Finance, Funding & Investments

EUROPE

Merck R&D and Qiagen Announce Major UK Investments

Merck is to invest up to £1 billion ($1.3 billion) to open a drug research facility in London.

The announcement was widely welcomed by the UK's beleaguered Brexit Government and heralded as evidence that big industry is still intent in UK-based investment, despite the current post-Brexit uncertainties.

Meanwhile, Germany's Qiagen will expand its investment in its DNA-based diagnostics for personalized healthcare at its existing campus in Manchester, England.

The UK life sciences sector is one of the UK's fastest developing industries, with a turnover in excess of £64 billion and employing 233,000 throughout the UK.

Regeneron Announces $100M Investment in Ireland

Regeneron Pharmaceuticals, Inc. one of the fastest-growing companies in the global biotechnology industry, announced further expansion of its Industrial Operations and Product Supply (IOPS) bioprocessing campus in Ireland with an investment of $100 million and an additional 300 jobs, bringing the total expected employment at the site to 800 and a total investment to $750 million.

Regeneron's 400,000 square-foot, state-of-the-art production facility in Limerick, SW Ireland is the largest scale bulk biologics production facility in Ireland and one of the largest biologic production operations in the world. The additional $100 million investment will support the construction of a number of manufacturing suites to increase drug substance production capacity and enable the company to meet demand for its life-transforming medicines for patients with serious diseases.

Clinigen Strengthens Global Access with Japanese Purchase

With an already strong managed access presence in Europe, Clinigen is now one step closer to becoming the field's global leader.

The company has bought International Medical Management Corporation (IMMC), Japan's largest supplier of unlicensed medicines.

The news came one year after the CRO and pharma hybrid launched its Japanese business with the establishment of Clinigen K.K., and a month later, it decided to buy up compatriot Quantum Pharma for £150.3 million ($200 million).

Clinigen made a move in the Japanese market in 2015 via an acquisition of medicines and medical devices supplier Link Healthcare.

Elsalys Biotech Acquires Worldwide Rights of LEUKOTAC

France-based Elsalys Biotech, a new player in immuno-oncology, has acquired from Jazz Pharma, the development and commercialization rights of LEUKOTAC® (inolimomab), a monoclonal antibody that has recently demonstrated its clinical superiority in the treatment of Steroid-Resistant Acute Graft-versus-Host Disease (steroid-resistant aGvHD), an orphan disease with a very poor prognosis.

NorthSea Therapeutics Secures €25M Funding for Clinical Development of NASH Drug

NorthSea Therapeutics, a newly established Dutch biotech company, has completed a €25 million Series A funding for the development of icosabutate, as a novel, oral approach for the treatment of non-alcoholic steatohepatitis ('NASH').

The fundraising was led by Forbion and BVG, with the participation of Novo Seeds and New Science Ventures.

NASH is the leading cause of liver disease, affecting a total of 15-30 million patients in the US, Western Europe and Japan.

According to Allergan, NASH is now the leading cause of liver cirrhosos and cancer and nothing currently exists to effectively treat it. Earlier this year, French Biopharma Genfit estimated the untapped NASH market to be worth €37 billion per annum.

UNITED STATES AND REST OF WORLD

Fresenius Kabi to Invest $100M, Add 445 Jobs in North Carolina

Following its $4.75 billion acquisition of generics maker Akorn and its $730 million purchase of Merck KgaA's biosimilars portfolio, Fresenius Kabi says it will now spend more than $100 million and add 445 jobs over five years, at its syringe and drug-making site in Wilson, North Carolina.

The deal includes $7.2 million in state aid over a 12-year period.

The investment is in addition to the $250 million that the company is investing in a sterile injectables manufacturing site in Melrose Park, Illinois.

Akari Therapeutics Announces Pricing of Public Offering

Akari Therapeutics (NASDAQ:AKTX), a biopharmaceutical company focused on the development and commercialization of innovative therapeutics to treat orphan autoimmune and inflammatory diseases has priced its previously announced underwritten public offering of 3,480,000 American Depositary Shares, or ADSs, at a public offering price of $5.00 per ADS.

