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Industry Update

June 2014, the period covered by this article, was characterized by continued prospective and actual acquisition activity and, although the very big potential merger between Pfizer and AstraZeneca was now quiet, some big possible deals such as AbbVie and Shire were still in prospect. Conference season was very much in full swing with news of clinical success in delivering therapeutic entities being reported at European League Against Rheumatism (EULAR), American Society for Clinical Oncology (ASCO) and American Diabetes Association (ADA) meetings and with a number of drug approvals employing delivery technologies being announced during the month. Finally, after a long journey, a new pulmonary delivery approach to insulin therapy, in the form of Alfrezza®, from MannKind, finally got approved by the US FDA.

Acquisitions & mergers

Valeant & Allergan

The prospect of this anticipated merger has figured on these pages in prior months but Canadian speciality pharmaceutical company Valeant announced their commencement of an exchange offer, originally made to the Allergan board in May, directly to Allergan stockholders on June 18th [1]. This was a development in the continued push to complete a transaction with Allergan which goes back to April of this year. In addition to a mixed cash and shares offer, there was the willingness to provide shareholders with an offer that recognized the contingent value of Allergan's yet-to-be-approved DARPIn® age-associated macular degeneration therapy, subject to Allergan engaging in negotiations to work out terms. The experimental therapy, anticipated as a potential competitor to Regeneron's Eylea® and Roche's Lucentis®, had an announced delay to transitioning to late stage clinical trials in May. There had been strong assertions by Allergan [2] about the strength of Valeant's business model and why acquisition would not make for good stockholder value, a perspective which was strongly rebuffed by Valeant. [3]. This story is expected to continue to develop over the next few months.

Abbott & Veropharm

Abbott announced on June 23rd a definitive agreement to acquire the leading Russian pharmaceutical manufacturer Veropharm by acquiring Garden Hills, a limited liability company that owns a significant controlling interest in Veropharm. Veropharm is expected to be more than 95% owned by Garden Hills by the time the transaction is expected to close. Abbott indicated that although it had a long standing presence in Russia of nearly 40 years duration, this acquisition would allow it to establish a manufacturing presence in Russia. This would be based on using and enhancing Veropharm's existing facilities in Pokrov, Belgorod and Veronezh, along with facilities under construction, and utilizing Abbott's manufacturing expertise to expand Veropharm's capabilities [4]. Veropharm has a portfolio of over 100 products and employs more than 2000 people.

AbbVie & Shire

There has been much debate in the press about the future of Shire, and the move by AbbVie to acquire them goes back to early May of this year. The AbbVie position evolved through June with rejection of several proposals by the Shire board. This

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culminated in a confirmation of the rejection of the evolved AbbVie acquisition terms by Shire on June 20th [5] and a further statement from AbbVie outlining its strategic rationale for combining the two businesses [6]. The latter outlined the fourth set of acquisition terms, cash and shares, and would represent one of the largest acquisition deals in the pharmaceutical sector so far in 2014 (as the Pfizer bid for AstraZeneca in the first half of 2014, which would have set that record, didn't proceed). This is another story that continues to unfold as the review period for this article was closing and will no doubt continue to develop.

Merck & Idenix

There is a significant degree of effort currently ongoing to bring directly acting antiviral agents targeting different aspects of the replication cycle of the hepatitis C virus to market in order to change approaches to therapy of infection with this virus away from interferon-based treatments to all oral regimens having improved efficacy and tolerability. Merck, Vertex, Johnson & Johnson, Gilead, AbbVie and Bristol-Myers Squibb all have products approved or undergoing regulatory review, with the opportunity to bring multiple oral agents targeting different parts of the viral replication mechanism together in a course of treatment offering the potential for high cure rates in short treatment durations across the range of virus genotypes. Each player in the field is looking to have a range of viral replication target therapies within their pipelines to combine to achieve this aim. To this end, Merck and Idenix indicated their intention to enter into a definitive agreement under which Merck would acquire Idenix in a cash transaction that valued Idenix at US\$3.85 billion [7]. The proposed acquisition, which is expected to complete in the third quarter of this year, is indicated by Merck to recognize the expertise at Idenix in nucleoside/nucleotide chemistry and development of prodrugs. In particular, it offers Merck compounds targeting viral polymerase (HCV NS5B) to complement existing Merck compounds that inhibit viral protease (HCV NS3/4A) and viral replication complex (HCV NS5A). Idenix also has a further compound, samatasvir, which targets HCV NS5A. Some of the other companies noted above already have compounds in development that interact with each of the three viral targets of interest, so the acquisition may enable Merck to compete with them.

