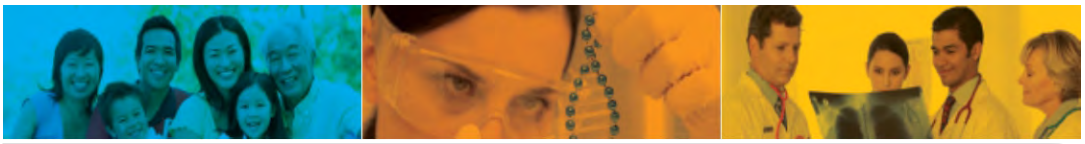

Clinical Research Newsletter Volume - 5, May 2015

LAMBDA

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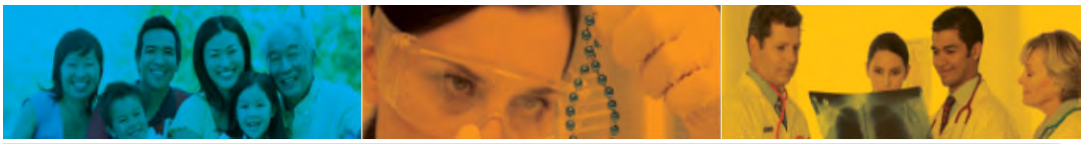


LAMBDA

GLOBAL NEWS

1.1. GSK expands vaccines presence in US by establishing new R&D centre at Rockville Apr 04, 2015

- GSK, one of the world's leading research-based pharmaceutical and healthcare companies, has announced it is further strengthening and expanding its vaccines presence in the US by establishing a new global centre for vaccines research and development (R&D) in Rockville, Maryland. The site will become one of three global vaccines R&D centres for GSK, complementing the company's existing global R&D centres in Rixensart, Belgium and in Siena, Italy, a site which GSK recently acquired from Novartis in March 2015.

1.2. DRL and its subsidiary Promius PharmaTM announce the filing of three NDAs with the USFDA

Apr 10, 2015

- Dr. Reddy's Laboratories (NYSE:RDY) and its subsidiary, Promius Pharma™, LLC today announced the filing of three 505(b)(2) New Drug Applications (NDAs) with the U.S. Food and Drug Administration (US FDA). The three NDAs - DFD-01, DFD-09, and DFN-11, are in support of Dr. Reddy's Proprietary Products group, focused on developing and commercializing therapies in dermatology and neurology.
- DFD-01 is a corticosteroid delivered in a novel non-irritating spray platform, intended for the treatment of patients suffering from psoriasis. DFD-09 is a modified release oral tetracycline intended for the treatment of rosacea. DFN-11, the first development program filed in support of a newly created vertical, focused on the US neurology market is a drug-device combination product intended to treat acute migraine episodes in certain patient populations who are inadequately managed with existing treatment regimens.

DOMESTIC NEWS

2.1. Abbott launches first-of-its kind glucose monitoring technology for diabetics in India

Apr 01, 2015

- Abbott has launched a glucose assessment device for the first time in India to empower doctors to help their patients manage their diabetes effectively. The technology is equipped with a software that can generate reports to provide Ambulatory Glucose Profile graph, a visual snapshot, which helps the doctors easily understand when sugar levels go high and low (hypoglycaemic or hyperglycaemic) over a typical 24 hour period, identify when patient presents hypoglycaemic or hyperglycaemic trends, detect overnight hypoglycaemia trends and identify postprandial (sugar levels after taking food) glucose spikes.

2.2. Intas Pharma Launches Etanercept Biosimilar Apr 07, 2015

- Ahmedabad-based Intas Pharmaceuticals has launched Intacept, the 'first' biosimilar to Amgen's Enbrel (etanercept). Intacept, Intas' etanercept, has been launched in two strengths, 25 mg in 0.5 ml and 50 mg in 1.0 ml preservative free solution, in pre-filled syringes. The biosimilar has been manufactured in India and is indicated for rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis and plaque psoriasis, all debilitating autoimmune diseases.

2.3. Sun Pharma and Technion, Israel tie-up to develop new oncology drugs Apr 16, 2015

- Sun Pharmaceutical Industries and the Technion Israel institute of technology, have entered into an exclusive worldwide research and license agreement through their subsidiaries. This collaboration is an excellent example of interactions between academic discovery and pharmaceutical companies demonstrating the valuable contribution academic institutions can make in bringing new products to help patients worldwide. It is also an important step to strengthen the NDDS portfolio of the company.

