Industry Update

September 2014, the period covered by this article, was characterized by continued prospective and actual acquisition activity and some big possible deals such as Valeant and Allergan, were still in prospect. A number of drug approvals for medicines with novel therapeutic targets such as anti-PD-1 for oncology or employing delivery technologies such as corticosteroid intravitreal implants for diabetic macular edema were announced during the month.

Business news

Acquisitions & mergers

Valeant & Allergan

The prospect of this anticipated merger has continued to figure in the news with a conclusion still not clear at the time of writing, although the push for completion of a transaction goes back to April of this year.

Back and forth correspondence arguing as to how the best value might be delivered to shareholders moved the participants to settle pending litigation in the Delaware Court and for Allergan to call a Special Meeting of stockholders on December 18th. The request for this meeting was from Valeant's partner Pershing Square Capital Management, who have, or have acquired, sufficient Allergan shares so as to comply with the stock holding requirements to allow them to validly make such a request. Meanwhile, Allergan continue to make their own acquisition plans around Salix Pharmaceuticals, which they state could enhance their business and support their management's assertion that a takeover by Valeant would not be needed to achieve enhanced shareholder value [1-5].

Pfizer & InnoPharma

Pfizer announced that it had completed its acquisition of InnoPharma, Inc., on September 25. The acquisition gives Pfizer the development capabilities of InnoPharma in sterile injectable products and will help build out

a strong pipeline in parenteral products for oncology and CNS disorders. InnoPharma has a portfolio of ten approved generic injectable products, 19 products under US FDA review and around 30 injectable or sterile ophthalmic products currently in development. Pfizer will acquire New Jersey-based InnoPharma for US\$225 million up front and up to US\$135 million in contingent milestone payments. The acquisition should bring to Pfizer the experience of InnoPharma in developing novel formulations of existing drugs, including hard-to-make products such as those requiring complex manufacturing or those with bioequivalency challenges [6,7].

Roche & InterMune

During the month, Roche progressed its acquisition of the biotechnology company InterMune through merger with Klee Acquisition Corporation, which is itself a wholly owned subsidiary of Roche. InterMune is focused on the research, development and commercialization of innovative therapies in pulmonary and orphan fibrotic diseases. In the former area it is especially engaged in identifying and commercializing therapies for the treatment of idiopathic pulmonary fibrosis (IPF). IPF represents a significant, unmet medical need, being a progressive, irreversible and ultimately fatal lung disease for which there are few treatment options. Pirfenidone, discovered by InterMune and

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recently approved in some countries, represents a new option for IPF patients and this acquisition takes Roche into the fibrosis therapeutic area [8,9].

OnCore Biopharma & NeuroVive

OnCore, based in Pennsylvania USA, announced its acquisition of the exclusive worldwide rights to a series of cyclophilin inhibitors, also known as sangamides, from Sweden's NeuroVive Pharmaceutical AB [10]. These compounds, based on new and unique polyketide chemistry that originated at Biotica Technology Limited in Cambridge UK, are considered as having potential as effective orally active antiviral agents in the treatment of hepatitis B infection. The lead compound is NVP018 and it is expected to enter clinical trials in 2015. Not unlike the structurally similar ciclosporin, the sangamides, derived from mixed peptide/polyketide chemistry, are macrocyclic compounds that have unexpectedly good oral bioavailability given their physicochemical properties and molecular weights, which translates to the favorable properties of the series of anti-virals acquired by OnCore. Oncore management have previous experience in the successful development of anti-viral therapies having been with Pharmasset, where they developed the Hepatitis C therapy sofosbuvir, which was eventually commercialized by Gilead after they acquired Pharmasset in 2011.

Acorda & Civitas

In late September, Acorda Therapeutics entered into an agreement to acquire Civitas Therapeutics, a deal which gives Acorda CVT-301, an investigational product in Phase III trials for the treatment of off episodes of Parkinson's disease [11]. CVT-301 is a dry powder inhalation formulation of L-dopa. The acquisition also includes rights to the Arcus™ pulmonary delivery technology and the commercial scale manufacturing for the technology. Phase III trials for CVT-301 are scheduled to start in early 2015, with a filing for regulatory approval in the USA expected at the end of 2016.

