At the turn of the 21st century, pharmaceutical companies began focusing on biotechnology to provide novel therapeutic treatment leading to the development of “biologic” drugs, which use biological systems (living cells) for their manufacture. Their success in treating chronic illness and in generating revenues has attracted companies to develop biosimilar, which are drugs that are almost an identical copy of an already approved biologic drug. The opportunity for biosimilar manufacturers can be gauged from Evaluate Pharma’s estimate of USD 87.4 billion worth of biological drug sales at risk from being supplanted by their biosimilar counterparts.

However, Biosimilars come with inherent risks and challenges, some of which have been listed below:

**Complex development** – manufacturing must be tightly controlled (since living cells are used) to provide a consistent product. In addition, these drugs are based on complex large protein based molecules (> 900 Daltons) which increase the development cycle.

**Immunogenicity** – Biosimilars have the potential to induce unexpected immune reactions, as differences in biological systems used in the manufacturing process may impact the drug.
Careful transport and storage – Since biological medicines including biosimilars are sensitive to high temperatures greater care needs to be taken during transportation and storage.

Relatively higher costs – biosimilar development costs range from USD 75 million to USD 250 million — almost 37.5 to 83.3 times higher than the cost of small molecule bioequivalent drugs. However, even at USD 250 million, the costs of the abbreviated pathway remain considerably less than the costs of going the full-therapeutic biologic applications route which is USD 800 million.

Clinical trial requirements – Since generic drugs have the same pharmacological effects as their brand name counterparts, they are exempt from costly clinical trials. However, biosimilars are subject to clinical trials in order to confirm their similarity to the originator biologic product.

Globally, regulations for biosimilars are still evolving with most countries referring to the Food and Drug Administration (FDA) and European Medicines Agency (EMA) for regulatory aspects. The EMA was the first agency to introduce guidelines for biosimilars in 2005, followed by the World Health Organisation (WHO) (2009) and finally the US with the passage of the Biologic Price Competition and Innovation Act 2010.

According to industry experts, the biosimilar market is expected to grow from USD 1.7 billion in 2014 to USD 30.0 billion in 2020 – a CAGR of 62.1%. Biosimilars are typically priced at ~30% lower than their Biologic counterparts. For example, in Japan the reimbursement price of Remicade is USD 750, compared to USD 513 for the biosimilar Remsima (100 mg I.V. for infusion). The potential savings from the use of biosimilars is another area of interest, especially to governments and payer organisations. In the EU, savings from biosimilars are expected to be in the range of USD 11 billion to USD 33 billion by 2020. While in the US, if the 11 most probable biosimilars were to hit the market, the potential savings could accumulate to USD 250 billion (2014-2020). The rising potential for biosimilars is evident from the increased corporate activity in the last couple of years. Some of the companies are partnering with each other to develop biosimilars (Mylan and Biocon), while other grow inorganically, for example, Sandoz (Novartis) acquired Pfizer’s biosimilar infliximab in the European Economic Area (2016).

With 150 reference products for biosimilars to emulate, including 40 in the blockbuster revenue range (>USD 1 billion per annum), the future for this segment looks bright.

Regulatory and legal update

Surge in award of orphan drug designations especially within the EU area indicates strong traction within the rare diseases drugs market.

- EU regulators assigned orphan drug status to an experimental therapy for Amyotrophic Lateral Sclerosis (ALS) called Masitinib, indicating that it has the potential to offer a significant benefit over existing treatment options.
- European Medicines Agency (EMA) granted orphan designators to Bellicum Pharmaceuticals for both its T-cell therapy product candidate BPX-501. These are used for the treatment of hematopoietic stem cell transplantation (HSCT) and Graft vs. Host Disease (GvHD).
- The FDA has granted orphan drug designations to two pharmaceutical companies. One was to Agilis Biotherapeutics for the treatment of Friedreich’s ataxia using its gene therapy product candidate, AGIL-FA. The other was to Arais Pharma for improving the survivability and improvement in functioning of pancreatic islets following transplantation.