2.4. Janssen introduces diabetic drug Invokana (Canagliflozin) in India Apr 17, 2015

- Janssen India, a division of Johnson & Johnson, has launched a diabetic drug, Invokana in India. Inkovana Canagliflozin is SGLT 2 inhibitor which has to be taken once daily. The clinical study submitted to US FDA proves the efficacy and safety of the drug. The study was carried out on a total of 11,000 patients and out of that more than 1000 were from India.

REGULATORY NEWS

3.1. New WHO statement on public reporting of clinical trial results announced Apr 16, 2015

- The WHO have announced a new statement on the public disclosure of clinical trial results which updates and expands a previous statement that noted the "the registration of all interventional trials is a scientific, ethical, and moral responsibility." The new statement includes timelines by which researchers are expected to report clinical trials results. A new element in the WHO statement is the definition of timelines for researchers to report the main findings of clinical trial results: by posting to the results section of the primary clinical trial registry within 12 months of study completion, and by publishing within a peer-reviewed journal within 24 months of study completion.

3.2. EMA & HMAs release EU medicines agencies network strategy 2020; invite stakeholders comments Apr 01, 2015

- The European Medicines Agency and the Heads of Medicines Agencies have released the 'EU Medicines Agencies Network Strategy to 2020', a draft common strategy to 2020 for the European medicines agencies network, for a three-month public consultation. Stakeholders are invited to send their comments before 30 June 2015. The joint strategy for the European medicines agencies network is based on a coordinated approach and a strengthened collaboration within the network over the next five years, to address the challenges and make the most of the opportunities to benefit human and animal health.

3.3. Govt to amend Schedule Y pertaining to authenticity of data submitted by applicants Apr 14, 2015

- The Union Health Ministry will soon amend the Note under Schedule Y of the Drugs and Cosmetics Rules, 1945 regarding the authenticity of the data or documents submitted by the applicant. The Note under Schedule Y provides that only authentic data should be submitted for the application for permission to import and/or manufacture of new drugs for sale or to undertake clinical trials. The data is required to be self certified. It also provides the licensing authority reserves the right to reject any data or any document(s) if such data or content of such document are found to be of doubtful integrity.

DRUG APPROVALS AND LAUNCHES

4.1. Two drugs Ramcirumab and Panitumumab got approval for metastatic colorectal cancer

Apr 07, 2015

- The U.S. Food and Drug Administration today approved ramucirumab (Cyramza) of Eli Lilly for use in combination with FOLFIRI (leucovorin, fluorouracil, irinotecan) for the treatment of patients with metastatic colorectal cancer whose disease has progressed on a first-line bevacizumab (Avastin)-, oxaliplatin-, and fluoropyrimidine-containing regimen.
- Amgen announced that The European Commission has approved a new use of Vectibix (panitumumab) as first-line treatment in combination with Folfiri for the treatment of adult patients with wild-type (WT) RAS metastatic colorectal cancer (mCRC). The European Commission approval of Vectibix as a first-line treatment in combination with Folfiri chemotherapy means physicians have another treatment option for adult patients with wild-type RAS metastatic colorectal cancer.

4.2. Roche's Avastin plus chemotherapy for women with advanced cervical cancer gets EU approval

Apr 09, 2015

- The European Commission (EU) has approved Roche's Avastin (bevacizumab) in combination with standard chemotherapy (paclitaxel and cisplatin or, alternatively, paclitaxel and topotecan in patients who cannot receive platinum therapy) for the treatment of adult patients with persistent, recurrent or metastatic carcinoma of the cervix. Avastin's EU approval in persistent, recurrent or metastatic carcinoma of the cervix is an important development in a disease area where, until now, treatment options were limited to chemotherapy.

4.3. Amgen's Corlanor (Ivabradine) gets US FDA nod to treat heart failure

Apr 15, 2015

- The US FDA approved Corlanor (ivabradine) to reduce hospitalization from worsening heart failure.
- Corlanor was reviewed under the FDA's priority review program, which provides for an expedited review of drugs that are intended to treat a serious disease or condition and may provide a significant improvement over available therapy. It was also granted fast track designation.
- The safety and efficacy of Corlanor was studied in a clinical trial of 6,505 participants. Corlanor reduced the time to first occurrence of hospitalization for worsening heart failure compared to an inactive drug (placebo).

4.4. Novo Nordisk launches weight management drug, Saxenda (Liraglutide) in US market

Apr 24, 2015

- Novo Nordisk, a world leader in insulin and diabetes care, has launched Saxenda (liraglutide 3 mg), the first glucagon-like peptide-1 (GLP-1) receptor agonist for weight management, in the United States. It is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with obesity (BMI $\geq$30 kg/m^2) or who are overweight (BMI $\geq$27 kg/m^2) in the presence of at least one weight-related co morbid condition.