The Merck move on Idenix is speculated as now raising possible bids for Achillion. Achillion announced June 10th that it had begun clinical trials of its uridine-analog nucleotide HCV NS5B polymerase inhibitor, ACH-3422, and that the FDA had lifted a hold on its HCV NS3/4A protease inhibitor sofosbuvir, allowing

clinical studies on that compound to continue [8]. As Achillion also has an HCV NS5A replication inhibitor, ACH-3102, in phase II trials, the outcome of the 7-day study with ACH-3422, and data from ACH-3102 later in 2014, may raise some interest in the company.

AstraZeneca & Synairgen

The media noise on the prospective acquisition of AstraZeneca by Pfizer was dying down during the review period covered by this article, given the final rejection of the Pfizer offer, and the protocol driven by UK requirements that Pfizer must wait 6 months (until around November) before making a further bid – unless invited back sooner (August according to the UK rules) by AstraZeneca. However, AstraZeneca were busy during June in the acquisition area themselves. AstraZeneca acquired rights to SNG001, a novel inhaled IFN- β product from Synairgen plc [9]. SNG001 supports the immune system by correcting a deficiency that makes patients vulnerable to respiratory infections and so is of potential utility in the treatment of respiratory tract viral infections in patients with severe asthma. SGN001 was a result of research at the University of Southampton, UK, where Synairgen is based. Phase II trials in severe asthma, building on existing studies in a broad asthma population, are expected to get underway in 2015, with AstraZeneca funding development costs. In addition to that investment in the compound, AstraZeneca will pay Synairgen a \$7.25 million upfront fee to acquire the asset and will commit to up to \$225 million in development, regulatory and commercial milestone payments, as well as royalties on commercial sales.

Collaborations

Pfizer & Cellectis

Pfizer and Cellectis announced, on June 18th, the creation of a global strategic collaboration to develop chimeric antigen receptor T cell (CAR-T) immunotherapies directed at selected oncology targets [10,11]. Cellectis has developed a platform technology that utilizes T cells harvested from healthy donors. These are then genetically engineered to specifically target and destroy cancer cells, and can be used in multiple patients (allogenic approach, as opposed to autologous approaches, modifying a patient's own T cells for treatment of that same patient). The agreement provides Pfizer with exclusive rights to pursue development and commercialization of CAR-T therapies directed at a total of 15 Pfizer-selected targets in the field of oncology, with the companies working together on preclinical research and Pfizer having the responsibility for development and potential commercialization of any CAR-T therapies for the Pfizer-selected targets. The

agreement further provides for collaboration on 12 Cellectis-selected targets, with the companies collaborating on preclinical research on four of those targets and Cellectis only pursuing the other eight. Cellectis has the responsibility under the agreement to undertake the clinical development and commercialization of CAR-T therapies for the Cellectis-selected targets, with Pfizer having right of first refusal to the four Cellectis-selected targets. Paris-based Cellectis indicated it will open a US site to enable closer working with Pfizer scientists.

ViiV & Janssen

ViiV Healthcare (the joint venture in development and commercialization of HIV therapies founded by GlaxoSmithKline, Pfizer and Shionogi) and Janssen announced a collaboration on June 12th to develop a new single-tablet regimen combining ViiV's integrase inhibitor, dolutegravir, currently marketed as Tivicay®, with Janssen's non-nucleoside reverse-transcriptase inhibitor, rilpivirine, currently marketed as Edurant® [12,13]. The single-tablet regimen approach to HIV treatment is of increasing importance, refining and simplifying the multiple-drug approach to the disease in a way that is more convenient for patients and so may improve compliance with medication. This collaboration represents ViiV's first external collaboration to develop a product involving another company's branded product. Studies are planned to start in first quarter of 2015, focused initially on patients already virally suppressed on a three-drug regimen. The development of pediatric fixed dose formulations is also planned.

MorphoSys & Merck Serono

Immuno-oncology is of growing therapeutic interest, bringing forward therapies that enable the patient's own immune system's ability to fight tumors. The CTLA4 immune checkpoint inhibitor, ipilimumab (Yervoy®, Bristol-Myers Squibb), is already approved, and drugs targeting PD-1/PD-L1 are in advanced development by Merck, AstraZeneca, Roche and Bristol-Myers Squibb. Merck Serono, with its own immuno-oncology assets in phase I clinical trials, signaled its own further expansion in this area by announcing a strategic collaboration with MorphoSys AG to discover and develop therapeutic antibodies against undisclosed immune checkpoints [14,15]. The Ylanthia antibody phage library, the industry's largest antibody Fab library to date, and the associated technology platform developed by MorphoSys, will be applied under this collaboration to identify antibodies against the targets of interest. Merck Serono will be responsible for execution of development from phase I clinical trials onwards.

