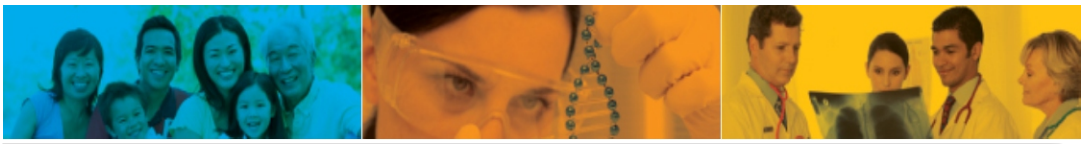

Clinical Research Newsletter Volume - 4, April 2014

LAMBDA

CONTENTS

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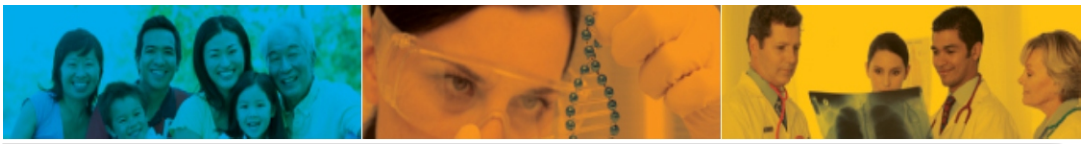

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GLOBAL NEWS

1.1. Germany extends drug price freeze to end-2017 Mar 02, 2014

- The German government has decided to extend a drug-pricing freeze through 2017. Originally set to expire at the end of last year, the pricing policy is just one of the spending moves that has crimped pharma's sales in that country. Legislators also voted to base wholesaler and pharmacy margins on negotiated drug prices, which would publicize discounts on drug brands, allowing other countries to press for lower prices as well.

1.2. Perrigo buys OTC products sold in Australia & New Zealand from Aspen for $51 mn Mar 03, 2014

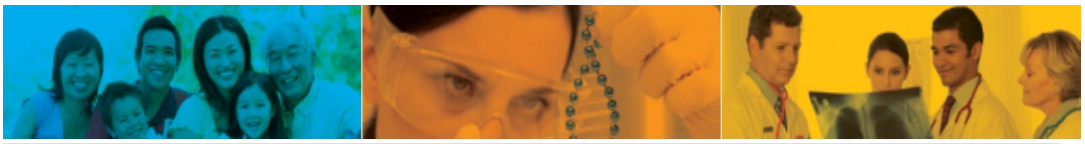
- Perrigo Company plc, a leading global healthcare supplier that develops, manufactures and distributes OTC and Rx pharmaceuticals, nutritional products, and APIs, has acquired a basket of value-brand OTC products sold in Australia and New Zealand from Aspen Global Inc. for $51 million in cash. The products are primarily sold through the mass retail channel and include the Herron range of analgesics, vitamins and supplements. This basket of products is expected to generate at least $20 million in annual revenue.

1.3. NICE tells Alexion: "explain high costs of Soliris" Mar 04, 2014

- In the first draft guidance produced by its Highly Specialised Technologies programme, the National Institute for Health and Care Excellence (NICE) has asked Alexion Pharma UK, why its rare blood disorder drug treatment Soliris (eculizumab) costs so much.
- Alexion says that NICE has asked it to provide additional information related to the budget impact of Soliris, but has not requested any further information regarding its clinical effectiveness. NICE's preliminary recommendations are available for public consultation until midday on March 25. The information sought from Alexion and NHS England will be considered at the next meeting of NICE's evaluation committee, in April.

1.4. CHMP recommends nine new drugs Mar 23, 2014

- Nine new medicines have been backed by the agency's Committee for Medicinal Products for Human Use (CHMP). First up, it has issued a positive opinion for a conditional approval of Merck & Co/Endocyte's Vynfinit (vintafolide), Folcepri (etarfolatide) and Neocepri (folic acid), Janssen's Sylvant (siltuximab), Boehringer Ingelheim and Eli Lilly's Jardiance (empagliflozin), Takeda's Entyvio (vedolizumab), Johnson & Johnson's Olysio (simeprevir), GlaxoSmithKline's Revinty, Ellipta (fluticasone/vilanterol), Actavis' Ebilfumin (oseltamivir).



