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Industry update May 2019

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The present industry update covers the period 1–31 May 2019. Sources of information included company press releases, regulatory and patent agencies notices, and various news websites. This month saw the announcement that world-renowned MIT scientist, Robert Langer is to be awarded the 2019 Dreyfus Prize for Chemistry for his contribution to drug delivery. Several notable collaborations were announced this month including Intec to partner with Merck on development of products using Intec's 'Accordion Pill' and Zylö Therapeutics to use its Nanopods™ in a partnership with Hoth Therapeutics to develop a treatment for lupus. Approvals this month include concept receiving 'Breakthrough Device designation' from the US FDA for its CE-marked sirolimus drug-coated balloon catheter, MagicTouch. Tocsagen and Insmad released positive late stage clinical trial results for products employing advanced delivery technologies.

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Robert Langer to be honored for discoveries & inventions of materials for drug delivery systems

It was announced on 9 May 2019 that world renowned MIT scientist Robert Langer is to be awarded the 2019 Dreyfus Prize for Chemistry at a ceremony MIT on 26 September 2019. Langer's contribution to the area of drug delivery has been immense. Its focus is at the interface of biotechnology and materials chemistry and in particular on the development of biocompatible polymers capable of zero-order drug delivery or predictable controlled and sustained delivery rates. Commercial products incorporating his innovations include those treating brain and prostate cancer, macular degeneration, schizophrenia and opioid addiction.

At the announcement of Matthew Tirrell, Chair of the Dreyfus Foundation Scientific Affairs Committee and Director of the Institute for Molecular Engineering at the University of Chicago commented: "There is no greater benefit that the chemical sciences provide to society than the many profound contributions to the science and technology of human health. Robert Langer created two rich fields at the intersection of chemistry and medicine: controlled release materials for delivery of therapeutic macromolecules and tissue engineering. His discoveries have been translated, often by Langer himself, to many products that profoundly impact human health. In a diverse field of chemists and chemical engineers with many powerful contributors, the enormous body and influence of Robert Langer's work stands out in a singular way" [1].

Financial

Spiral therapeutics closes series a financing worth \$5.6 million

The Californian based pharmaceutical company developing therapies for hearing loss, Spiral Therapeutics, announced on 6 May 2019 that it had closed its Series A funding round, bringing the total amount raised to approximately \$5.6 million.

Spiral Therapeutics are developing therapies for the prevention of/treatment of hearing loss based on proprietary therapeutic and delivery approaches. Their most advanced candidate is LPT99, which entered clinical trials in December 2018. LPT99 is a locally administered otoprotective agent that blocks apoptosis in the ear without interfering with antitumor activity of chemotherapeutic agents that are delivered systemically. Phase I clinical trials are currently underway in Australia with 32 healthy participants and the trials are expected to be completed by the second quarter of 2019 [2].

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press

Philogen announces €62 million financing round

Philogen (Sienna, Italy) recently announced that it had successfully raised €62 million from private investors to help fund its pipeline products through clinical development and expand manufacturing activities.

Philogen employs a 'vascular targeting' strategy, which targets the delivery of therapeutic agents to newly formed blood vessels at sites of disease. As newly formed blood vessels can be distinguished from mature blood vessels at a molecular level, Philogen uses splice variants of extracellular matrix proteins as 'vascular markers' to enhance the delivery of therapeutic agents to the vicinity of diseased cells. Philogen primarily focuses on the delivery of immunomodulatory cytokines.

The company has two products in phase III development for oncological indications: Daromun for the treatment of fully respectable stage III B/C melanoma and Fibromun in the treatment of metastatic soft tissue sarcoma [3].