Ventana Medical Systems & MedImmune

Ventana Medical Systems, which is part of the Roche group, and MedImmune, which is the global biologic research and development arm of AstraZeneca, announced their collaboration around joint development of a PD-L1 immunochemistry assay for use in clinical trials of MedImmune's investigational, engineered, human monoclonal antibody, MEDI-4736, for non-small-cell lung cancer. This personalized medicine approach to the trial will thus enroll only patients who express PD-L1 as indicated by the Ventana assay [16,17].

Product approvals & news

Triumeq® (ViiV healthcare)

The evolution of treatment of HIV infection to the use of single-tablet regimen therapies in maintenance therapy of the disease was noted earlier in this article. The prospective choice of single-tablet regimen options for patients and physicians increased in June with the positive Committee for Medicinal Products for Human Use (CHMP) opinion from the European Medicines Agency for Triumeq®, a once-daily single tablet fixed dose combination of dolutegravir, abacavir and lamivudine developed by ViiV Healthcare [18].

Afrezza® (MannKind Corporation)

After the positive advisory board review in April 2014, MannKind Corporation (CA, USA) at last received its long-anticipated approval from the FDA for Afrezza® (insulin human) inhalation powder [19]. Afrezza® is the first inhaled insulin product to enter the US market since Pfizer's Exubera® and is intended for use in improving glycemic control in adult patients with diabetes mellitus. The powder is delivered using a small easy-to-use inhaler device, and is administered at the start of a meal. Peak insulin levels are achieved 12–15 minutes post administration and decline to baseline levels by approximately 180 minutes. Pfizer's inhaled insulin product never really made significant inroads into the diabetes market, so it will be of interest as to how the convenient device from MannKind and the rapid acting, needle-free-delivery insulin therapy is received. Of additional interest will be if, and with whom, MannKind partners to commercialize this novel approach to the treatment of diabetes.

Bunavail® (BioDelivery Sciences International)

BioDelivery Sciences International received approval from the FDA for its Bunavail® buccal film, with an expectation of a third quarter 2014 launch. This is the first approved buccal film formulation containing buprenorphine and naloxone to enter and compete in the \$1.7 billion and growing US opioid dependence, being utilized as maintenance therapy. The product

uses BioDelivery Sciences' BioErodible MucoAdhesive (BEMA®) formulation technology that assures greater buprenorphine bioavailability with good adhesion to the inside of the cheek, so differentiating from sublingual delivery [20]. The BEMA technology provides for twice the bioavailability of buprenorphine from the novel buccal film relative to the already approved sublingual tablet formulation of buprenorphine (Suboxone®) and its adhesion to the cheek means that patients can talk, swallow and go about everyday activities more easily than with the sublingual tablet held in the mouth and also benefit from consistent drug absorption.

Jublia® (Valeant Pharmaceuticals)

Valeant received US regulatory approval for its topical solution formulation of the antifungal efinaconazole, for the treatment of toenail onychomycosis on June 10th. It is the first approved triazole topical antifungal for the treatment of toenail infection. The drug originated from Valeant's 2008 acquisition of Dow Pharmaceutical Sciences [21].

Insulin glargine biosimilar (Boehringer Ingelheim/Lilly)

The EU's CHMP issued a positive opinion on June 10th for the Lilly–Boehringer Ingelheim Diabetes Alliance's Marketing Authorization Application for its insulin glargine product. This will be the first insulin biosimilar recommended for approval in Europe and will be a competitor to the innovator insulin glargine, Lantus® [22]. It should be noted that the biosimilar designation is a regulatory designation that is not recognized in some countries, including the USA. The CHMP's recommendation is based on the companies' non-clinical and clinical development program, which included pharmacokinetic and pharmacodynamic studies, as well as phase III studies in patients with type 1 and type 2 diabetes. Insulin glargine is a basal insulin, which is intended to provide long-lasting blood sugar control between meals as an integral part of overall glycemic control.

Clinical trials

Once-weekly exenatide (Flamel Technologies)

Flamel Technologies announced their intent to undertake phase II clinical trials of a once-weekly formulation of exenatide, based on its Medusa drug delivery platform [23]. Exenatide is a glucagon-like GLP-1 agonist used to treat type 2 diabetes. The announcement reported on preclinical studies in minipigs, which indicated 100% bioavailability, a pharmacokinetic profile compatible with drug release over a period of 1 week in humans, and no initial release spike or burst effect.

