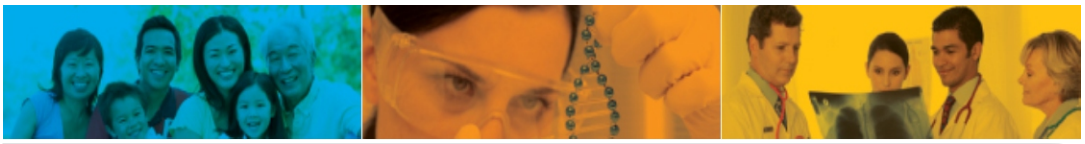

Clinical Research Update Volume - 10, October 2012

LAMBDA

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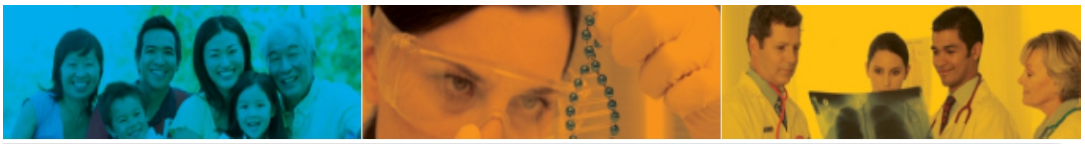


LAMBDA

GLOBAL NEWS

1.1. Ten Drug Majors Combine to Tackle Clinical Trial Inefficiency

Sep 20, 2012

- Abbott, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Pfizer, Roche and Sanofi have formed a non-profit organisation, called TransCelerate BioPharma, to accelerate the development of new medicines by "identify and solve common drug development challenges with the end goals of improving the quality of clinical studies".
- This is the largest ever initiative of its kind will be headed up by Garry Neil, a partner at Apple Tree Partners and former head of science and technology with J&J.

1.2. Novo Nordisk Boosts China R&D with $100M Diabetes Research

Sep 24, 2012

- Novo Nordisk cut the ribbon on a $100 million expansion of its R&D complex in China, which will make room for 70 more scientists and for a full range of protein research services in China, adding that the company will soon have 200 investigators at work in Beijing in the near future. Man force will be plugged in to a global R&D network, sharing ideas and creating new drugs with colleagues in Denmark and the U.S.

1.3. Atreca Lands $6M for Vaccine Research

Sep 25, 2012

- Atreca, a San Carlos, CA-based biopharmaceutical company, captured a $6 million investment from the Bill & Melinda Gates Foundation to accelerate the discovery and development of novel vaccines infectious diseases mainly focus on malaria, HIV/AIDS and tuberculosis. Atreca will apply its Immune Repertoire CaptureTM technology to a set of infectious diseases.

1.4. Boston Scientific Parkinson's DBS treatment wins CE Mark

Sep 28, 2012

- Boston Scientific gained a CE mark for its Vercise deep brain stimulation system for Parkinson's disease. It uses electrical signals on specific areas of the brain to address Parkinson's symptoms. The Natick, MA-based device company bills its system as the first on the commercial market able to use multiple independent current controls. Vercise could reach an enormous amount of Parkinson's patients, approx 6.3 million people globally, cited from the European Parkinson's Disease Association.

DOMESTIC NEWS

2.1. Mylan Selected As A Leading ARV Supplier To India's NACO

Sep 05, 2012

- Mylan Laboratories, a subsidiary of Mylan Inc., has been selected as a leading supplier of antiretroviral (ARV) drugs to India's National AIDS Control Organization (NACO). NACO is a division of India's Ministry of Health and Family Welfare and is responsible for overseeing HIV/AIDS control programs in India. NACO's objective is to halt and reverse the HIV/AIDS epidemic in India over the next 5 years.

- Approximately one-third of HIV/AIDS patients in developing countries depend on a Mylan ARV product, and Mylan has recently entered the Indian commercial market, starting with a portfolio of ARV drugs.