Akari expects to receive gross proceeds of approximately $17.4 million, assuming no exercise of the underwriters' option to purchase additional ADSs.

BioTime, Inc. Announces Closing of Public Offering

BioTime, Inc. (NYSE American and TASE: BTX), a late-stage clinical biotechnology company focused on developing and commercializing products addressing degenerative diseases, has announced the closing of its previously announced public offering of 9,615,385 shares of common stock, including 1,442,308 shares sold pursuant to the underwriters' exercise in full of their option to purchase additional shares.

The offering price to the public was $2.60 per share, and gross proceeds from the offering were approximately $28.8 million.

BioTime intends to use the net proceeds from this offering for general corporate purposes, including to fund clinical trials, research and development activities and for general working capital.

Immune Design Prices $80M Public Offering of Common Stock

Immune Design Corp. (Nasdaq:IMDZ) has announced the pricing of an underwritten public offering of 19,500,000 shares of its common stock at a price to the public of $4.10 per share. All of the shares of common stock are being offered by Immune Design. Proceeds to Immune Design from this offering are expected to be approximately $80 million, before deducting underwriting discounts and commissions and estimated offering expenses.

Immune Design plans to use the net proceeds of the offering to fund its Phase 3 clinical trial for CMB305 in synovial sarcoma patients, continue to develop CA21, its next-generation prime-boost product candidate, and file an IND for its initial development, as well as for working capital and general corporate purposes.

BaseHealth Raises $8.5M in Series C Funding

BaseHealth, the creator of the first predictive, evidence-based, and data-driven population health management solution, has announced that it has received an overall investment of $8.5 million, including $2.5 million from lead investor HBM Healthcare Investments (SIX HBMN), a listed healthcare investment company with net assets over $1 billion.

Strongbridge Biopharma plc Closes Public Offering of Ordinary Shares

Strongbridge Biopharma plc (NASDAQ:SBBP) has announced the closing of its previously announced underwritten public offering of 4,000,000 ordinary shares. The total net proceeds of the offering are approximately $23.4 million. The company intends to use the net proceeds from the offering for investment in expanded commercial infrastructure for Keveyis, continued development of Recorlev and veldoreotide, commercialization expenditures, and for other general corporate purposes.

Products & Pricing

EUROPE

Weight Loss Can Reverse Diabetes, Says UK Study

Patients with type 2 diabetes may be able to reverse the condition with a strict weight loss regime, according to the results from a new UK-based study.

The findings come from the first year of a two-year study called the Diabetes Remission Clinical Trial (DiRECT), where researchers say remission of type 2 diabetes is possible with a structured, low-calorie diet, and without a need for diabetic or blood pressure medication.

The trial involved 298 adults who had been diagnosed with type 2 diabetes in the previous six years. The weight loss program consisted of a low-energy formula diet of between 825 and 853 per day for three to five months compared to the usual NHS daily recommendation of 2,500 calories for men and 2,000 calories for women.

This was followed by a structured re-introduction of food over two to eight weeks in which dietary intake was aligned to about 50% carbohydrate, 35% fat and 15% protein.

The study, published in *The Lancet*, showed that after one year, participants had lost an average of 10kg (22lbs).

According to Diabetes.co.uk, the overall cost of treating diabetes is £14 billion per annum or 10% of NHS England and Wales total budget. Since 1996, the number of people diagnosed with diabetes in the UK has risen from 1.4 million to 3.5 million and is estimated to rise to four million by 2025.

Viagra Approved for OTC Sale in the UK

The UK Medicine and Healthcare products Regulatory Agency (MHRA) says it will reclassify 50 mg Viagra from its prescription-only status, enabling Pfizer to sell Viagra Connect, as a pharmacy OTC in the UK from Spring of 2018.

Purchasers will require the pharmacist's approval prior to purchase.

Pfizer filed to reclassify Viagra as a pharmacy medicine in the UK in Q1 2017 having previously filed for similar status in 2008 but Pfizer halted the application following EMA concerns then.