Flamel's Medusa technology is a hydrogel extended-release subcutaneous depot-injectable technology built around polymers of glutamic acid and alpha tocopherol. These amphiphilic polymers form hydrogels in aqueous environments, such as in the presence of tissue fluids, and it is the properties of these hydrogels which control the rate of drug release.

Exenatide once-a-year dosing (Intarcia Therapeutics)

Intarcia Therapeutics presented interim phase III data on their ITCA 650 exenatide drug-device combination product at this year's American Diabetes Association 74th Scientific Session held in San Francisco, USA, June 13–17th. The subcutaneous osmotic pump device is the size of a large matchstick and is designed to be inserted subdermally to provide continuous and consistent drug therapy over long extended periods of time. Intarcia has employed its proprietary formulation technology into the drug device combination to assure stability of the peptide at body temperature over the extended delivery time [24].

Data was disclosed on Type 2 diabetes patients in an open-label part of the trial. These patients had high HbA1C levels (>10%) and so were not appropriate for the placebo-controlled trial. Patients had treatment initiated with a device implanted delivering 20 µg/day exenatide for the first 3 months, which was then replaced by a device delivering 60 µg/day exenatide. Trial data to date showed good mean reductions in HbA1C of 2.5% at week 13, 2.9% at week 19 and 3.2% at week 26. HbA1C targets of <7% were achieved in 26% of subjects who had completed at least 13 weeks of treatment. The interim data suggested that the Intarcia exenatide investigational product has the potential to dramatically improve glycemic control in patients with severe hyperglycemia and longstanding diabetes.

SoluMatrix® meloxicam (Iroko Pharmaceuticals)

Iroko Pharmaceuticals LLC, a global speciality pharmaceutical company engaged in developing improved analgesic therapies, presented phase III results on its investigational SoluMatrix® meloxicam nonsteroidal anti-inflammatory drug at the 2014 EULAR Annual European Congress of Rheumatology in Paris, France (June 11–14th). SoluMatrix meloxicam-treated patients with osteoarthritis pain had significantly different responses at week 12 for patient global impression of change; also, these patients reported their condition as 'very much improved' or 'much improved' as compared with 'much worse' or 'very much worse' for placebo-treated control patients [25]. The effective doses were 30% lower than those normally regarded

as effective using conventional formulations of meloxicam. SoluMatrix® Fine Particle Technology is a patented technology from iCeutica that can produce submicron-sized drug particles using an approach that both grinds the drug particles to a superfine powder and protects them from subsequent agglomeration [26], thus enabling rapid dissolution of drug from a dosage form to enable absorption.

Intranasal sumatriptan (Avanir Pharmaceuticals)

An investigational drug-device combination product consisting of low-dose sumatriptan powder delivered intranasally utilizing a novel device has met primary efficacy endpoint in a phase III trial for the treatment of acute migraine in adults, using 100-mg oral sumatriptan tablets as comparison [27]. The device, the BiDirectional® Breath Powered® delivery technology, developed by OptiNose AS, [28] is activated by the user by exhaling into the device, automatically closing the soft palate and completely sealing the nasal cavity (which reduces swallowing of the drug or its inhalation into the lungs). Through a nosepiece inserted into the nostril, the exhaled breath carries medication from the device directly into one side of the nose. Medication is dispersed deep into the nasal cavity to areas where it is rapidly absorbed. The product, known as AVP-825, showed greater pain relief within 30 minutes of dosing with 22 mg of sumatriptan compared with the reference 100-mg tablet. In addition, migraine sufferers treated with the investigational product achieved pain freedom in a greater proportion of migraine attacks at 15, 30, 45, 60 and 90 minutes post dose, compared with the reference tablet product. There were no serious side effects in the study. Nasal discomfort and abnormal product taste were more common in subjects treated with

AVP-825, but these adverse events were classed as mild in nearly 90% of cases. Avanir have submitted a New Drug Application for US regulatory approval of AVP-825, which has the possibility of a fourth quarter 2014 approval [27].

PEGPH20 (Halozyme)

On June 4th the FDA removed the clinical hold on patient enrollment and dosing of Halozyme's PEGPH20, an investigational PEGylated form of their proprietary recombinant human hyaluronidase, being studied in an ongoing phase II trial evaluating PEGPH20 in patients with pancreatic cancer [29]. PEGPH20 is under development by Halozyme for the systemic treatment of tumors that accumulate hyaluronan. The company had halted the trial voluntarily in April over concerns of a possible difference in the rate of blood clots found in patients treated with PEGPH20 and those on approved cancer therapies. The revised study design that allowed the trial restart excludes patients who may be at risk of thromboembolic events and includes use of low-molecular-weight heparin as prophylaxis to prevent thromboembolic events.

Financial & competing interests disclosure

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