Clinical Research Newsletter Volume - 3, March 2016

LAMBDA

CONTENTS

Contact Us

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

Mr. Akshaya Nath, COO
akshayanath@lambda-cro.com

GLOBAL NEWS

1.1. Saliva gland test may help diagnose early Parkinson's disease

February 02, 2016

- Researchers from Mayo Clinic in Arizona and Banner Sun Health Research Institute have determined that testing a portion of a person's submandibular gland may be a way to diagnose early Parkinson's disease.
- Currently, there is no accurate diagnostic test for Parkinson's disease. The test involves inserting a needle into the submandibular gland under the jaw and withdrawing the needle to obtain the core of gland tissue within.

1.2. UK Plans Off-Label, Experimental Drug Database

February 04, 2016

- The United Kingdom government has thrown its weight behind legislation that would result in the creation of a database of innovative treatments being carried out by doctors in England, including both off-label uses of existing drugs and tests of unlicensed, experimental therapies.
- Officials are proposing to task the Health and Social Care Information Centre with the construction and maintenance of a database that would give doctors access to details of experimental therapies, as well as the outcomes generated using these novel approaches. The idea is to broaden access to knowledge about experimental treatments, whether they be off-label uses of existing drugs or new, as-yet-unlicensed therapies.

1.3. Rheumatoid Arthritis Treatment with TNF Inhibitors May Raise Cervical Dysplasia Risk

February 05, 2016

- A Swedish nationwide study in women with rheumatoid arthritis (RA) found an elevated risk for cervical dysplasia in those treated with tumor necrosis factor (TNF) inhibitors, a common RA therapy.
- Study results reveal that women with RA have a higher risk for precancerous cervical dysplasia, and the increase in those treated with TNF inhibitors is even higher. However, the cause for this phenotype and its relation to TNF inhibitor therapy still remains unclear.

1.4. ACR Encourages Safe Adoption of Biosimilars During FDA Public Hearing on CT-P13

February 10, 2016

- The American College of Rheumatology (ACR) provided recommendations for policy guidelines to implement as the committee decides whether to license additional biosimilars for sale in the U.S.
- If approved, CT-P13 [a proposed biosimilar to infliximab (Remicade)] will be the first biosimilar available for the possible treatment of rheumatic disease. Infliximab is currently used to treat rheumatoid arthritis, ankylosing spondylitis (a type of spondyloarthritis) and psoriatic arthritis..

1.5. HIV Drug During Pregnancy: May Result in Developmental Effects in Child

February 23, 2016

- The antiretroviral (ARV) drug atazanavirsometimes included in treatments to prevent mother-to-child HIV transmission during pregnancymay have small but significant effects on infant development, reports a study in the journal AIDS, official journal of the International AIDS Society.
- One-year-old whose mothers took atazanavir during pregnancy have slightly reduced scores for language and social-emotional development, compared to ARV regimens not containing atazanavir,

DOMESTIC NEWS

2.1. Sun Pharma Launches Imatinib Mesylate in USA February 02, 2016

- Sun Pharma announced launch of Imatinib Mesylate tablets (therapeutic equivalent to Gleevec® for indications approved by the FDA) in the U.S. market.
- Sun Pharma's subsidiary received final approval for Imatinib Mesylate from FDA in December 2015. Being a First-to-File product, it was granted 180 days of marketing exclusivity.

2.2. Indian firm files patent for Zika vaccine candidates February 05, 2016

- The Hyderabad-based Bharat Biotech has filed for global patent of two vaccine candidates - a recombinant vaccine and an inactivated vaccine - for Zika virus.
- The company announced that it could make available the inactivated vaccine in two years if the Indian Government fast-tracked the regulatory approvals once the pre-clinical trials proved to be successful.

2.3. India launches online import license application portal February 24, 2016

- The central government plans to tweak the current clinical trial norms to exempt academic institutions from some these stringent conditions, including paying compensation in most of the cases, so that research activities are not stymied.
- ICMR along with the Drugs Controller General of India and the Health Ministry is reworking on the guidelines to clarify some of the issues related to conduct of trials that would not lead to the registration of a new medicine.

REGULATORY NEWS

3.1. Newer biosimilars may prompt US FDA extrapolation rethink says expert February 01, 2016

- While data extrapolation is acceptable in approving US biosimilars across the same indications as its reference, the practice will not be applicable for the next generation of copycat biologics, a biotech expert says.
- According to guidance published by the US FDA, a biosimilar development can “extrapolate clinical data intended to support a demonstration of biosimilarity in one condition of use to support licensure of the proposed biosimilar product in one or more additional conditions of use for which the reference product is licensed.”