Pfizer's UK patent on Viagra expired in 2013, however its US patent runs until 2020. Teva Pharma will be allowed to market a generic version in the US by the end of this year.

The announcement is in line with a growing trend—from Ibuprofen to anti-malarial tablets—to provide access to useful medicines without doctors' pre-authorization.

Viagra was approved in 1998 and reached peak sales of more than $2 billion in 2012. Global sales last year topped $1.5 billion, although that was down from $1.7 billion in 2015.

Concordia Accused of UK Overcharging with 6,000% Price Hike

Canadian drugs firm Concordia has been accused of abusing its dominant market position in the UK by overcharging the UK NHS for its thyroid drug, Liothyronine, by more than £100 million ($130m) over a ten-year period.

The provisional ruling by The Competitions and Markets Authority (CMA) said that Concordia increased the price of a pack of liothyronine, over the decade from £4.46 in 2007 to £258.19 in July 2017 despite production costs remaining broadly stable.

As a result, the NHS's bill for the drug rose to £34 million in 2016 compared to £600,000 in 2006.

Concordia could be fined up to 10% of its worldwide revenues which were $816 million last year.

Concordia said it would review the ruling but that it did "not believe competition law has been infringed".

The CMA has been increasing its investigations into the drugs sector in recent years and is currently pursuing a total of seven probes related to medicine pricing.

Last year it fined Pfizer and Flynn Pharma nearly £90m ($120 m) for increasing the price of its anti-epilepsy generic by up to 2,600%—though both firms are currently appealing the ruling.

Merck Delays Ebola Vaccine Filing Until 2018

Despite its focused efforts, to complete testing on its Ebola vaccine, Merck & Co. will miss its target to file its candidate for approval this year.

In a statement, Merck said that though they are "committed to developing and seeking approval for our Ebola vaccine as quickly as possible," they now expect to file for approval with "major regulatory agency in 2018."

Merck has confirmed that it is working with the FDA and the EMA on its filings.

The delay could risk a $5 million advance purchase commitment from Gavi, the global vaccine alliance announced last year, as it was conditional on Merck filing for approval by the end of 2017.

UNITED STATES AND REST OF WORLD

FDA Approves Novo's Ozempic for Type 2 Treatment

The FDA has approved Ozempic to improve glycemic control in adults with Type 2 diabetes.

The once-a-week drug, Ozempic won FDA support based on clinical trial data showing it can reduce HbA1c levels compared to placebo and that the medication demonstrated an ability to help patients lose weight.

In a statement, the company said that its "unique clinical profile means Ozempic has the potential to set a new standard for the treatment of the disease."

Herceptin Biosim: Biocon Says It's Now FDA Ready

Biocon has resolved FDA concerns about a biologics plant in India, as it and its partner Mylan move closer to securing the first US approval for a Herceptin biosimilar.

Biocon says that it has been notified by the FDA that its inspection that faulted the Bangalore sterile plant, for a variety of shortcomings had been closed by the FDA.

Similar concerns raised by EMA inspectors led Biocon and Mylan to pull their applications for Herceptin biosimilars in Europe.

Novartis Considers Offloading Its US Generic Pills Business

Novartis is considering a sell-off of its oral solids business according to outgoing CEO Joseph Jimenez.

The CEO said that Novartis values the generics business outside the US, where biosimilars are giving Sandoz a leading position, however, it has question marks over the declining US generics market.

With downward price trends likely to continue for the foreseeable future, Sandoz is concentrating on biosimilars and complex generics, where product differentiation can provide some pricing leverage, according to Peter Goldschmidt, president of Sandoz.

Price competition for Novartis caused a 13% drop in its generic sales in the US in Q3 this year while Sandoz reported sales of $2.6 billion, up 1%, with rest of world sales growing by 9%.

Some months ago, Novartis hinted its thinking, saying; “we are currently experiencing above-average pricing pressure in our US portfolio. With several products no longer competitive in saturated markets, we have made the decision to discontinue or divest these limited growth products to optimize our product portfolio.”

