An industry update: the latest news in therapeutic delivery

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The present industry update covers the period 1–31 July 2017. Information was sourced primarily from company press releases, regulatory and patent agencies, scientific literature and various news websites. There was positive approval news this month for GlaxoSmithKline for its new self-injecting treatment for systemic lupus erythematosus but less positive news for Ocular Therapeutix, a new drug application for its treatment for postoperative ocular pain, DEXTENZA™ was rejected for a second time. Endo Pharmaceuticals agreed to withdraw its opioid formulation Opana®Er due to abuse concerns. Collaborations for novel therapeutic delivery research were announced this month by Takeda and BioSurfaces, Catelect and Rutgers University, Lilly and Purdue University and Titan Pharmaceuticals with Walter Reed and the Southwest Research Institute. A number of companies announced significant financing deals to allow for the clinical development of products with enhanced delivery options including Sebacia and Diasome.

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Business development

Takeda, BioSurfaces to collaborate on gastrointestinal drug-delivery devices

Takeda Pharmaceutical Company Ltd and BioSurfaces, Inc. (both MA, USA) announced on 25 July that they have agreed to initiate a research program with the aim of developing novel, innovative medical devices to treat patients with gastrointestinal (GI) diseases. This program will make use of BioSurfaces' proprietary nanomaterial technology which exploits the ability to produce nanofibrous materials with US FDA approved polymers. It is proposed that the BioSurfaces' process will allow for the incorporation of therapeutics for localized delivery to the GI tract. Financial details of the collaborative agreement were not disclosed [1].

Sebacia raises \$36 m for novel microparticle acne treatment

Sebacia (GA, USA) announced on 25 July that it had completed a Series D funding round and had leveraged additional debt facility from Hercules Partners.

Sebacia's proprietary technology, Sebacia Microparticle™ is composed of a silica core encapsulated in a gold coating and is designed to target the light from laser systems typically used by dermatologists. This targeted treatment aims to photothermally affect change in the sebaceous glands and thus treat acne.

The company announced that the finance raised would be used to complete US pivotal trials with results expected by Q3 2018. The technology is already CE marked in Europe and approximately 2000 procedures have been performed to date [2].

Gurnet Point acquire Innocoll

Athlone (Ireland)-based Innocoll announced on 24 July the completion of its acquisition by Gurnet Point through its wholly owned subsidiary Lough Ree Technologies Ltd. Announcing the acquisition Christopher Viehbacher, Managing Partner of Gurnet Point Capital commented, "Gurnet Point is pleased to announce that its acquisition of Innocoll is now effective. We are excited by the prospect of helping to develop and bring XaraColl to the market and we look forward to assisting with the re-submission of XaraColl for FDA approval and preparing for its commercialization".

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XaraColl is Innocoll's lead product – a bupivacaine HCl collagen-matrix implant in development for the treatment of postsurgical pain. In December 2016 received a 'Refusal to File' letter from the FDA for the New Drug Application (NDA) submitted for XaraColl. Following further meetings with the FDA, the company indicated that it intended to address certain issues raised in the Refusal to File by conducting an additional short-term pharmacokinetic study and several short-term nonclinical toxicology and biocompatibility studies. Gurnet Point now believes that these studies, if successful, may be completed in time for a resubmission of the NDA at the end of 2017 [3].

Diasome lands \$30 m to fund clinical trials of liver-targeted insulin

Diasome (OH, USA) announced on July 6 that it had concluded an agreement that allowed it to access of over \$30 m to fund the development of their liver-targeted insulin product. Medicxi, a European life sciences venture capital firm is the lead investor in this round of funding. Diasome's proprietary technology for targeting insulin to the liver is known as hepatocyte directed vesicles (HDV) and it preferentially allows insulin to be delivered to liver hepatocytes. The funding achieved will allow Diasome to progress their lead candidate, HDV-Insulin, through clinical trials. The HDV-insulin therapy is specifically designed to mimic the mealtime exposure of the liver to insulin and will include options for the treatment of both Type 1 and Type 2 diabetes (T1D and T2D), respectively.

Significant funding was provided from the JDRF T1D Fund, a Boston-based venture philanthropy fund dedicated to facilitating solutions to treat, prevent and cure T1D [4,5].