Regulators and governments in emerging markets such as China and India are facing increased scrutiny in pricing and drug registration rules

- Department of pharmaceuticals in India plans on embedding the maximum retail price (MRP) of a product into the bar codes to ensure compliance thereby benefiting the consumer. However, pharma associations are sceptical about its successful implementation in rural towns / cities and are trying to convince the government to not make it compulsory for domestic sales.
- China Food and Drug Administration (CFDA) issued new proposals to revamp China’s Drug Registration Rules (DRR); this is akin to revising the Food, Drug and Cosmetic Act in the US. Industry experts believe that the proposed changes could either boost or stall growth.
- Chinese health authorities have appointed a special investigation team to look into its vaccine distribution chains, which witnessed USD 90 million scandal involving illegal vaccines that were suspected of being sold in dozens of provinces.

Increased FDA scrutiny on drug manufacturers results in bans and closures

- FDA banned all products from Wockhardt’s third manufacturing plant (Ankleshwar, India).
- Pfizer had to shutdown its plant (Irungattukottai, Chennai in India), which it had acquired through the Hospira acquisition on account of FDA observations.
- Asymmetric dimethylarginine (ADMA) biologics candidate for treatment of primary humoral immunodeficiency disease was rejected by the FDA due to manufacturing deficiencies.

TOP STORIES

1. China proposes revised drug registration rules: Chinese Food and Drug Administration (CFDA) has issued new proposals to revamp China’s Drug Registration Rules, which could impact the future of the industry. The CDFA is accepting comments on the new policy until August 26, 2016.

2. Experimental ALS drug wins EU orphan status: An experimental therapy for Amyotrophic Lateral Sclerosis (ALS) called Masitinib has been assigned orphan drug status. The approval from the EU regulators indicate a significant milestone as it indicates that the drug can generate significant benefits over the current treatment.

3. Wockhardt plunges on U.S. Ban on third drug making factory: The FDA said that it had banned all drugs and drug products made by the factory, based in Ankleshwar, India. This is the third drug manufacturing plant in India banned by the FDA.
Merger and acquisition news

The pharma companies continue to acquire to diversify their product portfolio. Higher value merger and acquisition (M&A) deals continue to dominate the industry. Some of the major M&A deals are listed below:

- Jazz Pharmaceuticals plc announced the acquisition of Celator Pharmaceuticals, Inc. for USD 1.5 billion. The acquisition is a strong strategic fit and will further diversify Jazz’s product portfolio. The combination is also complimentary to Jazz’s clinical and commercial expertise in hematology/oncology.

- Shanghai Fosun Pharmaceutical Co. Ltd. announced the acquisition of Gland Pharma Limited for USD 1.26 billion. The deal will help Fosun in becoming a global leader in the generics injectables industry. The acquisition will strengthen Fosun pharma’s global presence and is in line with Fosun’s strategy of internationalisation.

- Medtronic Plc is to acquire HeartWare International Inc. for USD 1.1 billion. The acquisition will bulk up Medtronic’s portfolio of devices for treating heart diseases and pushing deeper into the market for less-invasive surgical products.

- Zimmer Biomet Holdings, Inc. acquired LDR Holding Corporation for USD 1.0 billion. The combination will create a differentiated and comprehensive spine technology portfolio, enhancing Zimmer Biomet’s innovation leadership in musculoskeletal healthcare.

Consortiums exiting their portfolio on the backdrop of higher valuations attained for their investments. Some major transactions include the following:

- A consortium led by England and Northern Ireland announced the sale of Bio Products Laboratory Ltd to Creat Group Corp for £820 million (USD 1.2 billion). This deal will help serve more customers and patients in a greater number of markets around the world.

- A consortium led by Teva Pharmaceutical Industries Ltd sold Broad portfolio of generic products to Impax Laboratories Inc for USD 586 million. It fits with Impax’s strategic priorities of maximizing generic platform, optimizing research and development and accelerating business development to create long term growth.

- A consortium led by Redmile Group LLC sold Afferent Pharmaceuticals Inc to Merck & Co Inc for USD 500 million. Deal enhances the potential of Merck portfolio to provide meaningful benefits to patients globally.

- A consortium led by TA Associates Management LP sold MIS Implants Technologies Ltd to Dentsply Sirona Inc for USD 375 million. This opens up new opportunities of growth and services for both the companies, which benefits customers and patients around the globe.

TOP STORIES

1. Jazz Pharmaceuticals to acquire Celator for USD 30.25 Per Share (USD 1.25 billion): a strong strategic fit that would add a new orphan product with the potential for short- and long-term revenue generation and expansion of international commercial platform.

2. Fosun Pharmaceutical (Group) Co. Ltd. to acquire an approximate 86% stake in Gland Pharma Limited for USD1.26 billion. Fosun Pharma will purchase all shares of Gland owned by KKR Floorline Investments Pte. Ltd.