La Jolla Pharma Announces Pivotal Clinical Study for Beta Thalassemia Patients

La Jolla Pharmaceutical Company (NASDAQ:LJPC) has announced the initiation of a pivotal clinical study of LJPC-401 (synthetic human hepcidin) in patients with transfusion-dependent beta thalassemia who, despite chelation therapy, have cardiac iron levels above normal.

A high level of cardiac iron puts patients at risk of cardiac complications such as heart failure and sudden death.

The primary efficacy endpoint of the study is the change in iron content in the heart after six months, as measured by cardiac magnetic resonance imaging (MRI).

Legal, Regulatory & Compliance

EUROPE

UK NICE Rejects Eisai’s Halaven for Earlier Use but Better News for Novartis and Pfizer

The UK’s price watchdog NICE has rejected Eisai’s cancer drug Halaven for earlier use.

Halaven was approved last year by NICE to treat breast cancer patients after two rounds of chemo but the Japanese company was hoping for approval for earlier use. In its draft guidance, NICE said that Halaven was too expensive for use in patients with locally advanced or secondary breast cancer who have had only one chemotherapy treatment.

It noted that Halaven met its criteria to be considered an end-of-life treatment and added an average of 4.6 months to the survival of patients compared with chemo alone. However, it said the Eisai drug didn’t increase the time during which the tumor doesn’t grow thereby leaving a doubt about whether improved survival was attributable to the drug itself or to the treatments that followed use of Halaven.

In the cost range from £36,244 to £82,743 ($48,000 to $110,000) per quality-adjusted year, the NICE Committee deemed it outside of what is normally considered acceptable for end-of-life treatments.

Roche Sues Pfizer for Biosim Patent Infringement

Roche is suing Pfizer for infringement of 40 patents protecting its cancer drug, Herceptin.

In a complaint in Delaware federal court, Roche claims that Pfizer's FDA application for its proposed biosim amounts to patent infringement and is seeking to block any potential launch.

Roche says it has spent "over two decades, and billions of dollars, developing Herceptin into the life-saving drug it is today” and it claims that Pfizer is using Roche studies to shortcut and prove safety and efficacy.

The FDA accepted Pfizer's application in August but Pfizer has not yet secured approval for its Herceptin biosim.

Herceptin generated $2.5 billion for Roche in the US last year but some of its patent protections lapse in 2019.

Europharma's Loses its GMP Certification in Denmark

The Danish Medicines Agency (DMHA) has withdrawn Europharma's GMP license.

The DMHA statement of non-compliance stated that the nature of non-compliance is a general lack of will and ability to adhere to the principals of good manufacturing and good distribution practices as well as examples of non-adherence by Europharma.

EU Closes Infringement Procedure Against Roche

The European Commission has closed the infringement procedure taken against Roche for failure to meet certain pharmacovigilance obligations. The Commission explained that after considering all the available evidence and being satisfied with the company's remedial actions, it has decided to close the case.

The infringement procedure was started by the European Medicines Agency (EMA) in October 2012, following an inspection carried out in 2012 by the MHRA which identified serious shortcomings in the pharmacovigilance processes of Roche.

The aim of the inquiry was to investigate allegations that Roche failed to comply with its pharmacovigilance obligations in relation to 19 of its centrally authorized products.

In a written statement submitted to the Commission, Roche said:

"Roche accepted all the inspection findings. It took them extremely seriously and fully understands the EMA's and Commission's concerns. It has worked diligently to remediate the deficiencies as quickly as possible and to enhance the company's medical compliance and PV systems to prevent any recurrence."

The Commission has now closed the case.

UNITED STATES AND REST OF WORLD

J&J and Bayer Lose with $28M Xarelto Verdict

A jury in Philadelphia has ordered Bayer and Johnson & Johnson to pay $28 million to plaintiff Lynn Hartman, after Harman's lawyers argued that her Xarelto blood thinning regime caused severe gastrointestinal bleeding.