New data to show cost effectiveness of Janssen's SPRAVATO™

The Janssen Pharmaceutical Companies of Johnson & Johnson (NJ, USA) released data at the International Society for Pharmacoeconomics and Outcomes Research Annual Meeting (ISPOR 2019) on 21 May 2019 that indicated the economic effectiveness of their newly approved SPRAVATO™. SPRAVATO™ was approved by the FDA in March 2019 with breakthrough designation for treatment-resistant depression. It is formulated as a nasal spray of esketamine; one of the two components of ketamine. Janssen has previously conducted five Phase III studies in patients with refractory depression: three short-term studies, one maintenance of effect study and a long-term safety study. Data from these studies indicated that the esketamine nasal spray provided a 'statistically significant, clinically meaningful, rapid and sustained improvement of depressive symptoms.'

Discussing the presentation of this data John Sheehan, Director, Real-World Value and Evidence at Janssen Scientific Affairs, LLC commented: "Given the profound emotional, functional and economic burden of treatment-resistant depression, it was extremely important to comprehensively assess the economic value newly approved SPRAVATO™ can bring to patients, payers and society. We demonstrated that because it can help more patients have a significant reduction in their depressive symptoms compared with an oral antidepressant plus placebo, SPRAVATO™, is a meaningful clinical and economic investment. Individuals who no longer experience ongoing depressive symptoms pay less to manage their disease, reduce the cost to the overall healthcare system, and are able to get back to their lives" [4].

Collaborations & agreements

Glenmark to expand portfolio with US copromotion agreement

Glenmark Therapeutics (NJ, USA) disclosed on 2 May 2019 that it had signed a copromotion agreement with San Diego-based Otonomy Inc., (a company focusing on the development of innovative therapeutics for neurology). Although financial details of the deal were not announced, the agreement grants Glenmark Therapeutics with an exclusive right to promote OTIPRIO (ciprofloxacin otic suspension) for the treatment of acute otitis externa in patients 6 months of age and older caused by *Pseudomonas aeruginosa* and *Staphylococcus aureus*.

OTIPRIO is a sterile, preservative-free, otic suspension of 6% ciprofloxacin administered as a single-dose and employs proprietary drug delivery technology that facilitates sustained drug release from a single local administration [5].

Second target selected under Halozyme-argenex agreement

Halozyme (CA, USA) the Californian-based biotechnology with proprietary drug delivery technology ENHANZE® announced on 22 May 2019 that the clinical-stage antibody focused company Argenex (Breda, Holland) had selected a second target as part of their February 2019 collaboration and licence agreement. Under the terms of this agreement, the target nomination has triggered a \$10 million milestone payment with potential future payments of up to \$160 million (subject to achieving agreed development, regulatory and sales-based milestones). In addition, Halozyme is also due to receive mid-single digit royalties on future commercial sales products.

ENHANZE® is based on a recombinant human hyaluronidase enzyme (rHuPH20), which enables subcutaneous rather than intravenous delivery. Halozyme has existing collaborations with many pharmaceutical/biopharmaceutical companies to develop formulations using this drug delivery technology including Roche, Lilly, Baxalta, Janssen, Alexion, AbbVie, Bristol-Myers Squibb and Pfizer [6].

Hoth Therapeutics to develop product to treat Lupus

Hoth Therapeutics (NY, USA) announced on 14 May 2019 that it had executed a term sheet with Zylö Therapeutics Inc. (SC, USA) to codevelop a new treatment for patients suffering from cutaneous lupus erythematosus, a chronic autoimmune disease that affects the skin. Reporting the deal, Robb Knie, CEO of Hoth Therapeutics stated: “Management is extremely pleased to partner with Zylö Therapeutics, enhancing our portfolio of unique treatments for patients suffering from various dermatological related ailments. Zylö’s initial work shows significant promise in combating cutaneous lupus erythematosus, and we look forward to working with them in order to bring this treatment to market.”

Zylö’s drug delivery system uses patented hydrogel-derived nanoparticles, termed Nanopods™, designed to topically deliver drugs in a sustained and controlled manner [7].