Endo & Auxilium

Endo International Plc, in moving to go beyond a portfolio dependent on pain relief products, made a US\$2.2 billion acquisition proposal for Auxilium Pharmaceuticals, which if it proceeds would add further men's health products to the Endo portfolio (they had a drug for the treatment of low testosterone earlier in the year) [12]. The Auxilium board responded that the Endo offer undervalued the company and that their own growth plans, a merger with Canadian QLT would continue [13]. Auxilium did leave the door open however by indicating that it would maintain the right to still engage in discussions with Endo, and Endo

quickly responded with comment that they had noted this and they reaffirmed their belief that the transaction for Auxilium they had offered would create benefits for both companies' shareholders, for patients, their customers and their employees [14].

Collaborations

Merck & Sun Pharma

Merck and Co (MSD outside the USA and Canada) and SunPharmaceutical Industries Ltd. announced an exclusive worldwide licensing agreement around an investigational therapeutic antibody candidate, with Sun Pharma acquiring worldwide rights to Merck's tildrakizumab (MK-3222) [15,16]. Tildrakizumab is currently being evaluated in Phase III clinical trials for the treatment of chronic plaque psoriasis. The deal gives Merck an \$80 million upfront payment and will have them continue all clinical and regulatory activities, which will be funded by Sun Pharma. Subject to regulatory approval, Sun Pharma would assume responsibility for further regulatory activities (subsequent submissions, post-approval studies, pharmacovigilance, manufacturing and commercialization). Merck would also gain undisclosed milestone-based payments and royalties on sales. The licensing deal is part of Merck's global initiative to focus its R&D and commercial efforts, including prioritizing its late stage pipeline.

Pfizer & Kyowa Hakko Kirin

Pfizer and Kyowa Hakko Kirin agreed to collaborate on the exploration of the therapeutic potential of the combination of two immuno-oncology agents, one from each of their pipelines. Pfizer's 4-1BB (CD-137) signaling pathway stimulator PF-05082566 and Kyowa Hakko Kirin's anti-CCR4 antibody mogamulizumab are the subject of the agreement between the two companies and the plan is to take the combination into a Phase Ib study to investigate the safety and the tolerability of the combination in patients with solid tumors [17,18]. The agreement to study the use of the two agents together reflects on the growing interest in immuno-oncology agents with different targets as combination therapy approaches to improve outcomes in the treatment of a range of cancers.

Merck Serono & Sutro Biopharma

Merck Serono, the biopharmaceutical division of Merck Kga, and Sutro Biopharma announced their collaboration and license agreement to develop antibody drug conjugates (ADCs) [19,20]. ADCs combine an antibody and a cytotoxic drug through a linker so enabling the antibody to specifically target and deliver the cytotoxic drug to cancer cells. Although this concept has been the subject of academic and industrial research

for many years it is now at last starting to look like a clinical reality, and there are many other players active in the field.

The two companies indicate that they see their collaboration as bringing together Merck Serono's knowledge in target biology with Sutro's technological and discovery capabilities to jointly develop ADCs. Sutro brings its cell-free protein synthesis platforms, Xpress CF™ and Xpress CF+™ to this collaboration and will be responsible for delivering ADCs for Phase I trials. Merck Serono will have responsibility for clinical development and commercialization of any resulting products.

Infinity & AbbVie

Infinity Pharmaceuticals, Inc. and AbbVie Inc. announced their intention to enter into a global collaboration to develop and commercialize duvelisib, also known as IPI-145 [21]. Duvelisib is an orally administered inhibitor of phosphoinositide-3 kinases, (PI3K)-delta and PI3K-gamma, and is being advanced for the treatment of a broad range of cancers. The PI3K family of enzymes is involved in multiple cellular functions including cell proliferation and survival, cell differentiation, cell migration and immunity. The isoforms that are targeted by duvelisib are preferentially expressed in white blood cells and therefore enable its use as a potential therapy in the treatment of hematologic malignancies. At the time of the announcement, Infinity had a Phase I trial ongoing in patients with advanced blood cancers, Phase II trial underway in indolent non-Hodgkin lymphoma and a Phase III study in chronic lymphocytic leukemia in progress.

AbbVie & Calico

A new R&D collaboration to bring together AbbVie and Calico (California Life Sciences LLC) was announced [22,23]. The collaboration is intended to help the two companies discover, develop and bring to market new therapies for patients with age-related diseases, including for neurodegeneration and cancer. Calico is the Google-backed life sciences company led by two former Genentech executives, and the agreement will allow Calico to use its expertise to establish a research and development facility focused on drug discovery and early development. AbbVie brings to the collaboration capability in scientific and clinical development and commercial expertise in bringing new discoveries to market.