4.5. EMA recommends approval of Opdivo (Nivolumab) for treatment of advanced melanoma

Apr 27, 2015

- EMA has recommended granting a marketing authorisation for Opdivo (nivolumab). Opdivo is recommended to be used as monotherapy for the treatment of adult patients with advanced (unresectable or metastatic) melanoma. Nivolumab is a monoclonal antibody which is 'programmed death-1' (PD-1) receptor antagonist. By blocking the usual receptor interactions, Nivolumab leads to activation of the immune system to kill melanoma cells.

DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

5.1. Astellas, Medivation announce top line results from trial comparing enzalutamide with Bicalutamide

Apr 06, 2015

- Astellas Pharma Inc. and Medivation, Inc. announced top line results from the phase 2 STRIVE trial comparing enzalutamide with bicalutamide in a study population of men with non-metastatic or metastatic castration-resistant prostate cancer. The study achieved its primary endpoint demonstrating a statistically significant increase in progression-free survival (PFS) for enzalutamide compared with bicalutamide. Median PFS was 19.4 months in the enzalutamide group compared with 5.7 months in the bicalutamide group.

5.2. Rhythm begins phase 2b trial of relamorelin to treat diabetic gastro paresis

Apr 10, 2015

- Rhythm and Actavis plc announced the initiation of a phase 2b clinical trial assessing the efficacy and safety of relamorelin (RM-131), Rhythm's ghrelin agonist, for the treatment of gastro paresis in patients with type 1 and type 2 diabetes. Ghrelin is a peptide hormone produced in the stomach that stimulates gastrointestinal (GI) motility.

5.3. Merck's Keytruda demonstrates superior survival, PFS and ORR in advanced melanoma

Apr 20, 2015

- Merck, a global healthcare leader, known as MSD outside the United States and Canada, announced results from the randomized, pivotal phase 3 study, Keynote-006, in the treatment of unresectable advanced melanoma. In the study, Keytruda (pembrolizumab) was statistically superior to ipilimumab for progression-free survival (PFS), overall survival (OS), and overall response rate (ORR). In mid-2015, Merck plans to submit a supplemental Biologics License Application (sBLA) for Keytruda based on Keynote-006 for the first-line treatment of advanced melanoma.

5.4. Glide Technologies Completes Successful PoC Study with Novel SDF of Teriparatide SDI

Apr 23, 2015

- Glide Technologies announced that its novel solid dose formulation of teriparatide achieved successful results in a pre-clinical proof-of-concept study comparing it with the currently marketed liquid product (Forteo®/Forsteo®). Based on these results, the company intends to transfer the formulation production process to a contract manufacturing organization in the coming months, and to advance Glide teriparatide delivered with the company's needle-free solid dose injector (teriparatide SDI®) into clinical trials in 2016.

5.5. US FDA grants breakthrough therapy status to Pfizer's Xalkori (Crizotinib) for ROS1 positive NSCLC Apr 23, 2015

- The US Food and Drug Administration (FDA) have granted breakthrough therapy designation for Pfizer Inc's Xalkori (Crizotinib) for the potential treatment of patients with ROS1-positive non-small cell lung cancer (NSCLC). Crizotinib, a tyrosine kinase inhibitor is currently indicated in the US for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumours are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.

MERGER/ACQUISITIONS/COLLABORATION

6.1. BIND Therapeutics extends collaboration on Accurins with Pfizer Apr 02, 2015

- BIND Therapeutics and Pfizer have extended the terms of their global collaboration to create Accurins that enhance the therapeutic potential of two cancer drugs in the latter's pipeline. Accurins are targeted and programmable therapeutics churned out through BIND's nanoengineering platform. They selectively accumulate in diseased tissues and cells to deliver therapeutic payload at the site of the tumor, and thereby also reduce exposure to healthy tissues. BIND's technology has already caught the eyes of pharma heavyweights such Roche, AstraZeneca and Amgen, which are all collaborating on the development of Accurins based on their own investigational medicines.