LAMBDA

DOMESTIC NEWS

2.1. Leading diabetologists welcome findings of European review on safety of aspartame

Mar 31, 2014

- Leading diabetologists in the country have welcomed the recent safety review by the European Food Safety Authority (EFSA) on widely used aspartame and hoped that it would clear the apprehensions prevailing about it in India also. Aspartame, one of the most commonly used artificial sweeteners in the world, has been declared totally safe for human consumption at current levels of exposure by the EFSA. After a detailed analysis and considering all available information, the EFSA experts concluded that the current Acceptable Daily Intake (ADI) of 40 mg per kg of body weight daily does not pose any long- or short-term health concern for people.

2.2. Top 20 Japanese pharma cos eyeing India drug majors for acquisitions

Mar 31, 2014

- Top 20 Japanese companies like Takeda, Astellas, Mitsui, Mitsubishi Pharma, Dainippon Sumitomo etc. are seriously scouting for various business opportunities in Indian drug market. There is an increasing interest on India even for contract manufacture and procurement of finished formulations driven by rising product development costs in Japan. The Japanese companies are eager to grow to the next level. Many such enterprises from Japan are chalking out inorganic paths and therefore identifying acquisition targets here that fit into their line of business segments.

REGULATORY NEWS

3.1. GSK increases stake to 75% in Indian arm through open offer

Mar 10, 2014

- GlaxoSmithKline plc (GSK) has increased its stake in Indian arm GlaxoSmithKline Pharmaceuticals, from 50.7 per cent to 75 per cent. GlaxoSmithKline Pharma will remain publicly-listed. The Open Offer was announced on December 16, 2013 and is being managed by HSBC Securities and Capital Markets (India) Private Limited.

3.2. Health ministry planning to increase number of New Drug Advisory Committees to 50

Mar 19, 2014

- Even as criticism is levelled that the meetings of New Drug Advisory Committees (NDACs) many times did not have the presence of all the experts, the government is planning to raise the number of the NDACs from 12 at present to 50 on a gradual basis. The new proposal, as suggested by the technical committee and approved by the apex committee on clinical trials, is to increase the number of NDACs to 50 with a view to involve more experts in the process of clearing the clinical trials in a fool-proof manner. Sources said the process for getting approval for forming more NDACs had already been initiated.

3.3. Health ministry revokes ban on pain killer drug Analgin — Mar 19, 2014

- After several months of dilly-dallying on this contentious issue, the Union health ministry has finally revoked the ban on pain-killer drug Analgin, which the ministry had banned on June 18 last year on the plea that the use of Analgin and formulations containing Analgin for human use was likely to involve risk to human beings and safer alternatives to it are available in the market. The health ministry has issued a notification GSR 86 (E) dated 13.2.2014 revoking the ban on Analgin.

DRUG APPROVALS AND LAUNCHES

4.1. FDA approves first ICD to be evaluated in clinical trials for use in MRIs — Mar 14, 2014

- Biotronik, a manufacturer of cardiovascular medical devices, has announced that the FDA has approved the expansion of Biotronik's ongoing ProMRI trial. The new phase of the trial (phase C) will study the company's ProMRI technology in implantable cardioverter-defibrillator (ICD) devices. Biotronik is the only company in the world with an ICD that is approved for investigational use in an MRI (magnetic resonance imaging) scanner. The ongoing ProMRI study is the first step in making this standalone technology available in the U.S.

4.2. NICE yes for BI's lung cancer drug Giotrif — Mar 17, 2014

- The cost regulators look favourably on Boehringer Ingelheim's targeted therapy Giotrif (afatinib) for certain type of lung cancer. The National Institute for Health and Care Excellence (NICE) has published draft guidance recommending Giotrif as an option for treating locally advanced or metastatic non-small-cell lung cancer (NSCLC), specifically in people whose tumours test positive for the EGFR-TK mutation and have not received a EGFR-TK inhibitor. The Committee concluded that Giotrif is likely to have similar clinical efficacy to erlotinib and gefitinib, the other two NICE-approved options for this form of lung cancer, and that it is a cost-effective option for the NHS.