Boehringer Ingelheim & CureVac

CureVac is a biopharmaceutical company based in Tübingen, Germany which is advancing the field of mRNA-based technology platforms for therapeutic purposes and is pursuing development of mRNA-based

cancer immunotherapies and prophylactic vaccines for infectious diseases. They have collaborations in place with several companies for their prophylactic vaccines and are already collaborating with the Ludwig Cancer Research Institute to enable clinical testing of novel cancer immunotherapy options. They have most recently announced a collaboration with Boehringer Ingelheim under which Boehringer will acquire rights for development and commercialization for CureVac's investigational therapeutic cancer vaccine CV9202 for the treatment of lung cancer [24,25]. The vaccine will be used in the chemoradiation setting and also in combination with Boehringer Ingelheim's irreversible ErbB family blocker afatinib. The agreement is described as part of Boehringer Ingelheim's long-term commitment to delivering novel treatment options in oncology.

Eli Lilly & AstraZeneca

The oral β -secretase cleaving enzyme inhibitor AZD3293, originated by AstraZeneca and which was announced earlier this year as identified for progression into registrational trials, was the subject of a co-development agreement between AstraZeneca and Eli Lilly [26,27].

It was demonstrated in Phase I studies as being able to reduce levels of β -amyloid in the cerebrospinal fluid of healthy volunteers and Alzheimer's patients. This suggests that it may have activity in preventing formation of amyloid plaque and thus be of potential therapeutic utility in slowing the progression of Alzheimer's disease. The two companies aim to progress the compound rapidly into a Phase II/III clinical trial in patients with early Alzheimer's disease. Lilly will lead clinical development and AstraZeneca will be responsible for manufacturing. The companies will take joint responsibility for manufacturing and share all future costs equally for development and commercialization of AZD3293, as well as net global revenues post-launch. In the announcement, Lilly indicated that they have been committed to Alzheimer's disease research for more than 25 years. AstraZeneca also have had a significant historic investment in developing medicines in the neuroscience area.

Strategic decisions

Novo Nordisk discontinues inflammatory disorders research

At the beginning of September Novo Nordisk announced that it had decided to discontinue all its research and development activities within inflammatory disorders [28]. The announcement noted that the decision resulted from a strategic review of its position in the therapeutic area after the discontinuation of the company's most advanced compound in

this therapeutic space, anti-IL-20 for the treatment of rheumatoid arthritis. The discontinuation of this asset meant that the earliest possible entrance into this market for Novo, assuming success for the less advanced inflammatory disorder therapy assets in their portfolio, would be in the late 2020s with a much evolved competitive landscape. However, Novo indicated the continued opportunities within diabetes, including prevention, obesity and diabetes complication where they will be further increasing research and development efforts. The decision will directly impact about 40 employees, half of which could be offered alternative positions within the company.

Baxter's Baxalta

The separation of Baxter International Inc. into two publicly traded companies, likely to be launched mid 2015, was announced. The biopharmaceutical business evolving out of this would be known as Baxalta, 'Bax' derived from Baxter, to connect with the origin of the company and 'alta', derived from the Latin altus, meaning 'high' or 'profound' [29]. Baxalta's pipeline will be built on the Baxter legacy of innovation in bleeding disorders and immunology and will look to expand into niche areas of oncology as well as gene therapy.

Product approvals & news

Dulaglutide (Trulicity™)

The FDA approved dulaglutide (Trulicity™, Eli Lilly and Company) on September 18 as a treatment option for adults with Type 2 diabetes [30]. The once weekly subcutaneous injection of the GLP-1 receptor agonist is indicated as an adjunct to diet and exercise to improve glycemic control but is not recommended as first-line therapy for patients not adequately controlled on diet and exercise. Dulaglutide adds to the emerging class of GLP-1 receptor agonists now approved and is provided in a single dose pen that does not require any mixing, measuring or needle attachment before use.