2.2. Intercell's Jeev Vaccine Debuts in India Sep17, 2012

- Austrian biotech group Intercell's Japanese encephalitis vaccine hit the market in India. Intercell aims to win approval for the vaccines in other Asian countries, where Swiss drug giant Novartis will handle sales. The vaccine, called Jeev in India and Ixiaro in other markets, works against the mosquito-borne illness that can cause fever, convulsions and comas. The launch of Jeev vaccine in India marks a new milestone for Intercell's cell culture-derived technology, according to the company.

2.3. 348 Essential Drugs To Be Under Price Control Sep 28, 2012

- After several years of debates and discussions, the Group of Ministers (GoM) has finally approved the national pharmaceutical pricing policy to control the prices of all essential drugs and adopted the weighted average price (WAP) mechanism to cap the prices. The GoM has decided to bring all 348 essential drugs listed by the Health Ministry under the price control and would send the recommendations to the Cabinet for the final call. The essential drugs have a total sale of around ₹29,000 crore, accounting for almost 60 % of the domestic market. At present, only 74 bulk drugs and their formulations are under the control of the government.

REGULATORY UPDATES

3.1. Cancer Drugs Approved Faster than Others in Us, But not in EU Sep 07, 2012

- According to the study published by the US Tufts Center for the Study of Drug Development (CSDD), during 2002 to 2011 the times taken by US regulators to approve new drugs of cancer have been shorter than for the non-oncology drugs (on average 10 month lesser), while in the European Union (EU) the reverse has been observed (on average 2 months shorter for non-oncology drugs than for oncology). As per CSDD Impact Report, approval times for non-oncology drugs in the EU were 27% shorter than in the US, but 54% longer for oncology therapeutics; 39% of US approvals for orphan drugs were for oncology and for EU it was 37% during 2007-11 comparing to 2002-06, increased 31% for US and 28% for EU.

3.2. MHRA Issues Blue Guide on Advertising & Promotion of Medicine Sep 10, 2012

- Medicines and Healthcare products Regulatory Agency (MHRA) has just released the Blue Guide on advertising and promotion of medicines in the UK. It introduces controls on medicines advertising in the UK and provides background information on the development of Blue Guide.

3.3. EU Proposes Tougher Device Rules in Light Of Implant Scandal — Sep 26, 2012

- On the heels of Europe's faulty silicone breast implant scandal, the European Union is proposing to tighten regulations on medical devices around the continent. For starters, the EU wants to expand its definition of medical devices to include aesthetic implants, like the faulty silicone ones unmasked in the Poly Implant Prothese scandal.
- Otherwise, the EU proposes to expand the powers of independent regulators, allowing them to conduct random inspections of device manufacturers and regular product testing. The government also wants to focus on traceability, giving physicians and patients easier access to information on device failures.

3.4. FDA will Reorganise ORA for Drug Industry Globalization — Sep 28, 2012

- The FDA is planning to reorganize its Office of Regulatory Affairs (ORA), including creating new offices and reorganizing others, as it takes steps to dissolve cumbersome domestic and international distinctions and to keep up with increasingly global operations. The restructuring will also better position the ORA to address new legislative authorities included in the FDA Safety and Innovation Act (FDASIA), signed into law this summer, which boosts the FDA's supply chain oversight and inspection authority while allowing for risk-based approaches to both major changes that call for “new strategies” and enhanced coordination across the office, according to an agency fact sheet on the ORA reorganization.

DRUG APPROVALS

4.1. FDA Approves First Drug for Children with Rare Brain Tumor — Sep 03, 2012

- The FDA has approved Novartis' Afinitor Disperz (everolimus tablets for oral suspension), a new pediatric dosage form of the anti-cancer drug Afinitor used to treat subependymal giant cell astrocytoma (SEGA, a rare brain tumor). The action marks the first approved pediatric-specific dosage form developed for the treatment of a pediatric tumor.
- Afinitor Disperz is recommended to treat patients ages 1 year and older with tuberous sclerosis complex (TSC) who are diagnosed with SEGA that cannot be treated with surgery. Prior to approval of this new dosage form, Afinitor was recommended for use only in patient's ages 3 years old and older. Afinitor was granted accelerated approval in 2010 to treat SEGA in patients with TSC.