6.2. Indoco buys Piramal Enterprises' clinical research division of Hyderabad Apr 02, 2015

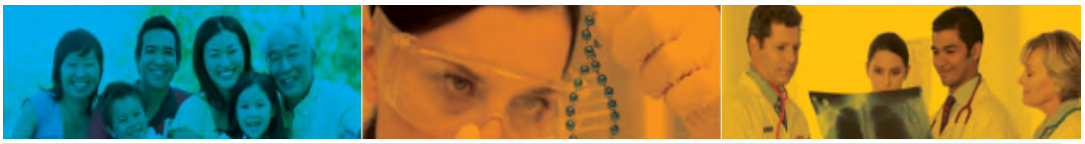
- Indoco Remedies, a Rs. 700 crore plus Mumbai based pharma, has acquired Piramal Clinical Research (PCL); a Hyderabad based clinical research division (CRO) of Piramal Enterprises on a going concern basis. This is an all cash-deal funded with internal accruals. The CRO specializes in conducting bioequivalence and bioanalytical studies for generic products.

6.3. Quest Life Sciences acquires Fortis Clinical Research Apr 06, 2015

- The Chennai-based Quest Life Sciences, one of the fast growing clinical research organisations (CROs) in India, has acquired Fortis Clinical Research Ltd (FCRL), a division of Fortis Hospitals Group. FCRL has been an established BA/BE centre in Faridabad. FCRL has accreditations from US FDA, ANVISA, Turkey, UK MHRA, WHO, etc and has been primarily servicing Ranbaxy for all their submissions globally. After Ranbaxy has been acquired by Sun Pharma, Fortis decided to sell out the company.

6.4. Roche in up to $555 million cancer deal with Indian firm Curadev Apr 21, 2015

- Curadev Pharma Private Ltd. has entered into a research collaboration and exclusive license agreement with Roche for the development and commercialization of IDO1 and TDO inhibitors. The agreement covers the development of the lead preclinical immune tolerance inhibitor and research collaboration with Roche's research and early development organization to further explore the IDO and TDO pathways. IDO1 and TDO are enzymes that mediate cancer-induced immune suppression.



LAMBDA

PATENT (NEW APPROVAL/ LITIGATION/SETTLEMENTS)

7.1. Evoke Pharma's intranasal delivery formulation of metoclopramide, EVK-001 receives EU patent Apr 13, 2015

- The European Patent Office has granted the Evoke Pharma, Inc. EU patent no. 2376075 for the formulatin used in product EVK-001, intranasal delivery formulation of metoclopramide for the treatment of symptoms related to diabetic gastro paresis in women. EVK-001, currently in a phase 3 clinical trials, is a novel treatment for gastro paresis, a disease that can hinder the absorption of oral medications due to symptoms including erratic gastric emptying, as well as nausea and vomiting.

7.2. Red Hill Biopharma's RHB-105 H. pylori bacterial infection treatment to receive US patent Apr 20, 2015

- The United States Patent and Trademark Office (USPTO) have issued a Notice of Allowance for US Patent No. 14/179,197 to Red Hill Biopharma for a new formulation patent application covering the RHB-105 formulation. RHB-105 is a proprietary fixed-dose combination therapy of two antibiotics and a proton pump inhibitor (PPI)- 12.5 mg rifabutin, 250 mg amoxicillin, and 10 mg omeprazole , in an all-in-one oral capsule, targeting an indication of first line treatment of H. Pylori infection.

TECHNOLOGY NEWS

8.1. Novo cure's Optune receives Japanese approval to treat recurrent glioblastoma Apr 01, 2015

- The Japanese Ministry of Health, Labour and Welfare (MHLW) has approved Novo cure's Optune, a Tumour Treating Fields (TTFields) delivery device, for the treatment of patients with recurrent glioblastoma (GBM). Optune is a portable, non-invasive medical device designed for continuous use by patients. In vitro and in vivo studies have shown that Optune slows and reverses tumour growth by inhibiting mitosis, the process by which cells divide and replicate. Optune creates a low intensity, alternating electric field within a tumour that exerts physical forces on electrically charged cellular components, preventing the normal mitotic process and causing cancer cell death.

8.2. Veracyte launches new genomic test to improve lung cancer diagnosis Apr 16, 2015

- Veracyte, Inc., a molecular diagnostic company pioneering the field of molecular cytology, announced the launch of its Percepta™ Bronchial Genomic Classifier, a new genomic test to resolve ambiguity in lung cancer diagnosis. The company will soon begin testing patient samples in its CLIA-certified laboratory. The Percepta test is designed to reduce the number of invasive biopsies and other procedures that can follow when suspicious lung nodules are found on CT scans.

8.3. ICON introduces Firecrest eConsent, a next-generation electronic informed consent solution Apr 27, 2015

- ICON plc, a global provider of drug development solutions and services to the pharmaceutical, biotechnology and medical device industries, announced Firecrest eConsent, a next-generation electronic informed consent solution that incorporates key recommendations from the FDA's recent draft guidance on informed consent.