3. Zimmer Biomet completes tender offer for outstanding shares of LDR Holding Corporation: Together with LDR, Zimmer Biomet will be a leader in the USD 10 billion global spine market and well-positioned in the cervical disc replacement segment.
New product development

August 9, 2016, Fierce Medical Device
Accuracy Incorporated announced that it has CE marked its radiaxt treatment delivery system, accuracy precision treatment planning system and iDMS data management system. The platform will be available in certain markets in the European Union, in addition to the U.S. market where it received FDA 510(k) clearance in June 2016.

August 9, 2016, Specialty Pharmacy Times
The Amyotrophic Lateral Sclerosis (ALS) association and ALS Finding a Cure awarded a USD2.96 million grant to support a phase two trial for Amylyx Pharmaceuticals’ investigational drug AMX0035, for the treatment of ALS.

The trial is expected to launch later this year to test the tolerability and safety of AMX0035, as well as the functional outcomes. A major part of the trial will be an analysis of biomarkers of inflammation, cell function and neuronal damage.

August 9, 2016, MDRBR
InSeal Medical has received CE mark approval for its large bore vascular closure device, InClosure VCD. Featuring the firm’s patented technology, the InClosure VCD will close large bore arterial punctures ranging from 12F to 21F.

August 9, 2016, Specialty Pharmacy Times
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FDA approves Boston Scientific’s Emblem MRI S-ICD system
August 9, 2016, Cardiovascular Business
The FDA approved the Emblem MRI subcutaneous implantable defibrillator system (Boston Scientific). The agency also approved magnetic resonance labelling for previously implanted Emblem S-ICD systems.

The Emblem MRI S-ICD system features magnetic resonance-conditional labelling as well as an updated technology that ensures patients receive the appropriate therapy and a detection tool that tells physicians when patients are identified as having atrial fibrillation.
August 9, 2016, Pharmabiz
Takeda Pharmaceutical Company Limited, a global, research and development driven pharmaceutical company, announced Takeda Canada has received approval from Health Canada for Ninlaro (ixazomib) capsules in combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.

August 8, 2016, GEN
Intelesens, a Northern Ireland-based company, garnered FDA’s 510(k) clearance for Zensor, a wearable device that remotely monitors a patient’s vital signs both in and out of the hospital. The device, which is battery operated, clips onto an adhesive patch embedded with electrodes. Zensor can be worn for up to seven days while it collects data on respiration rates, three-lead ECG, heart rate and movement.

August 6, 2016, Business News
ASX listed Analycia have achieved patent protection for their unique medical device in China. The People’s Republic of China recently granted Analycia’s patent application for the company’s “Peri-Coach” pelvic floor force sensing device. The Peri-Coach was designed to eliminate or greatly reduce urinary incontinence, a condition affecting nearly 230 million Chinese women. The Peri-Coach is able to send a signal to a smartphone to allow the user to determine if the correct series of pelvic floor muscles are exercised.

August 6, 2016, Pharmabiz
DNAtrix announced the award of a USD 2 million research grant from the FDA’s Office of Orphan Products Development to support its phase II clinical trial evaluating DNX-2401 with the checkpoint inhibitor pembrolizumab for patients with recurrent glioblastoma. DNX-2401 is a potent oncolytic adenovirus that targets and kills cancer cells, while leaving normal cells intact.

August 5, 2016, CNN
The FDA announced that it is officially giving OX513A, a genetically modified male mosquito developed by British company, Oxitec, a clean bill of health. The decision gives the federal green light for the use of the mosquito in a field trial this fall in a small Florida neighborhood. OX513A is a male Aedes aegypti mosquito, the primary species that carries the Zika virus. He is genetically engineered to pass along a lethal gene to wild females that makes the females’ offspring die. The gene creates a protein that interferes with cell activity, killing the mosquito before it can reach adulthood.

August 5, 2016, Mass Device
Egalet’s abuse-deterrent opioid painkiller Arymo ER, or morphine sulfate extended-release tablet, has been endorsed for approval by the FDA’s anesthetic and analgesic drug products and drug safety and risk management advisory committees to treat severe pain that requires daily, continuous opioid treatment in patients whose condition cannot be managed with alternative therapies. A decision from the agency is expected by Oct. 14.