3.2. MHRA: Safety Updates Will No Longer be Submitted to National EU Regulators Beginning in June February 19, 2016

- From 13 June 2016 onward, companies across Europe will no longer submit periodic safety update reports (PSUR) to national regulators but instead to a central repository at the European Medicines Agency (EMA).
- The repository was created under legislation introduced in July 2012 and also provides for the storage of associated assessment reports, additional data and comments.

3.3. CDSCO to release guidelines on biosimilars soon February 24, 2016

- ·To fast-track approvals of biosimilars or biologics in the country, guidelines on biosimilars are expected to be released soon after a thorough one and half year of consultations with the industry and the Central Drugs Standard Control Organisation (CDSCO).
- ·· The guidelines to be released will prescribe the quality, preclinical studies and clinical trial requirements of similar biologics in India. Says Dr G N Singh, Drugs Controller General of India (DCGI), "India specific biosimilars guidelines have been worked out finally in consultation with the industry to make the clearance of biologic products on a fast-track basis because the Indian patients can have access to them. The guidelines would be soon out in a couple of months time."

DRUG APPROVALS AND LAUNCHES

4.1. Entresto : A New FDA-Approved Drug For Heart Failure February 06, 2016

- A study published in the New England Journal of Medicine in 2014 showed that Entresto (sacubitril/valsartan) "reduced the risk of death from cardiovascular causes and heart failure hospitalization by 20 percent," according to the drug's manufacturer, Novartis
- Hopes are high for Entresto, a drug approved by the FDA to treat heart failure, which affects more than 5.1 million Americans and is one of the leading causes of death in the US.

4.2. New Anti-radiation Product to Assist in Cancer Radiation Treatment February 10, 2016

- The President of New Venture Medical, Geoff Perry, has announced the release of an anti-radiation product from their Research and Development group.
- This is a revolutionary breakthrough in the treatment of cancer using radiation and the treating of environmental radiation exposure. It will assist in the healing of radiation burns, even when open sores are present. It will also protect only the healthy cells from radiation damage. It selectively helps and protects the healthy cells and not tumors.

4.3. Pfizer Receives Expanded FDA Approval For IBRANCE (palbociclib) In HR+, HER2- Metastatic Breast Cancer February 19, 2016

- U.S. Food and Drug Administration (FDA) has approved a new indication expanding the use of IBRANCE® (palbociclib) 125mg capsules, Pfizer's metastatic breast cancer therapy.
- Now IBRANCE also is approved for the treatment of hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer in combination with fulvestrant in women with disease progression following endocrine therapy.

4.4. Briviact (brivaracetam) approved for treatment of partial onset seizures in patients with epilepsy February 22, 2016

- The U.S. FDA approved Briviact (brivaracetam) as an add-on treatment to other medications to treat partial onset seizures in patients age 16 years and older with epilepsy.
- Briviact's effectiveness was studied in three clinical trials involving 1,550 participants. Briviact, taken along with other medications, was shown to be effective in reducing the frequency of seizures.

4.5. European Commission approves Lilly's Portrazza for NSCLC February 24, 2016

- The European Commission has approved Eli Lilly's Portrazza (necitumumab), in combination with gemcitabine and cisplatin chemotherapy, as a first-line treatment for adult patients with an advanced form of lung cancer, who have not received prior chemotherapy.
- Portrazza is the first biologic licensed in the EU as a first-line treatment option for metastatic squamous non-small cell lung cancer (NSCLC): a hard-to-treat form of lung cancer, for which the five-year survival rate is less than 5%.

4.6. FDA Clears Zika Diagnostic for Emergency Use February 26, 2016

- The US Food and Drug Administration (FDA) on Friday approved the first diagnostic to detect the Zika virus under its emergency use authorization (EUA) pathway, which allows the agency to authorize unapproved products during a public health emergency.
- The authorization is significant as there are currently no other approved dignostics available to detect Zika, a mosquito-borne virus that has rapidly spread across much of Latin America and the Caribbean and is thought to be behind an increase in cases of microcephaly and Guillain-Barré Syndrome

DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

5.1. Allergan's Rapastinel Receives FDA Breakthrough Therapy Designation February 01, 2016

- A leading global pharmaceutical company announced that its Phase III ready investigational medication rapastinel received Breakthrough Therapy designation from the U.S. FDA for adjunctive treatment of Major Depressive Disorder (MDD). This follows the Fast Track Designation for rapastinel granted by the FDA in 2014.
- Rapastinel is the first Allergan medicine to be granted Breakthrough Therapy designation by the FDA, underscoring commitment to innovative research and development that addresses significant unmet medical needs.