4.2. Janssen R&D Gains FDA Priority Review for TB Drug — Sep 05, 2012

- The FDA has granted Janssen Research & Development priority review to the New Drug Application (NDA) for bedaquiline (TMC207) to treat pulmonary, multi-drug resistant tuberculosis (MDR-TB) in adults as part of combination therapy. The FDA grants priority review to medicines that may offer major advances in care or provide a treatment option where no adequate therapy exists. Under the Prescription Drug User Fee Act (PDUFA), the FDA will aim to complete its review within six months of the NDA submission. The NDA was submitted June 29, 2012.

4.3. First Drug for Rare Blood Cancer Gets UK Launch — Sep 11, 2012

- UK patients with a rare form of blood cancer will now, for the first time, have access to a targeted therapy against their disease following the launch of Novartis' Jakavi in the country. Myelofibrosis is a rare, potentially life-threatening blood cancer. Jakavi (ruxolitinib) is a first-in-class JAK 1 and JAK 2 inhibitor, and is now available to treat patients in the UK with disease-related enlarged spleen or various forms of myelofibrosis, which affects around 0.34-0.76 people in every 100,000.

4.4. Sanofi Snags FDA OK for oral MS Drug Aubagio, Prices at $45K — Sep 12, 2012

- Sanofi won a badly needed FDA approval for its oral multiple sclerosis drug Aubagio (teriflunomide), a prospective blockbuster breakthrough for the pharma giant. In a clinical trial, the relapse rate for patients using Aubagio was about 30 percent lower than the rate for those taking a placebo. MS treatment will be priced at $45,000 a year, angling in to grab market share. The price of Copaxone is 7% more, price of Avonex is 8% more and the price of Gilenya is 28% more than the price of Aubagio.

4.5. Mylan Launches First Generic Version of Diovan HCT® Tablets — Sep 21, 2012

- Mylan Inc. (MYL) announced that its subsidiary Mylan Pharmaceuticals has received final approval from the USFDA for its ANDA for Valsartan and Hydrochlorothiazide Tablets USP, 80/12.5 mg, 160/12.5 mg, 160/25 mg, 320/12.5 mg and 320/25 mg. This product is the generic version of Novartis' Diovan HCT® Tablets, which are indicated for the treatment of hypertension, to lower blood pressure in patients not adequately controlled with monotherapy or as initial therapy in patients likely to need multiple drugs to achieve their blood. The company will have 180 days marketing exclusivity.

DRUG IN DEVELOPMENT

5.1. Sophiris' Transrectal Injection for Enlarged Prostate Well Tolerated — Sep 03, 2012

- Sophiris Bio, a urology company based in La Jolla, Calif., released data from its transrectal safety study, in which PRX302, the company's drug candidate for the treatment of benign prostatic hyperplasia (BPH or enlarged prostate), was well tolerated through three months following a transrectal injection. The results support the use of a transrectal ultrasound (TRUS) guided injection for the delivery of PRX302 directly into the prostate. This route of administration will be used in future clinical trials of PRX302 in patients with BPH.

5.2. ESTEVE Announces Phase 1 Trial Results of E-52862 — Sep 05, 2012

- ESTEVE, a pharmaceutical chemical group based in Barcelona (Spain), announces the recent publication in the British Journal of Clinical Pharmacology of the results of phase I clinical trials of the new sigma receptor antagonist-1, E-52862, highly potent and selective, once-daily oral, developed by the team R&D of ESTEVE. The study results show a good overall safety profile, tolerability, pharmacodynamics and pharmacokinetics for all doses of E-52862 investigated.