Intec to partner with Merck

On 8 May 2019 Intec Pharma (NY, USA and Jerusalem, Israel) announced that it had entered into a strategic partnership for their proprietary Accordion Pill with Merck (NJ, USA). Details of the specific development programme was not released, but Intec’s Accordion Pill platform is designed as a drug delivery system that uses biodegradable polymeric films and relies on gastroretentive and controlled release properties, to offer sustained oral delivery of therapeutics.

Intec’s most advanced clinical candidates include; an Accordion Pill Carbidopa/Levodopa, in late-stage Phase III development for the treatment of Parkinson’s disease symptoms in advanced Parkinson’s disease patients, and the company has a feasibility agreement with Novartis Pharmaceuticals for the development and novel formulation of a propriety therapeutic employing the Accordion Pill [8].

QIAGEN to develop diagnostic test for Inovio’s novel targeted immunotherapy

Inovio (PA, USA) and Qiagen (Hilden, Germany) company announced on 16 May 2019 that they had established a collaboration to develop a novel diagnostic test to identify the patients most likely to respond to Inovio’s VGX-3100; an immunotherapy designed to treat advanced cervical dysplasia associated with the human papillomavirus virus (HPV). VGX-310 is currently in Phase III clinical trials (REVEAL 1 and 2) and the company hopes that it will become the first approved for the treatment of HPV infection of the cervix and in addition the first nonsurgical treatment option for precancerous cervical lesions associated with HPV.

VGX-3100 employs Inovio’s proprietary dMab™ technology platform, which encodes DNA to express a monoclonal antibody. The DNA plasmid is injected into a patient to stimulate *in vivo* monoclonal antibody production, which facilitates the patient’s own immune system to clear the HPV (16 and 18) infections and precancerous lesions.

Qiagen intends to develop a companion diagnostic, a liquid biopsy, to identify patients who would benefit from treatment with VGX-3100. Financial details of the collaboration were not announced [9].

Southwest Research Institute licenses nanoparticle system to MBF Therapeutics

Southwest Research Institute (TX, USA) (SwRI) disclosed on 9 May 2019 that it had licensed its patented calcium phosphate nanoparticle delivery system (CaPNP) exclusively to MBF Therapeutics (PA, USA) (MBFT), to develop advanced immunotherapeutic treatments for the treatment of canine melanoma.

SwRI are the owners of two issued patents for their CaPNP drug delivery system, which utilizes nontoxic, biocompatible polymers to create nano-encapsulated drug formulations.

Responding to the announcement Lorraine Keller, CSO of MBFT stated “SwRI’s nanoparticles are the ideal delivery vehicles for our immunotherapeutic vaccines. Beyond this agreement, we look forward to working with SwRI on other projects that will combine SwRI’s expertise in product formulation and MBFT’s checkpoint inhibitor portfolio, to create effective and durable immunotherapeutic vaccines for animal health” [10].

Pneuma Respiratory & Leads Biolabs, Inc. announce partnership

Pneuma Respiratory (NC, USA) and Leads Biolabs (MD, USA) have announced a partnership based on and exclusive licence to develop pulmonary formulations of Leads’ panel of immuno-oncology, monoclonal antibodies and fusion protein molecules by employing of Pneuma’s proprietary breath-activated digital inhaler. A recent publication indicated that in a small animal model study the suitability of the Pneuma digital inhaler for the pulmonary delivery of therapeutic monoclonal antibodies.

Speaking as the collaboration was announced, Pneuma Chief Executive Officer and cofounder Eric Hunter commented: “We are pleased to enter into a license agreement for Leads Biolabs monoclonal antibody portfolio. We look forward to working with their team to conduct studies that may lead to positive change in the future treatment of non-small cell-lung cancer”.

“We are very excited to have this license agreement with Pneuma Respiratory” Xiaoqiang Kang, Chairman and CEO of Leads Biolabs, commented: “The commitment by a leader in digital pulmonary delivery of drugs is an endorsement of the value of our portfolio. We believe that Pneuma’s digital inhaler technology combined with our antibody drugs will create very exciting new opportunities for both companies. We look forward to working with Pneuma to move our candidates into the clinic as quickly as possible” [11].