After three successful Xarelto defense cases in Louisiana and Mississippi, this is its first defeat. However, the drugmakers say they plan to appeal.

The Hartman case centered on whether physicians were properly instructed about the risks, but J&J and Bayer contend that the Xarelto label does so. A Janssen spokesperson said the "verdict contradicts years of scientific data and the US Food and Drug Administration's repeated confirmation of Xarleto's safety and efficacy."

Nonetheless, the company faces over 20,000 other liability cases.

Xarelto was granted FDA approval in 2011 and was Bayer's top-selling drug last year, delivering $3.24 billion in sales and $2.5 billion for J&J.

FDA Warns Amherst and Magna Over “False or Misleading” Claims

The FDA's Office of Prescription Drug Promotion has issued its third waring of the year so far. This time it was Amherst and Magna Pharmaceuticals were reprimanded for making "false or misleading" website and trade show claims about their insomnia treatment, Zolpimist.

In a letter, the FDA says that online and trade exhibition panels webpage failed to communicate any risk information and that claims of the product’s superior efficacy were not supported and said that the claim that Zolpimist “induces sleep” in ten minutes was misleading as no reference data existed to support the claim.

Purdue Pharma Starts Opioid Settlement Talks

Bloomberg has reported that Purdue Pharma is initiating settlement talks following the spate of lawsuits that claim its aggressive OxyContin opioid marketing led to a nationwide epidemic.

Together with Endo International, Janssen, Teva Pharma and Allergan, Purdue Pharma is named in an opioid marketing investigation by attorney generals from 39 states. Their focus was primarily on Purdue initially but investigators expanded their investigation in September.

According to Connecticut Attorney General, officials are open to settlement talks on the basis that companies talked up the benefits of opioid treatment for pain but downplayed the risks.

Sanofi Testifies to Dengvaxia's Safety in Philippines

Sanofi has strongly defended the company's dengue vaccine in the Philippines.

Meanwhile, new media reports raised questions about the genesis of the country's immunization campaign, suggesting that the Department of Health's effort went forward in the face of contrary advice from its own experts.

During a public Senate hearing, Sanofi’s Head of Asia Pacific, Thomas Triomphe, said the company assures “each and every one of you that Dengvaxia is, and continues to be, a safe and efficacious vaccine.”

Triomphe told officials its recent decision to stop a national Dengvaxia immunization campaign will be a “regression” in the country’s approach to fighting dengue and a “disservice” to the public.

“We hope that knowing that other nations all over the world are not taking Dengvaxia off the shelf would prove that Sanofi Pasteur is telling you the truth that the vaccine is safe,” Triomphe said at the hearing and added that the vaccine is being used in 11 countries worldwide.

The Philippine authorities pulled the vaccinations shortly after Sanofi warned that Dengvaxia can cause infection to those who previously hadn’t had exposure to the virus. The Manilla authorities have also initiated a probe and there are talks of legal action, according to the country’s Health Ministers.

Dengvazia was 20 years in development at a cost of $1.5 billion but it has yet to prove its commercial despite big expectations and marketing approval granted in 19 countries.

EMA Recommends Seven Medicines for Approval

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) recommended seven medicines for approval at its December 2017 meeting, including two orphan medicines, one of which is also an advanced therapy medicinal product (ATMP).

The CHMP recommended granting a marketing authorization for the ATMP Alofisel (darvadstrocel), for the treatment of complex perianal fistulas in patients with Crohn's disease. Alofisel has an orphan designation.

The Committee recommended granting a pediatric-use marketing authorization (PUMA) for Alkindi (hydrocortisone), for the treatment of primary adrenal insufficiency, a rare hormonal disorder in infants, children and adolescents. PUMAs can be granted for medicines which are already authorized but no longer under patent protection, and have been developed specifically for children.

The committee recommended granting a conditional marketing authorization for Crysvita (burosumab), for the treatment of X-linked hypophosphataemia with radiographic evidence of bone disease in children and adolescents with growing skeletons. Crysvita has an orphan designation.