Catalent & Rutgers partner to study pediatric drug formulation & delivery

The Catalent Applied Drug Delivery Institute (NJ, USA) and Rutgers University (NJ, USA) announced on 20 July that they had initiated a partnership to identify diseases and therapies for which there is significant need for novel pediatric formulations.

The Catalent Applied Drug Delivery Institute was established in 2012 with an aim to accelerate the use of advanced formulations, dosage forms and delivery devices.

According to Dr. Cornell Stamoran, Catalent's VP Strategy, "*Most initiatives focus on individual new drugs or disease areas - we're collaborating to identify a broad platform, founded on rigorous stakeholder insights, to establish a foundation for future pediatric drug development*" [6].

Inovio looks to raise \$75 m in public offering

On 18 July, Inovio (PA, USA) announced that it was going to offer \$75.0 million of shares of its common stock in an underwritten public offering. Inovio intends that the proceeds from this offering be used for such purposes as, clinical trial expenses, research and development expenses, manufacturing expenses and other business development activities.

Inovio's therapeutic focus is the delivery of DNA-based immunotherapeutic with lead candidates in the area of cancers caused by the human papilloma virus, their proprietary electroporation technology facilitates delivery of the DNA vaccines to different target tissues [7].

Titan Pharmaceuticals partners with Walter Reed & the Southwest Research Institute for long-acting antimalarial implant

On 6 July, the Californian-based Titan Pharmaceuticals announced a collaboration with the Walter Reed Army Institute of Research (WRAIR) and Southwest Research Institute (SwRI) to evaluate ProNeura™, Titan's proprietary long-term, continuous drug delivery technology, for prevention of malaria.

ProNeura is a subdermal implant that can offer continuous drug release and nonfluctuating medication levels over a period of 3 months to a year. In 2016, the FDA approved Titan's first product employing this technology for the long-term maintenance treatment of opioid dependency, Probuphine® [8].

Eli Lilly & Purdue University announce strategic research collaboration

On 6 July, Purdue University and Eli Lilly (both IN, USA) announced a new \$52 million strategic research collaboration in the areas of improving the delivery of injectable medicines and also developing novel predictive models for clinical success that can reduce the risks associated with drug development and more effectively predict the outcome of new therapies.

This new agreement has a term of 5 years and builds upon the previous successful relationship between the company and the university and is Purdue's largest strategic collaboration with a single company [9].

pSivida licenses European rights for Durasert to Alimera

The Massachusetts-based specialty drug delivery company pSivida announced on 10 July that it had agreed to license European, Middle East and African rights for its product Durasert™ for the treatment of posterior segment uveitis in an amendment to an existing global collaboration agreement with Alimera (GA, USA).

Under the new agreement, pSivida will withdraw its centralized EU application for the drug's indication for posterior uveitis and allow Alimera to file an application for the indication in the countries where it is currently approved for Diabetic Macular Edema [10].

Developments & clinical trials

Submission of an NDA for opioid disorder by Camarus

Swedish company, Camarus, along with its co-development partner Braeburn Pharmaceuticals (NJ, USA) announced on 20 July that they had submitted an NDA to the FDA for their depot formulation of buprenorphine (CAM2038) for the treatment of opioid use disorder.

Camarus' proprietary technology FluidCrystal® is a drug delivery technology that is based on endogenous polar lipids that can spontaneously form liquid crystal nanostructures in aqueous environments. These lipid structures can then carry very high drug payloads and are suitable for formulation as intravenous bolus injections, infusion products and subcutaneous injection products.

Data from 944 study participants across seven Phase II/III clinical trials was submitted as part of the NDA submission for CAM2038 [11].

FDA grants priority review to Kaleo's auto-injector for children

The Virginia-based device company Kaléo announced on 27 July that the FDA had a Priority Review of its supplemental NDA for its AUVI-Q 0.1 mg product. This is the first epinephrine auto-injector specifically designed for the treatment of anaphylaxis in infants and small children weighing 16.5–33 pounds. The design of the device accommodates both a shorter needle length and lower dose than other marketed epinephrine auto-injectors [12].