5.2. TapImmune Granted Fast Track Designation by U.S. FDA for its Lead Vaccine TPIV 200 in the Treatment of Ovarian Cancer February 03, 2016

- TapImmune, Inc. a clinical-stage immuno-oncology company, announced that the U.S. Food & Drug Administration (FDA) has granted Fast Track Designation for its cancer vaccine TPIV 200 in the treatment of ovarian cancer.
- The FDA has designated the investigation of multiple-epitope Folate Receptor Alpha Peptide Vaccine (TPIV 200) with GM-CSF adjuvant for maintenance therapy in subjects with platinum-sensitive advanced ovarian cancer who achieved stable disease or partial response following completion of standard of care chemotherapy, as a Fast Track Development Program.

5.3. Flexion Therapeutics Reports Primary Endpoint Met in Pivotal Phase 3 Trial of Zilretta™ in Knee Osteoarthritis February 16, 2016

- Flexion Therapeutics, Inc. reported that the Phase 3 clinical trial for its lead drug candidate Zilretta (also known as FX006) met its primary endpoint at week 12, demonstrating highly significant, durable and clinically meaningful pain relief against placebo in patients with moderate to severe osteoarthritis (OA) knee pain.
- Zilretta achieved statistically significant analgesia against placebo at weeks 1 through 16. The Breakthrough Therapy designation was based on the results of a phase I/II trial in patients with unresectable, metastatic or recurrent synovial sarcoma who have received prior chemotherapy.

5.4. US FDA grants Breakthrough Therapy status to Novartis' PKC412 in acute myeloid leukaemia February 20, 2016

- Novartis announced that the U.S. FDA has granted Breakthrough Therapy designation to PKC412 (midostaurin).
- PKC412 (midostaurin) is an investigational treatment for adults with newly-diagnosed acute myeloid leukaemia (AML) who are FLT3 mutation-positive, as detected by an FDA-approved test, and who are eligible to receive standard induction and consolidation chemotherapy.
- The Breakthrough Therapy designation for PKC412 is primarily based upon the positive results from the phase III RATIFY (CALGB 10603) clinical trial.

5.5. Amgen And UCB Announce Positive Top-Line Results From The Phase 3 Study Of Romosozumab February 22, 2016

- Amgen and UCB announced top-line results from the Phase 3 placebo-controlled FRActure study in postmenopausal woMen with ostEoporosis (FRAME).
- These data showed FRAME met the co-primary endpoints by reducing the incidence of new vertebral fracture through months 12 and 24 in postmenopausal women with osteoporosis treated with romosozumab. The study also met the secondary endpoint of reducing the incidence of clinical fractures.

MERGER/ACQUISITIONS/COLLABORATION

6.1. Abbott to spend $5.8 billion to acquire Alere February 01, 2016

- Health care giant Abbott Laboratories said it has reached a deal to acquire diagnostics-testing company Alere for $5.8 billion.
- "The combination of Alere and Abbott will create the world's premier point of care testing business and significantly strengthen and grow Abbott's diagnostics presence," said Miles D. White, chairman and chief executive officer, Abbott, adding: "We want to offer our customers the best and broadest diagnostics solutions. Alere helps us do that."

6.2. GSK and Adaptimmune expand cancer collaboration February 02, 2016

- GSK has expanded the terms of its agreement with USA-based biotech firm Adaptimmune Therapeutics to accelerate Adaptimmune's lead clinical cancer program an affinity enhanced T-cell immunotherapy targeting NY-ESO-1 toward pivotal trials in synovial sarcoma.
- Under the original collaboration, Adaptimmune stood to gain approximately $350 million over seven years starting in 2014, in relation to NY-ESO and two additional programs.

6.3. ViaCyte Acquires BetaLogics Asset Rights for Potential Diabetes Cure February 08 , 2016

- Johnson & Johnson and privately held ViaCyte, Inc. are joining forces to speed development of a Type 1 diabetes cure.
- The companies have agreed to consolidate the assets of Johnson & Johnson's Janssen BetaLogics group into ViaCyte, giving ViaCyte an exclusive license to all BetaLogics intellectual property in the field of metabolic disease, including diabetes. As a result of the agreement, ViaCyte gains exclusive access to an additional 145 issued patents.

6.4. Sandoz acquires Pfizer's biosimilar infliximab in EEA February 13, 2016

- Sandoz, a Novartis company and a global leader in biosimilars, announced that it has acquired from Pfizer the rights for the development and commercialisation of PF-06438179 (biosimilar infliximab) in the 28 countries that form the European Economic Area (EEA).
- Under the terms of the deal, Sandoz plans to complete the clinical study programme and submit the biosimilar infliximab to the European Medicines Agency (EMA) for regulatory approval and registration with the European Commission.