Approvals & regulatory updates

FDA clears RemUnity drug pump codeveloped by Deka, United Therapeutics

United Therapeutics (NC, USA) and Deka Research and Development Corp. (NH, USA) indicated in a press release on 7 May 2019 that they have received FDA 510(k) clearance for the codeveloped RemUnity system. This subcutaneous delivery system has been designed to deliver Remodulin (treprostinil) injections. The device is a small, lightweight, durable pump designed to have service life of at least 3 years and the delivery of Remodulin is via disposable cartridges.

Remodulin injections are indicated to reduce symptoms associated with exercise for patients with pulmonary arterial hypertension.

Announcing the 510(k) clearance Martine Rothblatt, Chairman and Chief Executive Officer of United Therapeutics stated: “We developed the RemUnity system to address safety and patient convenience problems with current subcutaneous infusion pumps. We believe the RemUnity system reduces the risk of bolus dosing due to pump failures and provides wider arrays of notifications, alerts and alarms than current pumps. Most importantly, the acoustic volume sensing technology and solid-state actuator of the RemUnity system enables it to control Remodulin flow rates without the use of a motor” [12].

SORILUX approved for the treatment of adolescent plaque psoriasis

The Australian pharmaceutical company Mayne Pharma Group Limited (AUS) announced on 22 May 2019 that the FDA had approved its product termed SORILUX[®] Foam, for the treatment of plaque psoriasis in adolescents.

The active ingredient in the formulation is calcipotriene; a synthetic vitamin D analog with a similar receptor binding affinity as natural vitamin D.

Mayne’s SORILUX[®] is based on its proprietary foam delivery platform, which is one of a number of patented drug delivery technologies utilized in Mayne’s product portfolio, including modified-release tablets and capsules, immediate-release tablets and capsules, powders and semisolids [13].

Stryker receives approval for device to treat brain aneurysms

Stryker (MI, USA) announced on 20 May 2019 that it had received the premarket approval of the Neuroform Atlas Stent System by the US FDA. Stryker’s Neuroform Atlas Stent System has been designed as a self-expanding nitinol stent to be utilized in conjunction with metal coils to pack aneurysms within the brain. During intervention to occlude the aneurysm, the stent is positioned across the aneurysm neck.

Discussing the Atlas Stent is the Director of the NeuroEndovascular Fellowship program at the University of Pittsburgh Medical Center and Co-Principal investigator of the study utilized to achieve the preapproval Brian Jankowitz, who stated: “Enhanced stent conformability, a low-profile delivery system and high deployment accuracy even in distal anatomy puts Neuroform Atlas in a category of its own. This product is changing my clinical practice by allowing more patients with difficult aneurysms an option at endovascular treatment while improving the quality and safety of treatment” [14].

Breakthrough device designation for Concept Medical’s MagicTouch

Tampa (FL, USA) based medical device company, Concept Medical Inc., announced on 2 May 2019 that it had received ‘Breakthrough Device designation’ from the FDA for Magic Touch; its CE-marked sirolimus drug-coated balloon catheter, designed for the treatment of coronary in-stent restenosis.

In-stent restenosis is a major issue observed in approximately 10% of patients following a drug eluting stent implantation and in more than 30% of patients who undergo bare-metal stent implantation.

The CE-marked product, Magic Touch, has already been implanted in more than 25,000 patients globally and the company anticipates that this designation will facilitate its assessment and review in the USA [15].

Clinical trials

Insmed provides update on Phase III study of ARIKAYCE®

Insmed Inc (NJ, USA) released data from their Phase III CONVERT study of ARIKAYCE® (amikacin liposome inhalation suspension) in patients with refractory mycobacterium avium complex lung disease on 20 May 2019. The results of the study indicated that the addition of ARIKAYCE to guideline-based therapy was associated with sustained culture conversion through the end of treatment, in combination with durable culture conversion 3 months post-treatment compared with guideline-based therapy alone.