August 4, 2016, Radiology Business
The FDA has recently given EndoChoice clearance for its Lumos imaging software system, which can improve detection for more nuance when making any adjustments.

August 4, 2016, Mass Device
Masimo won CE Mark approval for a pediatric indication on its O3 regional oximetry with the O3 pediatric sensor. The O3 regional oximetry system uses near-infrared spectroscopy to monitor absolute and trended regional tissue oxygen saturation in the cerebral region, which can detect imbalances in oxygen delivery. The new indication clears the use of the O3 sensor for pediatric patients less than 88 lbs.
and provide clearer images to physicians. Lumos contains two different settings for giving physicians better images for detection of abnormal tissues. The first setting is capable of enhancing images of tissues that have been selected, the second setting gives further insight into the inspection of the tissues. A study was conducted to show the just how well Lumos worked and results showed enhanced images of lesions with pit patterns, leading to a quicker detection of the tissue abnormalities.

Natco’s generic version of Roche’s Tamiflu gets approval from the FDA
August 4, 2016, Smartbrief
The first generic version of Roche’s Tamiflu, or oseltamivir phosphate, has been approved by the FDA for the treatment of influenza A and B in patients aged two weeks and older and prevention of the condition in patients aged one year old and older. The generic, which is manufactured by Natco Pharma, will be available in 30-, 45- and 75-mg dosage strengths.

HHS awards USD 5.1 million for speedier Zika test
August 3, 2016, Fierce Medical Device
InBios International — a medical diagnostic company based in Seattle — will receive a USD 5.1 million boost from HHS to expedite the development of a blood test that may reduce the time for results from days to hours. The current blood test used to diagnose Zika was developed by the CDC and requires two to three days to return results and must be conducted in labs designated by the agency. The InBios blood test has the potential to return results in four hours and could be used in commercial and healthcare facilities.

Kite licenses UCLA platform for developing allogeneic T-cell therapies
July 26, 2016, Fierce Medical Device
Kite Pharma said today it has licensed technology from the University of California (UC) designed to advance the development of off-the-shelf allogeneic T-cell therapies from renewable pluripotent stem cells. “This platform provides a renewable source of T cells and can be further exploited with gene engineering, including chimeric antigen receptors, T-cell receptors, and other gene modifications of interest, to generate potent T-cell products that have the potential to be resistant to rejection and to bear no risk of graft-versus-host disease,” David Chang, M.D., Ph.D., Kite’s evp, R&D, and CMO, said in a statement.

Malvern firm’s next-generation heart beat monitor approved by the FDA
July 26, 2016, Fierce Medical Device
The FDA granted marketing clearance to BioTelemetry for its next-generation mobile cardiac outpatient telemetry (MCOT) device: the MCOT Patch. Joseph H. Capper, BioTelemetry’s president and CEO, said the new patch incorporates the irregular heart detection capability of the company’s existing MCOT system into a lightweight, easy-to-use form, which BioTelemetry believes will lead to more patients using it. “Moreover, due to its advanced capabilities and flexible design, our new sensor is also anticipated to have commercially viable applications in other areas of health care,” Capper said.

Allergen receives positive opinion for IBS drug
July 26, 2016, Fierce Medical Device
Allergan plc announced that the committee for medicinal products for human use (CHMP) has adopted a positive opinion for Truberzi (eluxadoline) in the EU. Truberzi is an oral medication taken to relieve the main symptoms of irritable bowel syndrome with diarrhoea (IBS-D) in adults. In two pivotal trials, Truberzi significantly reduced two of the most bothersome symptoms of IBS-D, abdominal pain and diarrhoea, with sustained relief demonstrated over six months.

Claris receives ANDA approval for local anaesthesia drug
July 26, 2016, Fierce Medical Device
Claris Lifesciences Ltd. has received the abbreviated new drug application (ANDA) approval from US FDA, for a local anaesthesia drug Bupivacaine Hydroxochloride. Bupivacaine Hydroxochloride in dextrose injection is a local or regional anaesthesia used for a long acting anaesthetic during surgical procedure.

Sight Sciences wins IDE for Visco 360
July 26, 2016, Mass Device
Venture-backed ophthalmic medical device company Sight Sciences has received FDA investigational device exemption approval to initiate a clinical trial of its Visco 360 Viscosurgical System for treating patients with glaucoma.