Ozempic (semaglutide) received a positive opinion for the treatment of type 2 diabetes.

One biosimilar medicine was recommended for approval by the Committee: Herzuma (trastuzumab), for the treatment of breast and gastric cancer.

Two generic medicines received a positive opinion: Anagrelide Mylan (anagrelide), for the reduction of elevated platelet counts in at-risk essential thrombocythaemia patients; and Efavirenz/Emtricitabine/Tenofovir disoproxil Krka (efavirenz / emtricitabine / tenofovir disoproxil), for the treatment of HIV infection.

EMA & UK Gov Publish Brexit Guidance for Pharma Companies

The European Medicines Agency (EMA) has published the first version of its procedural guidance for industry which outlines the practical and simplified requirements that companies should follow to make sure that necessary changes to their marketing authorization are made by the end of March 2019, to allow for the continued marketing of their medicine in the European Economic Area (EEA) after Brexit, taking into consideration, that as of 30 March 2019 the United Kingdom will become a third country, from an EMA perspective.

The Agency and the European Commission have published additional and updated guidance to help pharmaceutical companies prepare for the United Kingdom's withdrawal from the European Union wherein companies are reminded to plan for the situation that the United Kingdom (UK) will leave the EU on 29 March 2019, in order to avoid any impact on the continuous supply of medicines for human and veterinary use within the EU.

The latest version is an update on the initial questions-and-answers document that was published in May 2017 and includes additional information on how the UK's withdrawal from the EU will affect marketing applications and authorizations for different types of medicinal products, including, generic, hybrid and biosimilar medicines.

The UK Pharma industry had an output of £12.8 billion ($17 billion) in 2016. It accounts for 1% of total UK output, 7% of manufacturing output and provides employment to 36,000 taxpayers. Medicine and pharma products represent 8% of goods exported from the UK and 5% of goods imported into the UK.

In a sector of such importance to the UK economy, the UK's House of Commons Research Library Service has issued a "Brexit & Medicines Regulation Briefing Paper." It refers to a statement from Sir Michael Rawlins, Chairman of the MHRA where he expressed a concern that "one of the biggest worries I have about Brexit and standing alone as a regulator is that we are only 3% of the world market for new drugs and if we are not careful, we are going to be at the back of the queue behind Japan, America and Europe."

The document also cites the example of Switzerland (a country not within the EMA but with a number of bilateral mutual recognition agreements with the EMA) where regulatory process means that marketing approvals are agreed on average 157 days after EMA approval.

PRAC Confirms Suspension of Modified-Release Paracetamol

The EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has confirmed its recommendation that modified- or prolonged-release paracetamol containing medicines (designed to release paracetamol slowly over a longer period than the usual immediate-release medicines) should be suspended from marketing.

It follows a re-examination of a previous suspension recommendation made in September 2017 by the Committee, following which the PRAC is still of the opinion that the advantages of having a longer-acting product did not outweigh the disadvantages—if an overdose of the medicine were taken—since the usual treatment procedures developed for immediate-release products are not appropriate for modified-release paracetamol.

The EMA says that in many cases, medics may not be able to determine whether an overdose of paracetamol involves immediate-release or modified-release products, making it difficult to decide what type of treatment is needed.

The Committee therefore recommended that marketing of modified-release paracetamol medicines should be suspended.

The review of modified-release paracetamol was initiated in June 2016 at the request of Sweden.

Germany's Boehringer Ingelheim's Humira Biosim Approved by E.U.

Germany's Boehringer Ingelheim has confirmed that the European Commission has granted marketing authorization for Cyltezo, a biosimilar to AbbVie's Humira, for the treatment of multiple chronic inflammatory diseases in adults and children, including rheumatoid arthritis, psoriatic arthritis and active ulcerative colitis.

"Cyltezo is the first biosimilar from Boehringer Ingelheim approved in Europe, and marks a significant step forward for us in offering effective, and more affordable treatment options for patients with chronic inflammatory diseases," said a company spokesperson.