ARIKAYCE is administered once daily via the Lamira® Nebulizer System (PARI Pharma GmbH) and received accelerated approval from the FDA in September 2018 for the treatment of adult patients with refractory mycobacterium avium complex lung disease, as part of a combination of antibacterial drug regimen for those who have limited or no other treatment options [16].

Respirant to commence Phase IIb dosing for RVT-1601

Respirant Sciences (CA, USA) disclosed on 20 May 2019 that it had commenced dosing in its Phase IIb trial for its RVT-1601 RVT-1601, a proprietary inhaled formulation of a mast cell stabilizer with pleiotropic immune modulating activity, for the treatment of persistent cough due to idiopathic pulmonary fibrosis (IPF). Delivery of the therapeutic is achieved directly to the lungs via Respirant's proprietary electronic nebulizer device; PARI eFlow®. The PARI eFlow® is still an investigational device and is a portable, handheld closed-loop device that produces a soft mist that patients can easily inhale.

In the previous Phase IIa clinical trial, RVT-1601 was demonstrated to be well tolerated by IPF patients and produced a clinically meaningful and statistically significant reduction in cough frequency. SCENIC; the Phase IIb trial being conducted in the USA, Canada and Europe, is designed to confirm that RVT-1601 reduces cough and improves the quality of life for IPF patients, and aids in the selection of the optimal dose of RVT-1601 for a Phase III clinical study. It is anticipated that top-line data from this Phase IIb study will be available by the end of 2020 [17].

Positive Phase IIb results for Windtree Therapeutics

Windtree Therapeutics (PA, USA) announced on 9 May 2019 at the Pediatric Academic Societies Meeting, that additional analysis of its previously disclosed Phase IIb results, indicated that their investigational combination drug/device product AEROSURF® may reduce the overall incidence and severity of bronchopulmonary dysplasia in premature infants with respiratory distress syndrome, regardless of whether or not the patient was ultimately intubated.

AEROSURF, which has received Fast Track designation from the FDA, is being developed to reduce or eliminate the need for endotracheal intubation and mechanical ventilation in the treatment of premature infants with respiratory distress syndrome. AEROSURF is a combination drug/device product that employs a proprietary KL4 surfactant and aerosolization technologies.

Based on the results of the AEROSURF Phase II clinical programme, Windtree anticipates that it will conduct a 70-patient bridge study of its new Phase III Aerosol Delivery System medical device and subsequently work with regulators to develop a Phase III regulatory and clinical plan [18].

Oramed completes enrolment for their ORMD-0801 Phase IIb clinical trial

It was announced by Oramed Pharmaceuticals Inc. (NY, USA) on 21 May 2019 that the company had completed patient enrolment into the 90-day dose-ranging Phase IIb clinical study of its oral insulin capsule main cohort. This brings the total number of patients recruited to over 300 with 70% of them having completed the study.

Commenting on the recruitment of this cohort Oramed's CEO, Nadav Kidron stated: "Having completed recruitment of close to 300 patients, we are on track to announce top-line data in the fourth quarter this year. We expect to begin our Phase III clinical trial design immediately following the results".

Top-line data for this clinical trial in Type 2 diabetes patients is expected in Q4 2019. The Oral Insulin Capsule ORMD-0801 is based on the proprietary, Oramed's Protein Oral Delivery (POD™) technology. This technology,

also employed in another of Oramed's lead candidates, ORMD-0901; a glucagon-like peptide-1 (GLP-1) also indicated for the treatment of Type 2 diabetes [19].