The multi-center, randomised trial will compare ab interno canaloplasty with the Visco 360 system against selective laser trabecuoplasty. The study will investigate the safety and effectiveness of the Visco 360 system in canaloplasty versus SLT for reducing intraocular pressure in primary open angle glaucoma patients, the company said.

FDA approves AbbVie’s once-daily Viekira XR for HCV-1
July 25, 2016, Fierce Medical Device
The FDA approved AbbVie’s VIEKIRA XR (dasabuvir, ombitasvir, paritaprevir and ritonavir) extended-release tablets, a once-daily, extended-release co-formulation of the active ingredients in VIEKIRA PAK. The new product is indicated for the treatment of patients with chronic hepatitis C virus (HCV) genotype 1 infection, including those patients with compensated cirrhosis (Child-Pugh A).
Austin medical device company receives approval to sell rare cancer monitoring tool

July 25, 2016, Fierce Medical Device

Asuragen Inc. has received federal clearance to sell a first-of-its-kind test to monitor patients with a rare form of cancer. The Austin medical device company said that the US FDA has given it premarket clearance for the diagnostic tool, called Quantidex qPCR BCR-ABL IS. Asuragen executives said it is the first test to receive the FDA’s approval to monitor those diagnosed with chronic myeloid leukemia, or CML, which represents 10% of all leukemia cases.

European CHMP recommends Shire’s Onivyde to treat metastatic adenocarcinoma

July 25, 2016, Fierce Medical Device

The European Medicines Agency’s (EMA) Committee for Medicinal Products for Human Use (CHMP) has given a positive opinion for Shire’s Onivyde (irinotecan pegylated liposomal formulation) to treat metastatic adenocarcinoma.

The Onivyde, which is also known as nal-IRI or MM-398, in combination with 5-fluorouracil (5-FU) and leucovorin (LV), has been recommended, for the treatment of metastatic adenocarcinoma of the pancreas in adult patients who have progressed following gemcitabine based therapy.

Penumbra launches Ace68 reperfusion thrombectomy catheter

July 25, 2016, Fierce Medical Device

Penumbra recently announced the U.S. launch of the Ace68 reperfusion thrombectomy catheter designed for extracting thrombus in acute ischemic stroke patients.

“With the Ace68 reperfusion catheter, I can easily deliver full aspiration power to the occlusion. The Ace68’s large lumen increases the likelihood of capturing the clot fully within the catheter or the canister, potentially reducing the number of passes to achieve complete revascularisation and minimise ENT,” Dr. Johanna Rili of New York’s Mount Sinai Health System said in a press release.

Inova receives FDA Clearance

July 25, 2016, Fierce Medical Device

Inova Diagnostics has earned FDA clearance for its QUANTA Flash dsDNA, QUANTA Flash Jo-1, and QUANTA Flash Scl-70 assays, the California-based company announced.

The dsDNA is designed to facilitate the diagnosis of systemic lupus erythematosus, whereas Jo-1 and Scl-70 are designed to detect myositis and systemic sclerosis, respectively, the company confirmed.

Breakthrough status for Pfizer/Spark haemophilia gene therapy

July 22, 2016, PharmaTimes

Pfizer and Spark Therapeutics say their investigational haemophilia B drug SPK-9001 has been awarded breakthrough therapy status by the US FDA.

“We are extremely pleased to have been granted breakthrough therapy designation for SPK-9001, which has shown early promise in achieving our goal of eliminating the need for regular infusions to control and prevent bleeding episodes in patients with haemophilia B through a potentially one-time, intravenous administration of a highly optimised gene therapy,” said Jeffrey D. Marrazzo, CEO of Spark Therapeutics.

INTRACEPT nerve ablation system for lower back pain

July 22, 2016, Fierce Medical Device

Relievant Medsystems obtained FDA clearance for its INTRACEPT intraosseous nerve ablation system. It’s a minimally invasive device that’s used to kill the basivertebral nerve responsible for generating regular pain signals in people with damaged vertebra in the lower back.

The technology is indicated for treating one or more levels between L3 and S1 in people that have not responded to more common treatments for over six months.

FDA approves Vasorum’s Celt ACD

July 22, 2016, FDA News

Irish devicemaker Vasorum recently that the US FDA has granted premarket approval to its vascular closure device Celt ACD.

The single-use device for closing femoral artery punctures comes in three sizes.

It can be used in both diagnostic procedures and for interventional cardiology and radiology procedures.