AbbVie's Humira, the world's biggest-selling drug, generated ~ $14 billion in sales in 2016 and accounted for 64% of AbbVie's net revenue.

VBL Therapeutics Gets Orphan Drug Designation for VB-111 in Europe

VBL Therapeutics (Nasdaq:VBLT), a clinical-stage biotechnology company focused on the discovery, development and commercialization of first-in-class treatments for cancer has announced that the European Medicines Agency (EMA) has designated ofranergene obadenovec (VB-111) as an "orphan medicinal product" for the treatment of ovarian cancer, adding to the orphan status already granted for glioblastoma in the US and Europe.

VB-111 is the company's lead product candidate currently being studied in a Phase 3 pivotal trial for recurrent glioblastoma, with launch of a Phase 3 in platinum-resistant ovarian cancer expected by the end of the year.

Immune Design Gets Orphan Drug Designation by the EMA for the Treatment of Follicular Non-Hodgkin's Lymphoma

Immune Design (Nasdaq:IMDZ), a clinical-stage immunotherapy company focused on oncology, has announced that the European Medicines Agency (EMA) has granted Orphan Drug Designation for G100, Immune Design's investigational intratumoral therapy, for the treatment of follicular non-Hodgkin's lymphoma.

The EMA orphan drug designation is assigned to products targeting the treatment of rare diseases, which are defined as having a prevalence of not more than five in 10,000 people in the EU. This designation provides the sponsor with certain benefits, including protocol assistance, reduced fees for regulatory activities and up to ten years of market exclusivity in the EU upon marketing approval for the designated indication.

G100 has also been granted orphan drug designation by the FDA Drug for the treatment of follicular non-Hodgkin's lymphoma.

Rexahn Pharma Gets Positive Opinion from EMA for Orphan Drug Designation

Rexahn Pharmaceuticals, Inc. (NYSE AMERICAN:RNN), a clinical stage biopharmaceutical company developing innovative, targeted therapeutics for the treatment of cancer, has announced that the European Medicines Agency's (EMA) Committee for Orphan Medicinal Products (COMP) has issued a positive opinion recommending orphan medicinal product (orphan drug) designation for RX-3117 for the treatment of pancreatic cancer.

Pancreatic cancer is classed as a rare disease with a very poor prognosis and limited treatment options.

Applications for orphan designation are initially reviewed by the COMP. Positive opinions are then forwarded to the European Commission, which is responsible for formally granting the orphan designation. Orphan medicinal product designation in the European Union is given to products that are intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating; where prevalence of the condition in the EU is less than five in 10,000; and where the product represents a significant benefit over existing treatments.

Herceptin Biosim: Samsung Gets Green Light in EU

Samsung Bioepis' Ontruzant has become the first trastuzumab to be approved in Europe with EMA approval for marketing in the 28 EU member states plus the European Economic Area member states of Norway, Iceland, and Liechtenstein.

Medtech Highlights

TransEnterix Announces First US Purchase Agreement for Senhance™ Surgical System

TransEnterix, Inc. (NYSE American: TRXC), a medical device company that is pioneering the use of robotics to improve minimally invasive surgery, has announced that Florida Hospital has entered into an agreement to purchase the Company's Senhance™ Surgical Robotic System.

The Florida Hospital Orlando campus will be home to the first commercial unit of the Senhance Surgical System to be installed in the US.

The recently FDA-cleared Senhance Surgical System represents an innovative technology designed to assist surgeons in performing minimally invasive surgery. The system features multiple robotic arms that are controlled by a surgeon seated

comfortably at a console. The surgeon controls small surgical instruments with robotic precision while at the same time moving a small scope that tracks the eye movement of the surgeon.

The Senhance is the first surgical robotic system to offer the security of haptic force feedback that allows surgeons to feel the forces the instruments generate when handling delicate tissue. The Senhance represents a new era of digital laparoscopy designed to support responsible economics for the hospital, patient and today's value-based healthcare system.