EnGeneIC commences dosing in Phase I/IIa advanced-stage pancreatic cancer clinical trial

9 May 2019 saw EnGeneIC Limited (NY, USA) commencing dosing of the first advanced stage pancreatic cancer patients for the Phase I/IIa clinical trial, using their proprietary EDV™ nanocell platform to deliver a nemorubicin derivative (D682). This trial has enrolled patients that have exhausted all other treatment options. The trial is being carried out in Sydney, Australia.

The platform technology being employed in this trial is second-generation EDV™ nanocells, which deliver D682 directly to solid tumors via EGFR, targeting on the tumor cell surface, thus limiting damage to healthy tissue. The EDVs™ have also been formulated to incorporate an immune-boosting adjuvant to further augment the antitumor immune response stimulated by the bacterially derived EDVs™.

EnGeneIC's bacterially derived EDV™ nanocell platform (EnGeneIC Dream Vector), is a first-class, cyto-immunotherapy technology for the treatment of various cancers. EDV™ has been designed to deliver cytotoxic payloads, targeted to tumors and stimulates the adaptive immune system to augment the antitumor response [20].

TARIS Bio initiates new clinical study of TAR-302 in overactive bladder

TARIS Bio (MA, USA) announced on 1 May 2019 that it had the initiation of a new clinical investigation of TAR-302, for the treatment of an overactive bladder. This study is a follow on from a previous Phase Ib trial and has been designed to study the safety, tolerability and preliminary efficacy of a single 12-week dose for the investigational therapeutic.

TAR-302 is TARIS' lead investigational therapeutic for the treatment of overactive bladder, it has been designed to continuously release (over a number of months) the antimuscarinic agent; trospium, in the bladder, yielding local concentrations several times higher than achievable with the current oral treatment options.

TARIS' proprietary delivery system features a dual-lumen silicone tube, containing a solid drug core in one lumen and a super-elastic wire form in the other. This design enables the continuous release of a therapeutic into the bladder over a period of weeks or months. The TARIS system operates by insertion into the bladder by a urologist, which can be performed during an office visit [21].

Patenting

Intec granted patent strengthening their Accordion Pill platform

Intec Pharma Ltd (Jerusalem, Israel) announced on 20 May 2019 that it had been issued with a notice to grant European Patent No. 2997953 titled, "DELIVERY DEVICE FOR ORAL INTAKE OF AN AGENT". This patent protects Intec's gastro-retentive drug delivery device with perforated external film. This issuance will extend protection of the Accordion Pill platform to 2027.

Intec's Accordion Pill is a proprietary drug delivery system developed using biodegradable polymeric films, which combine and load drugs and the actives ingredients onto films, which folds them into an undulated shape. These films are then placed inside a capsule allowing for gastric retention of the dosage form and predictable, programmable release of the actives [22].

CytRx announce additional patents for Aldoxorubicin

The Californian-based biopharmaceutical company CytRx (CA, USA) disclosed on 8 May 2019 that it has a patent; US patent no. 10,278,981, entitled "Cytotoxic Agents for the Treatment of Cancer". From the US Patent and Trademark Office. According to the company, this patent will cover the use of Aldoxorubicin in the treatment of brain cancer. A patent covering the use of Aldoxorubicin intravenously, intra-arterially or intramuscularly for the treatment of brain cancer was exclusively licensed by CytRx to NantCell, Inc. in July 2017.

CytRx's Aldoxorubicin is in late stage clinical trials for a number of oncology indications. Aldoxorubicin is a rationally engineered cytotoxic, which is designed to deliver doxorubicin, directly into tumors. Aldoxorubicin utilizes a proprietary acid-sensitive linker, LADR™ (linker activated drug release) technology that allows selective binding to albumin, which may allow the cytotoxic payload to preferentially accumulate in the tumor. The proposed mechanism leverages the tumor's low pH environment and accompanying dependency upon circulating albumin to fuel growth, to enable the enhanced, targeted delivery of the standard dosing of doxorubicin [23].

Financial & competing interests disclosure

The author has no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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