Arena Pharma’s chronic weight management drug, Belviq XR gets US FDA approval

July 21, 2016, PharmaBiz

Eisai Co. Ltd., a research-based human health care company, has announced that the US FDA has approved a new drug application for Belviq XR, a once-daily formulation of lorcaserin hydrochloride (generic name, US brand name: Belviq) for chronic weight management. Belviq XR is scheduled for launch in autumn 2016.

Belviq XR is a sustained release formulation which enables once-daily treatment, increasing the convenience of administration compared to twice-daily Belviq tablets.
Eisai joins hands with Biogen on Phase III Alzheimer’s BACE trial

August 9, 2016, Fierce Pharma
Tokyo-based Eisai, citing a U.S. FDA go-ahead, said it would jointly enter a phase III trial with Biogen (USDBIIB) for early-stage Alzheimer’s oral candidate BACE inhibitor E2609, focused on blocking amyloid beta linked to the disease.

Belviq XR is a sustained release formulation which enables once-daily treatment, increasing the convenience of administration compared to twice-daily Belviq tablets.

OSU centre for health systems innovation launches new centre for predictive medicine

August 9, 2016, Fierce Biotech
Oklahoma State University’s Center for Health Systems Innovation announced the launch of its Center for Predictive Medicine.

The center will use the largest clinical database in the country to develop and implement information-technology tools designed to improve patient care.

FDA puts Adaptimmune cancer therapy study on partial hold

August 3, 2016, FiercePharma
The FDA is tapping the brakes on one of Adaptimmune T-cell studies, looking for some clarifications before it gives the green light to start testing NY-ESO SPEAR T-cell therapy in myxoid round cell liposarcoma.

National Institutes of Health (NIH) kicks off phase I trial for Zika vax as the number of cases rise in the US

August 3, 2016, FiercePharma
As the number of Zika cases continues to rise in the U.S., researchers at the National Institutes of Health are launching a clinical trial of a vaccine meant to ward off the virus and prevent serious complications in infants.

The NIH’s National Institute of Allergy and Infectious Diseases (NIAID) will run an early-stage study of the investigational DNA vaccine for Zika at three study sites in the U.S., including its Bethesda, MD-based clinical center. Researchers plan to enroll at least 80 healthy volunteers between the ages of 18 to 35, the NIAID announced.

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Singapore’s TauRx Phase III fails in mild to moderate Alzheimer’s trial

July 27, 2016, Fierce Pharma
A major phase III clinical trial of a tau inhibitor aggregation (TAI) therapy by Singapore’s TauRx failed to meet its primary endpoint, though the work showed an identified subgroup with a statistically significant benefit as a monotherapy.

Arena Pharma’s chronic weight management drug, Belviq XR gets US FDA approval

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TOP STORIES

Three Zika vaccines effective in monkeys, human trial set to begin this fall, researcher says.

1. In another key step toward a vaccine against Zika virus, scientists have found that three different experimental vaccines are safe and effective in monkeys.
2. Human trials have not yet begun, but experts said the results in monkeys are a critical step in developing a vaccine against the mosquito-borne virus.
3. U.S. health officials announced that a potential vaccine for the Zika virus has entered early clinical trials to assess its safety in humans.

With FDA approval, GM mosquitoes could join Florida's Zika fight:

1. Genetically modified (GM) mosquitoes could be let loose in Florida’s battle against the Zika virus if regulators approve them - and a decision is expected imminently, according to British firm Oxitec that engineers the insects.

July 25, 2016, Fierce Pharma

AbbVie and Bristol-Myers Squibb (BMS) said today they will launch an oncology clinical collaboration to assess two combination treatments for relapsed, extensive-stage, small-cell lung cancer (SCLC).

AbbVie and BMS said they aim to determine if the targeted cell killing and antigen release caused by Rova-T further enhances the effect of immunotherapy.

Bigfoot Biomedical launches artificial pancreas trial

July 25, 2015, Fierce Biotech

Bigfoot Biomedical is launching a clinical trial of its Smartloop automated insulin delivery system at medical centers in California and Colorado.

FDA officials recently approved Bigfoot’s investigational device exemption submission for the trial of its first clinical study of Smartloop, a device designed to treat patients with Type 1 Diabetes. Plans call for making it a closed-loop device combo that continuously monitors glucose levels and delivers insulin relying on a proprietary algorithm.