Fluocinolone acetonide intravitreal implant (Iluvien®)

Prescription ophthalmic pharmaceuticals company Alimera Sciences announced the approval by FDA of its sustained release intravitreal implant product Iluvien, containing fluocinolone acetonide 0.19 mg per implant [31]. They expect the launch of the product, which will be indicated for patients with diabetic macular edema (DME) who had been previously treated with a corticosteroid and who did not experience a clinically significant rise in intraocular pressure. DME is a common complication of diabetes and a leading cause of loss of sight in diabetics. The implant, which is designed to

deliver submicrogram levels of the corticosteroid for 36 months, can provide for a continuous, long-term, low-dose anti-inflammatory, which Alimera describe as an important option for patients who have DME that persists.

Dexamethasone intravitreal implant (Ozurdex®)

A further drug for DME was approved in the EU in September. Allergan's Ozurdex, dexamethasone intravitreal implant, is a sustained release biodegradable implant formulation of the corticosteroid provided in an applicator [32]. It is indicated for the treatment of visual impairment due to DME in patients who have an artificial lens implant or who are considered insufficiently responsive to, or unsuitable for non-corticosteroid therapy. Ozurdex was approved in the USA earlier in 2014.

Pembrolizumab (Keytruda®)

Pembrolizumab (Keytruda, Merck) was the first anti-PD-1 therapy to be approved in the USA when the FDA approval was announced at the beginning of September [33]. The approval was granted for the use of pembrolizumab for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab (Yervoy®, Bristol-Myers Squibb) and, if BRAF V600 mutation positive, a BRAF inhibitor. This was an accelerated approval based around submitted data on observed tumor response rate and durability of response. Improvements in survival or disease-related symptoms with pembrolizumab are not yet established. The regulatory review leading to this approval was under FDA's Breakthrough Therapy designation. Pembrolizumab is a humanized monoclonal antibody that blocks the interaction between the PD-1 receptor and its ligands, PD-L1 and PD-L2, and consequently increases the body's immune system's ability to recognize tumor cells and eliminate them. It is one approach in a new field of cancer therapy, being referred to as immuno-oncology. As the receptor and its ligands also function in healthy cells, adverse events noted are commonly immune-mediated such as pneumonitis, colitis, nephritis, hepatitis and hyper- or hypo-thyroidism, which can be managed by the withdrawal of pembrolizumab and administration of corticosteroids.

The potential utility and effectiveness of anti-PD-1 therapies across a wide range of tumor types has led to many other companies pursuing the development of candidates with this mechanism of action, with Roche, AstraZeneca and Bristol-Myers Squibb probably having the most advanced candidates in development to date.

Nivolumab, (Opdivo®)

Nivolumab is also a human anti-PD-1 monoclonal antibody that is being developed as an immunoncology agent with potential to treat a number of cancers. This one also gained its first approval during the review period of this article, in Japan, and was launched as Opdivo by Ono Pharmaceutical Co., Ltd in that market at the beginning of September for the therapy of unresectable melanoma [34]. Ono indicated that nivolumab is the world's first approved drug targeting PD-1. Nivolumab was discovered under a research agreement between Ono and US-based biotechnology company Medarex, Inc. When Medarex was acquired by Bristol-Myers Squibb (BMS) in 2009, the rights for development and commercialization of the compound in North America were assigned to BMS. In subsequent agreements between Ono and BMS, Ono retained rights to commercialize nivolumab in Japan, Korea and Taiwan with BMS having exclusive rights to the compound for the rest of the world.

Naltrexone hydrochloride & bupropion hydrochloride (Contrave®)

Takeda and Orexigen announced that the FDA had approved Contrave extended release tablets as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial BMI of 30 kg/m² or greater (i.e., obese), or 27 kg/m² or greater (i.e., overweight) in the presence of one weight-related comorbid condition [35].

The emergence of new medicines to support weight management has developed significantly in the last few years, with products under clinical evaluation now, like this one, meeting the critical regulatory criteria for approval by demonstrating safety and efficacy in specified patient groups.

Methylnaltrexone bromide (Relistor®)

Salix Pharmaceuticals and their partner Progenics Pharmaceuticals announced the approval by FDA for their subcutaneous injection formulation of the peripherally acting mu opioid receptor agonist methylnaltrexone bromide (Relistor). This product is indicated for the treatment of opioid-induced constipation in patients taking opioids for chronic non-cancer pain [36]. As methylnaltrexone does not act centrally on opioid receptors, it does not interfere with the analgesic properties of the opioid medication. Patients who experience constipation while taking opioids for chronic non-cancer pain may find traditional laxatives ineffective, and some may then lower the dose of their pain relief to ameliorate the constipation, resulting in increased pain levels.

