximately US$ 635 million i.e. Rs. 3,400 crore.
- DRG provides high quality, web-enabled research, predictive analytics via proprietary databases and consulting services to the global healthcare industry.

6.4. Takeda Buys Brazil's Multilab in $266.3 Million Deal — May 25, 2012

- Takeda Pharmaceutical Co is expanding its global reach by acquiring Brazilian drugmaker Multilab Industria e Comercio de Produtos Farmaceuticos. The Japanese major is initially paying 500 million R$ ($246.5 million) in cash, plus up to 40 million R$ in additional future milestone payments.

MEDIFACTS

7.1. Calcium Supplements Linked to Significantly Increased Heart Attack Risk — May 25, 2012

- Calcium supplements might increase the risk of having a heart attack, and should be "taken with caution". Calcium supplements are commonly recommended to elderly people and women who have gone through the menopause to prevent bone thinning. The calcium should be used as an important component of a balanced diet, and not as a low cost panacea to the universal problem of postmenopausal bone loss.
- The analysis looked at vitamin/mineral supplements, it found that those who took calcium supplements regularly were 86% more likely to have a heart attack than those who didn't use any supplements.
- The study suggests that increasing calcium intake from diet might not confer significant cardiovascular benefits, while calcium supplements, which might raise [heart attack] risk, should be taken with caution.

7.2 High BMI May Reduce Efficacy of Infliximab — May 25, 2012

- Patients with ankylosing spondylitis (AS) who have a high body mass index (BMI) may derive less benefit from infliximab (IFX) than patients with a lower BMI, according to the results of a retrospective analysis in Arthritis Research & Therapy. IFX is prescribed based on body weight, and yet huge variations of inter-individual serum concentrations have been reported in different inflammatory diseases. Thus, the consequence of excess fat mass on drug metabolism could be a serious problem when placed in the context of the increasing number of obese patients worldwide. The authors conclude that further studies are needed to determine how their results should influence the treatment of patients with rheumatoid arthritis and AS.