Surmodics to launch pivotal trial for drug-coated balloon

Surmodics (MN, USA) a company that specializes in surface modification technologies for intravascular medical devices announced on 26 July that it had received an investigational device exemption from the FDA to initiate a pivotal clinical trial of its SurVeil™ drug-coated balloon (DCB). This new DCB incorporates new proprietary coating for interventional treatment. This trial will evaluate the safety and effectiveness of the device for treatment of subjects with symptomatic peripheral artery disease due to stenosis of the femoral and/or popliteal arteries and will enroll up to 446 subjects at 80 sites in the USA and elsewhere [13].

Samumed granted orphan drug status for inhaled idiopathic pulmonary fibrosis therapy

Samumed (CA, USA) announced on 25 July that it had been granted orphan drug status for its SM04646, to treat idiopathic pulmonary fibrosis (IPF). Development of the therapeutic as an inhalable, nebulized formulation is ongoing. IPF is incurable and current treatment options are very limited. IPF is the most common interstitial lung disease in USA, with an estimated prevalence of 13.2–27.9 per 100,000 women and 20.2–63.0 per 100,000 men. After diagnosis, the estimated median survival for IPF patients is between 2.5 and 3.5 years [14].

Mylan, Theravance's inhaled chronic obstructive pulmonary disease therapy: positive late stage clinical trial results announced

Mylan (Dublin, Ireland) and Theravance (Hertfordshire, UK) announced on 19 July positive results for the Phase III study of revefenacin (TD-4208) in patients with chronic obstructive pulmonary disease (COPD).

TD-4208 is an investigational long-acting muscarinic antagonist and a proposed once-daily, nebulized bronchodilator for the treatment of COPD. Theravance Biopharma and Mylan have established a strategic collaboration to develop and commercialize nebulized revefenacin products for COPD and other respiratory diseases. TD-4208 is delivered via Mylan's dry-powder drug-delivery platform technology. TD-4208 was acquired from Theravance in 2015 by Mylan in a \$265 million deal [15].

Aequus to launch trial for anti-nausea patch

The Vancouver-based Canadian company Aequus announced on 5 July that it had received approval from Health Canada to initiate a proof of concept trial for its novel anti-nausea patch, AQS1303. The patch contains a combination of pyridoxine and doxylamine and it is hoped that it will offer a more convenient option for patients who currently receive the medication in the oral form up to four-times daily. The company also announced that in parallel to the Canadian Proof of Concept study it will also prepare for pre-Investigational New Drug (pre-IND) meeting with the FDA to define the clinical strategy for regulatory approval in the USA [16].

AntriaBio commences Phase I studies for their insulin product

It was announced on 6 July that AntriaBio (CO, USA) had commenced its Phase I first-in-human clinical trial of its lead product candidate, AB101. This initial study is a single ascending dose study to assess the safety and tolerability, pharmacokinetics and pharmacodynamics of AB101 in patients with Type 1 diabetes mellitus. The company aims for this trial to facilitate the demonstration of clinical proof of concept for AB101 as a once-weekly insulin therapy. AntriaBio's sustained delivery technology is based on poly-lactide co-glycolic acid (PLGA) microspheres with encapsulated Peg (5 kDa)-insulin [17].

Biohaven commences Phase III pivotal trials for migraine treatment

The dates 24 and 31 July saw two announcements from Connecticut's Biohaven on their Phase III studies for the treatment of migraine with their oral rimegepant formulations. Rimegepant is one of a family of calcitonin gene-related peptide receptor antagonists under clinical evaluation by Biohaven for a number of indications including migraine and was licensed exclusively from Bristol-Myers Squibb Company [18,19].

Early stage development

Researchers create unique thermal ablation system to enable transdermal protein delivery

It was reported on 27 July on the website www.news-medical.net that Japanese scientists from the University of Kumamoto are researching a novel thermal ablation system to enable the transdermal delivery of therapeutic proteins. To facilitate the transdermal delivery while minimizing damage to the skin, the researchers used a combination of transparent gel patches, gold nano-rods and near-infrared light. In initial *in vivo* and *in vitro* tests with murine skin, the researchers discovered that the near-infrared-irradiated gold nano-rod patches heated the skin to approximately 43°C and the fluorescently labeled ovalbumin (FITC-OVA) they used as model therapeutics were significantly translocated. Although this work is at a very early stage of development, the research group is confident that in time, they can advance the current state of the art in transdermal delivery [20].