4.3. FDA approves Impavido to treat tropical disease leishmaniasis — Mar 20, 2014

- The FDA has approved Impavido (miltefosine) to treat a tropical disease called leishmaniasis. The FDA granted Impavido Fast Track Designation, Priority Review and Orphan Product Designation. These designations were granted because the drug demonstrated the potential to fill an unmet medical need in a serious disease. Impavido's safety and efficacy were evaluated in four clinical trials. A total of 547 patients received Impavido and 183 patients received either a comparator drug or a placebo. Results from these trials demonstrated that Impavido is safe and effective in treating visceral, cutaneous and mucosal leishmaniasis.

4.4. NICE plans OK for Velcade in multiple myeloma

Mar 21, 2014

- The National Institute for Health and Care Excellence (NICE) has published draft guidance recommending Janssen-Cilag's Velcade (bortezomib) as a treatment for some patients with newly-diagnosed multiple myeloma. Determination (FAD), NICE recommends Velcade's use in combination with dexamethasone, or with dexamethasone and thalidomide, for the induction treatment of adult patients with previously-untreated multiple myeloma who are eligible for high-dose chemotherapy with bone marrow transplant.

DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

5.1. GSK cancer vaccine fails in lung cancer trial

Mar 20, 2014

- GlaxoSmithKline has suffered a setback after announcing more disappointing late-stage data from a non-small cell lung trial of its cancer vaccine MAGE-A3. The news follows a failure in a Phase III melanoma trial for the cancer vaccine last September but it appears that GSK is not giving up just yet. Regarding the MAGRIT study, it will continue in order to assess the third co-primary endpoint designed to identify a subset of MAGE-A3 positive patients that may benefit from the treatment.

5.2. Pfizer's Xalkori shines as first-line lung cancer therapy

Mar 26, 2014

- Pfizer has reported positive late-stage data on a trial of Xalkori compared to chemotherapy in previously-untreated lung cancer patients with a specific gene mutation. The Phase III study of Xalkori (crizotinib) met its primary objective of significantly prolonging progression-free survival in previously-untreated patients with anaplastic lymphoma kinase (ALK)-positive advanced non-squamous non-small cell lung cancer (NSCLC) when compared to standard platinum-based chemotherapy regimens. The trial is the second late-stage study that evaluated Xalkori against chemo.

MERGER, ACQUISITIONS AND SETTLEMENTS

6.1. Eisai, Biogen Idec ink collaboration

Mar 06, 2014

- Eisai Co., Ltd. a research-based pharmaceutical company, and biotechnology company, Biogen Idec have entered into a collaboration to develop and commercialize two of Eisai's clinical candidates for Alzheimer's disease (AD), E2609 and BAN2401. The agreement also provides Eisai with an option to jointly develop and commercialize two of Biogen Idec's candidates for AD, the anti-amyloid beta (Aß) antibody BIIB037 and an anti-tau monoclonal antibody. The collaboration initially will be centred on the co-development and co-commercialization of Eisai's two candidates: E2609, a ß-site amyloid precursor protein cleaving enzyme (BACE) inhibitor, and BAN2401, an anti-Aß antibody.

6.2. CRL to acquire Galapagos CRO businesses for up to €134 million Mar 18, 2014

- Charles River Laboratories (CRL), the US-based provider of drug discovery and development services, has filled out its portfolio with upstream in vitro capabilities by agreeing to acquire the contract-research services division of Galapagos NV. Acquiring the Belgian company's Argenta and BioFocus businesses for a total cash consideration of up to €134 million will make CRL the only contract research organization that can offer clients integrated in vitro and in vivo drug-discovery and early-stage development capabilities from target discovery through to preclinical development.