5.3. Novartis Drug Lucentis® Confirms Long-Term Efficacy & Safety Sep 05, 2012

- New data for Lucentis® (ranibizumab), the only anti-VEGF therapy licensed across three ocular indications, show that individualized treatment with Lucentis provides sustained improvement in vision with a low number of injections. It is estimated that over 80% of visual impairment is preventable when due to conditions such as wet age-related macular degeneration (wet AMD), diabetic macular edema (DME), and visual impairment due to macular edema secondary to retinal vein occlusion (RVO). These conditions can eventually lead to blindness if left untreated.

5.4. Novartis CF Therapy Sails through FDA Advisory Panel Review Sep 06, 2012

- Novartis found it relatively easy to convince a lopsided majority of experts on an FDA advisory panel to sign off on its new powdered formulation for an inhaled cystic fibrosis therapy. The inhaled antibiotic is intended to treat lung infections that afflict CF patients, and by a vote of 13 to 1 the outside experts recommended it to regulators for approval.
- Novartis has been pushing for an easier form of delivery, replacing the nebulizer that had been required to deliver tobramycin in favor of an inhaler.

5.5. PsiOxus Launches Phase I/II Trial of Oncolytic Vaccine Sep 26, 2012

- PsiOxus Therapeutics, a U.K.-based development stage biotech, has initiated Evolve (EValuating OncoLytic Vaccine Efficacy) study which is the first clinical trial of the systemically available oncolytic vaccine ColoAd1, a highly potent, broad-spectrum, anti-cancer therapeutic capable of destroying tumor cells at minute concentrations. The safety, biological activity and efficacy of ColoAd1 will be evaluated in 126 patients, with initial results expected by the end of 2013.

5.6. Vertex announces Positive Results of ALS-2158 for Hepatitis C Sep 27, 2012

- Vertex Pharmaceuticals Incorporated and its collaborator Alios BioPharma have announced results from a viral kinetic study of the adenosine nucleotide analogue pro-drug ALS-2158 for the treatment of hepatitis C. Data showed that seven days of dosing with up to 900 mg of ALS-2158 was well-tolerated in people with genotype 1 chronic hepatitis C, but there was insufficient antiviral activity to warrant proceeding with further clinical development.

MERGER, ACQUISITION AND COLLABORATION

6.1. CLC Bio Acquires Molegro Sep 05, 2012

- CLC bio, a provider of bioinformatics solutions, has acquired Molegro, a specialized software company focusing on molecular docking, including prediction and analysis of protein-ligand interactions, screening of compound databases for activities against a receptor and determination of molecule similarity. The acquisition of Molegro supports CLC bio's strategy of continuously expanding their bioinformatics offerings beyond Next Generation Sequencing, as well as in bioinformatics areas of value to their customer base.

6.2. Panacea Biotec Ties-up with Osmotica Pharmaceutical Sep 11, 2012

- Panacea Biotec has entered into a strategic alliance with Osmotica Pharmaceutical for the research, development and commercialization of drug delivery based, high barrier to entry generic and branded pharmaceutical products in US and key strategic markets across the globe. The collaboration is designed to build upon each company's highly complementary strengths and quality assets.

6.3. Clinipace Worldwide Acquires Paragon Biomedical Sep 25, 2012

- Clinipace Worldwide, a global digital contract research organization (dCRO), and Paragon Biomedical, a global, full-service CRO, have jointly announced a definitive merger agreement under which Morrisville, N.C.-based Clinipace Worldwide has acquired all outstanding shares of privately-held, Irvine, Calif.-based Paragon and its subsidiaries.

6.4. Accenture completes acquisition of Octagon Sep 28, 2012

- Accenture, a global management consulting, technology services and outsourcing company, has completed the acquisition of Pennsylvania based Octagon Research Solutions, Inc., a provider of clinical and regulatory information management solutions and software for the pharmaceutical industry.