6.5. Capsugel & Pulmatrix to Develop & Manufacture Novel Inhaled Therapeutics February 16, 2016

- Capsugel and Pulmatrix, Inc. have formed a collaboration to develop novel inhaled therapeutics to treat serious pulmonary diseases.
- The agreement provides Capsugel exclusive rights to manufacture clinical trial and commercial batches of iSPERSE™-based inhaled therapeutic candidates being developed by Pulmatrix and its potential development partners.

PATENT (NEW APPROVAL/ LITIGATION/SETTLEMENTS)

7.1. NLS Pharma Acquires A Portfolio of Strategic Patents IN ADHD February 17, 2016

- §NLS Pharma announces the acquisition of four patents including one linked to an innovative compound that NLS Pharma seeks to develop for the treatment of ADHD.
- The patent acquisition, from a leading French healthcare institution, allows NLS Pharma's work towards a potential novel therapy in ADHD to reach a key § milestone. The IP portfolio acquired in this transaction includes mazindol, a non-amphetaminic psychostimulant.

7.2. IntelGenx receives US patent for Rizaport oral film to treat acute migraines

February 20, 2016

- IntelGenx Corp., a leading drug delivery company, announced United States Patent and Trademark Office (USPTO) has granted a patent protecting Rizaport, an oral thin film formulation of rizatriptan benzoate for the treatment of acute migraines with for rapid onset of action and higher bioavailability.
- The patent application, entitled "Instantly Wettable Oral Film Dosage Form Without Surfactant or Polyalcohol" covers rapidly disintegrating film oral dosage forms and is expected to be valid until 2034 once granted.

7.3. Novogen gets Australian patent for Cantrixil & Trilexium

February 22, 2016

- The US-Australian drug discovery company, Novogen Limited announced that a patent for the superbenzopyran (SBP) family, covering the lead candidates Cantrixil and Trilexium, has been granted in Australia. This patent provides full protection of Novogen's intellectual property (IP) for the SBP family until 2035.
- In addition, the key patent application covering the first lead anti-tropomyosin (ATM) compound, Anisina, has been examined and accepted by the Australian Patent Office. The application has now entered the standard three-month opposition window prior to being granted.

TECHNOLOGY/NDDS NEWS

8.1. The Future of Medicine Could be Found in a Tiny Crystal Ball

February 04, 2016

- A Drexel University materials scientist has discovered a way to grow a crystal ball in a lab. Not the kind that soothsayers use to predict the future, but a microscopic version that could be used to encapsulate medication in a way that would allow it to deliver its curative payload more effectively inside the body.
- Crystals form this way because their molecules are predisposed to align themselves in a way that links them via the strongest electrochemical bond available.

8.2. Sandoz teams with delivery tech firm MedinCell to get under the skin of cancer

February 04, 2016

- Novartis subsidiary Sandoz will commercialise small and large molecule injectables using French delivery tech firm MedinCell's subcutaneous controlled release platform.
- Long acting sub-cutaneous drug depots can offer advantages in the form of patient compliance, efficacy and tolerability over alternative delivery mechanism. Novartis looks to bolster its line of subcutaneous drugs with MedinCell's delivery clout by reducing the frequency of administration, improving patient tolerability and ultimately reducing costs.

8.3. New ADHD Drug for Patients who Struggle to Swallow Tablets February 11, 2016

- The recent FDA approval of Neos Therapeutics' Adzenys, an orally disintegrating drug developed to treat attention deficit hyperactivity disorder (ADHD), will provide patients who have problems swallowing pills with easy-to-administer drug options, according to an analyst with research and consulting firm GlobalData.
- Adzenys, which is intended for use in patients aged six years or older, uses the company's proprietary Rapidly Disintegrating Ionic Masking (RDIM) technology.

8.4. Novel Cancer Treatment to Inhibit Chemo-Resistance February 25, 2016

- Despite numerous advances in oncology since the War on Cancer began, many patients develop resistance to standard therapies and eventually relapse. Moffitt Cancer Center researchers hope to improve treatment outcomes with development of a novel therapeutic strategy, called adaptive therapy, which is based on evolutionary principals and aims to keep resistant cells in check by maintaining a population of chemo-sensitive cells.
- The study showed that adaptive treatment with the AT-1 regimen increases vessel density and blood flow throughout the tumor. This allows chemotherapeutic drugs to be delivered to the tumor more effectively and reduces tumor cell invasion..