Medtronic Acquires Gastro Diagnostics Crospon in $45M Deal

Medtronic has acquired gastrointestinal disorder diagnostic company Crospon. Medtronic has not confirmed the exact value of the deal but London's Times newspaper has reported it could be worth up to $45 million (EU €38 million).

West of Ireland based Crospon, produces endoscopic diagnostics, including its FDA approved Endoflip system, which includes the company's Flip topography module designed to allow for the assessment of patient motility disorders during endoscopy.

The system includes imaging software that displays esophageal contractility patterns in real time on a touchscreen display and allows for the investigation of conditions including achalasia, GEJ outflow obstruction, and other major or minor peristalsis disorders during endoscopy.

FDA Approves First Medical Device Accessory for Apple Watch

AliveCor has announced FDA clearance of KardiaBand in the US, allowing Apple Watch users to discreetly capture their EKG anytime, anywhere in order to quickly detect normal sinus heart rhythms and atrial fibrillation (AFib), the most common heart arrhythmia.

KardiaBand is the first FDA-cleared medical device accessory for Apple Watch. It can record an EKG in 30 seconds with just a touch of its integrated sensor. Results from the Kardia App are displayed on the face of Apple Watch.

KardiaBand retails for $199 plus an annual subscription fee of $99 a year.

Hancock Jaffe Laboratories Sets Terms for $13M IPO

Hancock Jaffe Laboratories, which is developing bioprosthetic devices for cardiovascular surgeries, announced terms for its IPO. The Irvine-based company plans to raise $13 million by offering 1.88 million shares at a price range of $6 to $8. At the midpoint of the proposed range, Hancock Jaffe Laboratories would have a market value of $62 million.

It plans to list on the Nasdaq. WallachBeth Capital and Network 1 Financial Securities are working joint on the deal. IPO timing has not been disclosed.

Virtual Incision Announces $18 Million Series B Funding for Miniaturized Surgical Robots

Virtual Incision Corporation has raised $18 million in Series B funding.

The round was co-led by new investor Sinopharm Capital, the private equity fund initiated by Sinopharm Group, China's largest healthcare company, and existing investor Bluestem Capital, with participation from PrairieGold Venture Partners and others.

This financing will support the company's premarket notification submission to the US FDA for its next-generation miniaturized robotically assisted surgical device (RASD). The Virtual Incision RASD is designed to enable physicians to perform less-invasive general surgery abdominal procedures that today are usually performed via large, open incisions, including multi-quadrant surgeries such as colon resection.

While similar to other RASDs with regard to intended use, Virtual Incision's technology takes a new and unique approach to robotically assisted surgery by using a small, dexterous and self-contained surgical robot that does not require a dedicated operating room or specialized infrastructure.

The company's key focus is on the under-served 80% of the market where smaller and simpler solutions are in demand.

Genesis Innovation Group Launches $10M Cultivate (MD) Medtech Venture Fund

Michigan-based Genesis Innovation Group has created a Cultivate(MD) Capital Fund, which aims to manage $10 million to invest in early stage healthcare companies with a focus on medical device and orthopedic technologies.

The company says it expects the fund to be fully operational and seeking companies to invest in by early 2018. The fund will focus on investing in early stage medtech companies with "demonstrated evidence of effectiveness" with goals of reducing the cost of healthcare while improving outcomes for patients.

Align Global Consulting is one of the world's leading providers of global structuring solutions for the pharma industry. For information contact Sean M. King at sking@alignglobalconsulting.com or visit www.alignglobalconsulting.com.

With offices in London, Dublin, Research Triangle Park and Silicon Valley, Align Global Consulting is a globalization consulting and advisory firm that represents clients expanding globally or improving existing operations by providing creative legal and tax solutions to address commercial, trade, investment and regulatory matters. Align's comprehensive list of services includes global structuring, global business transactions, cross-border M&A transactions, and international tax planning for outbound and inbound investment. Align assists companies in all stages of growth, from emerging growth companies to the Fortune 100. With "big firm" credentials and experience, Align handles matters traditionally entrusted to larger firms, while maintaining a commitment to the lost art of one-on-one client service.