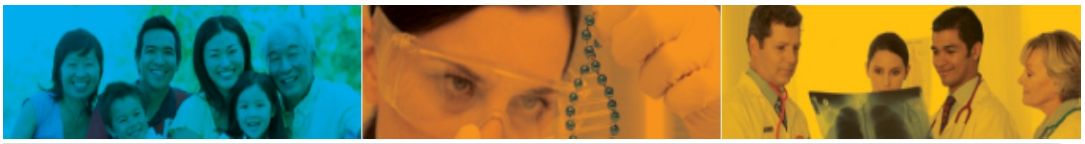

Clinical Research Newsletter Volume - 7, July 2014

LAMBDA

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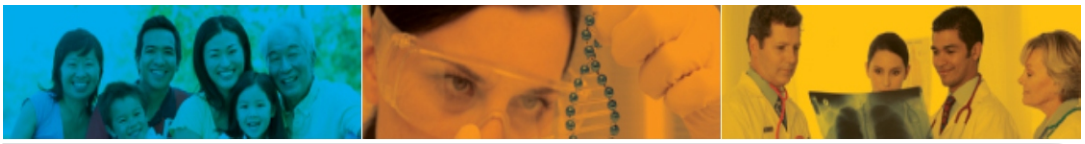
Contact Us

Dr. Mrinal Kammili, Director Global Head - BD
mrinal@lambda-cro.com

Dr. Manish Sharma, AVP, Medical Affairs
manishsharma@lambda-cro.com



LAMBDA

GLOBAL NEWS

1.1. Pharmacyclics/J&J's ibrutinib could revolutionise CLL Jun 02, 2014

- Pharmacyclics and Johnson & Johnson's ibrutinib has caused a stir at the American Society of Clinical Oncology meeting in Chicago, with many observers predicting that it will revolutionise treatment of chronic lymphocytic leukaemia. Approved by the US FDA in February for CLL (it was also approved for mantle cell lymphoma in 2013) and marketed as Imbruvica, ibrutinib is poised to replace standard of care, particularly for elderly CLL patients who are unable to tolerate traditional chemotherapy.

1.2. Eli Lilly begins sharing of clinical trial data through website Jun 04, 2014

- Eli Lilly and Company announced it will begin sharing its clinical trial data with scientific researchers through www.clinicalstudydatarequest.com. This website, which houses data from several clinical trial sponsors, was created in support of ongoing efforts by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) to increase access to and transparency of clinical trial results with researchers around the world.

1.3. Novo Nordisk to hire 6,000 new employees in Denmark by 2022 Jun 12, 2014

- Novo Nordisk, a global healthcare company with more than 90 years of innovation and leadership in diabetes care, to hire 6,000 new employees in Denmark by 2022, half of whom will work within research and development. The new jobs will have the derived effect of boosting employment by more than 15,000 jobs nationally.

1.4. NICE U-turn on Novartis' Glivec in GIST Jun 26, 2014

- In a U-turn from previous guidance, the National Institute for Health and Care Excellence is now planning to recommend National Health Service use of Novartis' Glivec (imatinib) for the treatment of digestive system tumours. The cost watchdog has now published draft guidance endorsing the drug's use as an adjuvant treatment for up to three years for adults who are at high risk of relapse after surgery for KIT (CD117)-positive gastrointestinal stromal tumours (GIST), three and a half years since original guidelines rejected the drug.

REGULATORY NEWS

2.1. Expert panel on FDC to assess safety, efficacy of several FDCs on June 11 Jun 09, 2014

- The union health ministry's expert panel, constituted for the massive exercise of examining and regularising the thousands of fixed dose combinations (FDCs) permitted for manufacture and sale in the country without due approval from the Drugs Controller General of India (DCGI), will hold its fourth meeting on June 11 to scrutinise several FDC applications filed by different pharma companies. The expert panel, set up by the CDSCO following the huge number of applications, running over 5000, has already held three meetings and examined several FDC drugs.

2.2. FDCs licenced prior to Sept 21, 1988 excluded from proving safety, efficacy to DCGI Jun 09, 2014

- Thousands of FDC drug manufacturers in the country engaged in production of drugs, licensed prior to September 21, 1988, can now heave a sigh of relief as the Drugs Controller General of India (DCGI) has excluded such drugs from the requirement of proving the safety and efficacy of FDC drugs licenced by the State licencing authorities (SLAs) without due approval from the DCGI. On January 15 last year, the DCGI had asked the manufacturers to prove the safety and efficacy of the FDCs approved before October 1, 2012 and had made it clear that those FDCs approved by the SLAs from October without the permission of the DCGI will be considered for ban.

2.3. FDA grants priority review to AbbVie hepatitis C combo Jun 14, 2014

- Regulators in the USA will make an accelerated assessment of AbbVie's investigational all-oral interferon-free hepatitis C therapy. Specifically, the US Food and Drug Administration has granted a priority review to the combination for the treatment of chronic genotype 1 HCV infection. The therapy consists of three antivirals - ABT-450/ritonavir (150/100mg) co-formulated with ombitasvir (ABT-267) 25mg, dosed once daily, and dasabuvir (ABT-333) 250mg, dosed twice daily.