Celgene drug fails to extend survival in lymphoma study

July 25, 2015, Fierce Pharma

Celgene Corp said that its flagship drug Revlimid failed to extend survival as a maintenance therapy for a type of blood cancer after patients had responded to prior treatment.

As a result, the U.S. biotechnology company said it would not seek an additional approval for Revlimid for that use.

Memorial Sloan Kettering tests wearables, apps, in small cancer trial

July 21, 2016, Mobi Health News

Memorial Sloan Kettering Cancer Center is working with Medidata to launch a small patient-generated health data trial of 40 patients with multiple myeloma, a blood cancer that accumulates in the bone marrow. Patients in the trial will track their activity and sleep with wearable devices and use an app to answer survey questions about quality of life measures like fatigue and appetite.

Inovio Pharmaceuticals and GeneOne Life Science receive approval for first-in-Man Zika vaccine clinical trial

June 20, 2016, Fierce Biotech

Inovio Pharmaceuticals, Inc. and GeneOne Life Science, Inc. announced that they have received approval to initiate a phase I human trial to evaluate Inovio’s Zika DNA vaccine (GLS-5700) to prevent infection from this concerning virus.

Clinical evidence for ProMetic Life Sciences’ plasminogen is growing, says Paradigm

May 03, 2016, Fierce Biotech

ProMetic announced it had successfully treated another plasminogen-deficient patient in the US under a compassionate use investigational new drug. “We observed a progressive and systematic healing of all the wounds on the patient’s hand over a period of two weeks from his first plasminogen infusion. Within three hours after that first infusion, we saw minor bleeding from the wounds, which stopped spontaneously — the first sign of plasminogen’s effectiveness. This was followed by the formation of scabs on the wounds which started to fall off after 12 days, just as in the normal healing process,” said ProMetic’s chief medical officer, Dr. John Moran.
Company
Specific News

Abbott employee committed suicide on account of immense sales pressure from the healthcare company
Trouble is surrounding Abbott India as it is facing the allegations of following unethical practices to fuel sales by forcing its sales representatives to perform tests on patients for various ailments in an effort to step up business for doctors, who would in return prescribe Abbott drugs. One of the employees of the company committed suicide as he couldn’t achieve the sales target.

Union affiliated to the federation of medical and sales representatives’ association of India has urged the company to take action against the managers responsible and has demanded compensation for the family.

A national union of drug sales workers has asked for new government rules to rein in sales practices industry-wide.

Pfizer’s plant in India stopped production temporarily for not being able to demonstrate good manufacturing practices
• A team comprised of world’s four leading regulators identified deficiencies at the site.
• The company has plans to expand into new markets, including the US, Central and South America.

US agency issues fine on one of the world’s largest suppliers of antibodies for research
• Santa Cruz has agreed to pay USD 3.5 million on account of the allegations that goats and rabbits were mistreated on their facility. The outcome of the case has also led the company to close down its lab and give up its animal dealer license.

Federal regulatory body aims for a civil penalty in packaging lapse against the drug maker
US Agency (US Consumer Product Safety Commission) has claimed that Dr. Reddy’s Labs has failed to maintain child resistant packaging in at least five prescription drugs.
Regulatory body claims that the company has violated federal laws: Consumer Product Safety Act and Poison Prevention Packaging Act.

TOP STORIES

1. Big Biotech firm under the scrutiny of US Justice Department: Celgene received a federal subpoena claiming that the company has been funding the large sums to patient assistance charities to help boost sales of its pricey therapies (Revlimid).

2. US Prosecutors investigating drug maker for defrauding insurers: The U.S. Attorney’s Office in the Southern District of New York is considering pursuing criminal charges against Valeant on the ground of hiding from insurers its relationship with a specialty pharmacy that helped boost its drug sales.

3. Penalty for following anti-competitive practices: Lupin has been charged with a penalty of USD 10 million by CCI for ‘co-operating’ with the Karnataka Chemists and Druggist Association (KCDA) which was indulged in the anti-competitive practice.
JLT Specialty Limited provides insurance broking, risk management and claims consulting services to large and international companies. Our success comes from focusing on sectors where we know we can make the greatest difference — using insight, intelligence and imagination to provide expert advice and robust — often unique — solutions. We build partner teams to work side-by-side with you, our network and the market to deliver responses which are carefully considered from all angles.

For more than a decade we have been the leading liability broker for larger life science companies, working with the majority of the leading players in the sector, from pharmaceutical and agricultural to chemical and research institutes.

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