Hydrogel-based capsules may help patients' compliance

An article published in 25 July edition of the MIT News (<http://news.mit.edu/>) reported a paper published in Nature Communications by researchers MIT's Koch Institute for Integrative Cancer Research group on triggerable tough hydrogels (TTH). The group has been working with the Bill and Melinda Gates Foundation to develop ultra-long-lasting capsules, which might last for the entire course of a treatment, or could be taken once a week or once a month, depending on the device. Initial preclinical studies, including large animal studies, have indicated that capsules made from the novel hydrogels may have the capacity to deliver therapeutics over a significant time (days, even weeks). The hydrogels used are manufactured from a combination of polymer networks, one is alginate the other is a polyacrylamide, and these give additional strength and durability to the device/capsule. However, the scientists have also included crosslinking features within these intertwined networks which can be dissolved on demand using biocompatible trigger compounds and this allows for rapid removal and/or dissolution of the device should it become necessary [21].

Preclinical studies on oral monoclonal antibody for autoimmune diseases

Tiziana Life Sciences (London, UK) published an article in the *Journal Clinical Immunology* on 28 July that described the results of preclinical studies for Foralumab (NI-0401). Tiziana claim that these studies on the orally available, fully human anti-CD3 monoclonal antibody (mAb) demonstrated prevention of skin xenograft rejection in humanized mice. Until recently, it was thought that oral delivery of mAbs was not achievable. According to Dr Gabriele Cerrone, Chairman of Tiziana Life Sciences, "New data demonstrating oral efficacy in animals with

foralumab is a major milestone and opens a novel avenue for the treatment of NASH and autoimmune diseases with fully human mAbs" [22,23].

Antibiotic-releasing polymer may help eradicate joint implant infection

On 18 July, a team of investigators from Massachusetts General Hospital discussed their recently published article in the *Journal Nature Biomedical Engineering*. The paper describes the development of a novel antibiotic-releasing polymer for the treatment of prosthetic joint infection. Using mathematical and statistical models, researchers developed polyethylene materials which 'doped' with antibiotic clusters. These clusters were designed to release the antibiotic over extended periods of time without compromising the strength of the material. Preclinical models of prosthetic joint infection were produced either by injecting a *Staphylococcus aureus*-containing solution into the prosthesis or implanting a titanium rod covered with a *S. aureus* biofilm. When the novel antibiotic/polymer matrices were tested, the antibiotic-releasing polymer successfully eliminated the infection. As a control, the antibiotic was also incorporated into the bone–cement spacer but this was not effective in treating the infection [24].

Molecular hitchhiker on human protein signals tumors to self-destruct

Researchers from Vanderbilt University (TN, USA) have reported, in a paper published in the *Proceedings of the National Academy of Sciences USA*, that by making slight modifications to a small-interfering RNA molecule, called siRNA-L2, it can effectively 'hitchhike' on the human protein albumin. The ability of this modified siRNA molecule to bind to the albumin allows it to circulate around the body for a number of days – much longer than typically is observable with siRNA-loaded micro/nanoparticles. The authors propose that this mechanism may be used to develop more successful tumor-targeting therapeutics. Initial *in vitro* results were encouraging – looking at the siRNA-L2 in human breast tumor tissue removed from a donor, the modified molecule appeared to be more effective in targeting the tumor, with siRNA-L2 more than three-times as present in the tumor than siRNA delivered with synthetic nanoparticles [25].

Researchers develop light-sensitive hydrogel for drug delivery

A report published on the EurekaAlert website on 6 July reported that Hong Kong based-researchers from the University of Science and Technology had developed a B12-dependent light-sensing hydrogel. The hydrogel was created by covalently attaching the photoreceptor C-terminal adenosylcobalamin binding domain (CarHC) proteins. The researchers claim that the hydrogels created via this process allow for the design of 'smart' materials. It is proposed that these photoresponsive hydrogels would provide 'tuneable' drug-delivery opportunities as they undergo a rapid gel–sol transition caused by light-induced CarHC disassembly. It is claimed that these novel hydrogels would be particularly suitable for the delivery of stem cells and protein molecules. The initial article describing this work was published in the 6 June edition of the *Proceedings of the National Academy of Sciences USA* [26,27].