PATENT (LITIGATION/SETTLEMENTS)

7.1. Teva Sues Perrigo over Proair Asthma Inhaler Patents Sep 07, 2012

- Teva Pharmaceutical Industries Ltd. has filed patent infringement suit with the US District Court of Delaware against Perrigo Company and Catalent Pharma Solutions Inc. over their joint generic version of ProAir HFA aerosol inhaler. Perrigo and Catelent partner filed an ANDA with the USFDA for the asthma treatment.

7.2. IPAB Rejects Bayer's Plea for Stay on Grant Of Compulsory License Sep 07, 2012

- India's Intellectual Property Appellate Board (IPAB) rejected the German drug major Bayer's request for a stay order against the grant of compulsory license on its anti-cancer drug Nexavar to Natco Pharma. This case is important as it will test Section 84 of the Indian Patent Act, under which the CL mechanism kicks in when generic competitors request a CL.

7.3. Depomed Files Suit Against FDA for Gralise's Orphan Drug Exclusivity Sep 07, 2012

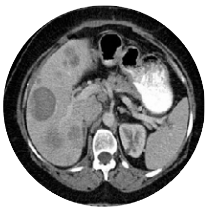
- Depomed announced that it has filed an action in federal district court for the District of Columbia against the Food and Drug Administration, seeking an order requiring the FDA to grant Gralise® (gabapentin) Orphan Drug exclusivity for the management of postherpetic neuralgia (PHN). A grant of orphan drug exclusivity would provide Gralise marketing exclusivity in the United States for the management of PHN until January 28, 2018, seven years after the date of Gralise's approval for PHN.

LAMBDA - MEDICAL IMAGING CAPABILITIES

Imaging based surrogate endpoints have become essential for clinical trials to provide an insight to drug safety and efficacy much faster than traditional clinical endpoints because central reviews are preferred by regulatory agencies for authenticity and acceptability of clinical study data.

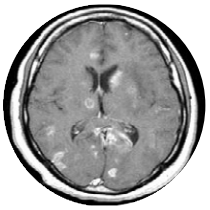
Lambda, with its state-of-the-art Imaging Technologies ("Cent - Re - View") and industry experienced team, is well placed to offer full spectrum of Central Review Services for wide range of therapeutic segments. Lambda Imaging offers highly cost effective Central Review Services and consultation for our Sponsors as standalone or as part of package.

THERAPEUTIC EXPERTISE



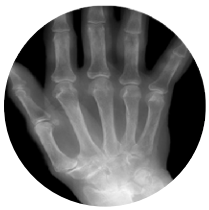
Oncology

- Solid Tumours
- Lymphoma
- Melanoma



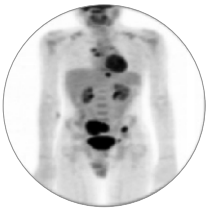
CNS and Neuro - Oncology

- Brain Tumours / Glioma
- Alzheimer's Disease
- Stroke
- Multiple Sclerosis
- Brain Injury



MSK

- Rhumatoid Arthritis
- Osteoarthritis
- Spinal Devices Osteoporosis
- Fat Segmentation
- Orthopaedic



Others

- Echo, MRI, Angiography
- Surgery, Contrast Media, Uterus
- wherever you can think of CT / MRI / USG/ PET scans

ASSESSMENT CRITERIA EXPERTISE

- RECIST 1.0 and 1.1
- WHO
- Volumetric Assessment
- IWG 2007
- MAcDonald Criteria
- RANO
- Van der Heidje Modified Sharp Score
- Fracture Healing Assessment

KEY STRENGTHS

- End-to-End Imaging Review Services for range of therapeutic areas for various assessment criteria
- Cent - Re - View - A 21CFR Part11 compliant Central Imaging Review Platform for performing central independent review in all therapeutic segments
- Web-based Image upload from sites anywhere across the globe in compliance of HIPAA & local regulations
- No "Manual Errors" due to automated calculations & in-built logic checks
- Complete Audit Trail from Image Upload till Data Export