DRUG APPROVALS AND LAUNCHES

3.1. Bayer bags rights to haemophilia A gene therapy Jun 24, 2014

- Bayer has linked up with Dimension Therapeutics to develop a gene therapy for haemophilia A in a deal that could be worth about $250 million to the US biotech. The German group has long been a major player in haemophilia A with its recombinant factor VIII (rFVIII) blockbuster Kogenate and earlier this year it unveiled plans to invest more than 500 million euros at two manufacturing sites to prepare for the production of two investigational treatments for the bleeding disorder.

3.2. Intas launches Azadine in India Jun 25, 2014

- Reinforcing its oncology product range, Intas Pharmaceuticals recently introduced azacitidine molecule in Azadine in India to help fight Myelodysplastic Syndrome (MDS) and acute myelogenous leukaemia (AML). Azadine has been priced with an objective to make it accessible to a majority of the needy patients and is priced at 1/5th of the innovator brand.

DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

4.1. Phase 3 study of Velcade-based therapy significantly improves PFS Jun 03, 2014

- The Takeda Oncology Company announced results from the primary analysis of an international, randomized phase 3 study that showed treatment with a Velcade (bortezomib)-based combination therapy demonstrated a 59 per cent relative improvement in the study's primary endpoint of progression-free survival (24.7 vs. 14.4 months; Hazard Ratio among previously untreated patients with mantle cell lymphoma (MCL) compared to treatment with a standard therapy. These data were presented at the annual meeting of the American Society of Clinical Oncology (ASCO).

4.2. Novartis phase III trial of LBH589 shows improved PFS Jun 04, 2014

- Novartis presented results from a pivotal phase III trial showing a 37 per cent improvement in progression-free survival (PFS) when using the investigational compound LBH589 (panobinostat) in combination with bortezomib and dexamethasone compared to treatment with the same regimen with placebo in patients with relapsed or relapsed and refractory multiple myeloma, meeting the primary endpoint of the study (hazard ratio=0.63 [95 per cent confidence interval (CI): 0.52 to 0.76]; p<0.0001). The PANORAMA-1 (PANobinostat ORAl in Multiple MyelomA) trial results were presented in an oral session at the 50th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago.

4.3. Vertex Pharma announces positive results from proof-of-concept study Jun 06, 2014

- Vertex Pharmaceuticals Incorporated, a global biotechnology company, announced the results of a two-part proof-of-concept study of ivacaftor in 24 people with cystic fibrosis (CF) who have a residual function mutation. The first part of the study evaluated ivacaftor, compared with placebo, in a two-week crossover design over two treatment cycles, and the second part of the study evaluated ivacaftor in an eight-week open-label design. In part one, a statistically significant improvement in mean absolute lung function (percent predicted forced expiratory volume in one second; PPFEV1) was observed after treatment with ivacaftor for two weeks compared with placebo.

4.4. AbbVie begins phase III study of Veliparib in patients with advanced breast cancer Jun 28, 2014

- AbbVie announced the initiation of a Phase III clinical trial evaluating the safety and efficacy of its investigational compound, veliparib (ABT-888), when added to carboplatin and paclitaxel, two chemotherapeutic medicines, in patients with advanced breast cancer. Specifically, the combination of veliparib, carboplatin and paclitaxel will be compared to treatment with carboplatin, paclitaxel and placebo in patients with human epidermal growth factor receptor 2-(HER2) negative metastatic or locally-advanced breast cancer, containing BRCA1 and/or BRCA2 gene mutations.

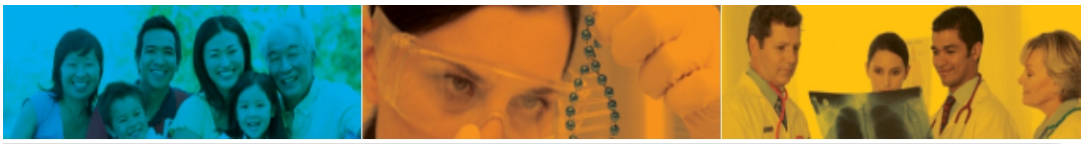
MERGER, ACQUISITIONS AND SETTLEMENTS

5.1. Meiji Seika Pharma of Japan to acquire Medreich Ltd Jun 12, 2014

- Meiji Seika Pharma Co Ltd, a business subsidiary of Meiji Holdings Co Ltd of Japan, has set to acquire Medreich Ltd, India for a total consideration of Rs.141 crore ($290 million). Meiji Holdings and its affiliates have entered into a share purchase agreement with the promoters of Medreich which is indirectly own through Med Holdings (UK) Ltd, Nokha Holdings Pvt Ltd and V-Sciences Investments Pte Ltd owned by Tamasek Holdings, Singapore.

5.2. Medtronic buys Covidien for $42.9 billion Jun 16, 2014

- The USA's Medtronic is buying Ireland-based Covidien for $42.9 billion in cash and stock. The combined group will have annual revenues of $27 billion, including $3.7 billion from the emerging markets, and have 87,000 employees in more than 150 countries.



LAMBDA

5.3. Cipla to acquire 51% stake in Yemen based Pharma Company Jun 30, 2014

- Cipla Ltd has signed a definitive agreement to acquire a 51 per cent stake in a pharmaceuticals manufacturing and distribution business in Yemen (in turn owned by a UAE based parent company). Given the recent preference to local manufacturing, this secures company's presence in a fast growing market. It already has a leading position in Yemen with over 200 products.