Defymed reveals development of novel insulin delivery device

The Strasbourg-based company Defymed announced its novel delivery device for insulin for the treatment of Type 1 diabetes, ExOlin[®] on 10 July.

ExOlin is a novel medical device under development by Defymed, the company claims that if it proves successful in clinical trials, it will allow for instant administration of an intraperitoneal injection of insulin using a simple subcutaneous injection (via an external connection to a syringe, pen, insulin pump, etc.). The company aims to enter clinical trials in 2018 predicts that the product could be commercially available by the end of 2020 after obtaining CE marking [28].

Regulatory news & approvals

Endos' Opana[®] ER removed from market

Endo Pharmaceuticals (Dublin, Ireland) announced on 6 July that following consultation with the FDA, it had decided to voluntarily remove OPANA[®] ER from the market. This move follows on from a request by the FDA in June 2017 that Endo remove its opioid pain medication Opana ER from the market due to risks of abuse. The company was very keen to reiterate that the withdrawal did not reflect a finding that the product was not safe or effective when taken as prescribed. As a result of the decision to remove the product from market, the company

indicated that it expected to incur a pretax impairment charge of approximately \$20 million in the Q2 of 2017 to write-off the remaining net book value of its Opana ER intangible asset [29,30].

GlaxoSmithKline receives FDA approval for a self-injectable formulation of belimumab for systemic lupus erythematosus

GlaxoSmithKline (London, UK) announced on 20 July that the FDA has approved Benlysta – a self-injectable formulation for systemic lupus erythematosus (SLE). Benlysta is the first subcutaneous self-injection treatment option approved for patients with SLE. SLE is the most common form of lupus. It is a chronic, incurable autoimmune disease which produces autoantibodies that can attack almost any system in the body. This product will be the second formulation of belimumab and it complements the existing intravenous formulation which was approved in 2011. It is expected that the product will be commercially available by the end of August 2017.

Belimumab is a human mAb that inhibits B-cell activating factor (also known as B-lymphocyte stimulator [BLyS]). Belimumab was developed by Human Genome Sciences and Cambridge Antibody Technology. GlaxoSmithKline acquired Human Genome Sciences, took belimumab through Phase III clinical trials and markets belimumab [31].

Spectranetics receives approval from the FDA for Stellarex DCB

Spectranetics (CO, USA) and medical device company that were recently acquired by the Dutch Royal Philips company, announced on 26 July that it had received premarket approval of its Stellarex™ DCB. Stellarex DCB was designed to restore and maintain blood flow to the superficial femoral and popliteal arteries in patients with peripheral arterial disease. Clinical trial data obtained during the pivotal studies indicated that it was successful in treating patients with low paclitaxel drug dose. According to Dr Sean Lyden the co-principal investigator of the study *“When considering options, I think most clinicians would prefer to use a lower drug dose if they can also achieve great patency results”* [32].

FDA rejects Ocular’s Dextenza for a second time

Ocular Therapeutix™ (MA, USA) disclosed on 11 July that it had received a complete response letter (CRL) from the FDA, regarding its resubmission of an NDA for DEXTENZA™ (dexamethasone insert) 0.4 mg for the treatment of ocular pain following ophthalmic surgery. The CRL stated that the FDA has determined that it cannot approve the NDA in its present form. This was the second submission of the NDA for the company. In the CRL, deficiencies observed during a pre-NDA approval inspection in May 2017 in manufacturing processes and analytical testing related to manufacture of drug product for commercial production were disclosed. DEXTENZA was designed to deliver dexamethasone to the ocular surface for up to 30 days for the treatment of postocular surgery associated pain. According to the company’s President and CEO, Amar Sawhney, the company hopes these issues can be resolved and will allow for DEXTENZA to be approved in the future [33].

Patents

Biohaven (CT, USA) announced on 13 July that it had received a notice of allowance from the US Patent and Trademark Office (USPTO) for its patent application number 14/385551. This patent application covers claims that concern prodrugs of riluzole – a glutamate modulating agent. These prodrugs are being developed by Biohaven for the treatment of obsessive compulsive disorder, anxiety disorders and cancers [34].

Financial & competing interests disclosure

E Harris is a partner in Innovation21 Ltd, providing consultancy, advisory and evaluation services to pharmaceutical/biotechnology companies and government funded agencies.

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