Budenoside rectal foam (Uceris®)

Salix announced that the FDA had granted tentative approval for its rectal foam formulation of the corticosteroid budenoside, indicated for the induction of remission in patients with active mild-to-moderate distal ulcerative colitis extending up to 40 cm from the anal verge [37]. The tentative approval reflects that the product, while meeting all of the FDA's manufacturing quality and clinical safety and efficacy standards, cannot move to final approval until patent issues are resolved. Salix indicate that they expect the patent issues to be resolved in the fourth quarter of 2014 and that the product will be launched in the first quarter of 2015. Uceris is described by Salix as having a unique delivery system that can overcome current treatment limitations by allowing medication to reach the affected area of the distal colon and keeping it there long enough to be effective.

Idelasib (Zydelig®)

The European Commission granted marketing authorization for idelasib (Zydelig, Gilead Sciences, Inc) for the treatment of the hematologic cancers chronic lymphocytic leukemia (CLL) and follicular lymphoma (FL) [38]. For CLL it is approved for administration with rituximab and is for use as monotherapy for FL. Idelasib is an orally active inhibitor of PI3K-delta, which plays a role in the activation, proliferation and viability of B cells, a critical component of the immune system. The protein is active in many B-cell leukemias and lymphomas, hence its inhibition blocks pathways key to B-cell viability.

Clinical trials

Peglispro

Eli Lilly reported that their basal insulin peglispro (pegylated lispro insulin, LY2605541) demonstrated statistically significant lower HbA1c compared with insulin glargine (Lantus®, Sanofi) at the 26 and 52 week time points of Phase III trials. Basal insulins are intended to have extended duration of action, a flat pharmacodynamic profile and have low day-to-day variability. They should therefore maintain plasma glucose stable between meals. By conjugating insulin lispro with a 20 kDa polyethylene glycol chain a new compound is produced that appears to exhibit these desirable properties. With the Phase III trials now complete, Lilly expects to file a submission with regulators in the first quarter of 2015 [39].

Loteprednol etabonate ophthalmic gel

Bausch + Lomb announced positive results from their Phase III study of a submicron loteprednol etabonate suspension ophthalmic gel in eliminating

inflammation and pain following cataract surgery [40]. The submicron steroid particles in the novel gel formulation enabled better tissue penetration of the drug and so allowed the use of a lower concentration, 0.38% compared with the existing 0.5% loteprednol etabonate ophthalmic gel (Lotemax®, Bausch + Lomb) currently available for this indication.

Omarigliptin

DPP-4 inhibitors have made a significant impact in the treatment of Type 2 diabetes and approaches that simplify the treatment of disease by patients are continuing to be sought. Merck recently announced results for their investigational DPP-4 inhibitor omarigliptin, which only requires once-weekly administration. In a study in Japanese patients it significantly reduced Hb1Ac levels compared with placebo and demonstrated similar efficacy to reference DPP-4 inhibitor (and market leader in the class) sitagliptin. The Phase III study was a double-blind, non-inferiority trial to assess the efficacy of omarigliptin 25 mg given weekly compared with sitagliptin 50 mg given daily, and to placebo. Merck intends to file for approval of omarigliptin in Japan by the end of 2014 [41].

Tenofovir alafenamide

As individuals suffering HIV infection now can live longer, several decades post-diagnosis and initiation of treatment, there is a continuing drive to bring forward newer, improved therapies to improve safety,

convenience and deal with resistance emergence. Gilead announced that two Phase III trials of a single tablet regimen containing its novel form of the reverse transcriptase inhibitor tenofovir, tenofovir alafenamide (TAF), met their primary endpoints in the treatment of HIV-1 infection in treatment-naïve adults [42]. The single tablet regimen therapy, a rapidly establishing approach to the treatment of HIV-1 infections, is based on a dosage form that combines TAF, 10 mg, with 150 mg elvitegravir (integrase inhibitor), 150 mg cobicistat (inhibitor of drug metabolising enzymes) and 200 mg emtricitabine (reverse transcriptase inhibitor). As well as good efficacy, the TAF-containing therapy showed more favorable renal and bone safety compared with Stribild®, Gilead's existing, marketed single tablet regimen therapy, which has the same ingredients with the exception that the established form of tenofovir, tenofovir disoproxil fumarate, is employed, in place of TAF.

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