MEDIUS DEAL WATCH

August 2015

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This month, some companies seem determined to prove that not all of Europe closes for business and disappears off to the beach during August! Very deal busy and present in the headlines were AstraZeneca, Sanofi and Shire with a range of deals, bids and acquisitions.

Topping the table with an anticipated headline value of $30.6bn was the announcement by Shire of its bid to acquire Baxalta. Planned as an all-stock transaction, the offer represented a 36% premium at $45.23 per share. Baxalta was of course only spun out from its parent company Baxter in July so this bid is fairly fast and the offer was, not surprisingly, met with a lukewarm response. So it was no surprise that by the end of the month Baxalta was rumoured to be countering with deal activity of its own with discussions to buy Ariad Pharmaceuticals, an oncology speciality company with a $2bn offer.

DEAL WATCH

BAXALTA

- Spin out announced Sept 2014 effective 1 July 2015
- Global revenues of $6bn, 16,000 employees
- Operations in 100 countries, R&D spend $600m
- Pipeline: haematology, immunology, gene therapy, biosimilars
- Recent deals: acquired Chatham Therapeutics [$70m]; collaboration Coherus Biosciences, divested vaccines to Pfizer [$625m], global licence Cell Therapeutics for pacritinib.

Baxalta aside, it has been a busy year for Shire which in February [reported in DW no 56] acquired the company Meritage bringing in a phase 3 ready oral budesonide solution for eosinophilic oesophagitis [an orphan indication].

Interestingly, the right to make the Meritage acquisition came via the purchase of ViroPharma.

Before engaging with Baxalta, Shire announced the acquisition of Foresight Therapeutics paying $300m cash and bringing FST-100 which is hoped to cure both bacterial and viral conjunctivitis. This fits well into Shire's ophthalmic business unit which was established in May 2014.

" Hostile take overs remained a topic of conversation this month"

Hostile take overs remained a topic of conversation this month as the Perrigo / Mylan saga played on; the vote taken by Mylan's shareholders on 28 August indicated support for the deal with two thirds voting in favour, which provides a firm launch pad for a formal offer. Perrigo had previously expressed concerns over Mylan's corporate governance noting the change from needing to secure an 80% shareholder approval to a simple majority to secure the deal. It will be interesting to see how these take overs progress into the autumn.

Licensing Deals

Other busy major companies [in terms of licences rather than acquisitions] included Sanofi and also AstraZeneca. Staying firmly on its diabetes therapeutic area focus, Sanofi elected to expand its collaboration with Evotec to develop a beta cell replacement therapy based on human beta cells derived from human stem cells. First mooted in December 2014, the companies had entered into a broad strategic alliance covering a five year period as part of an open innovation initiative. This new collaboration triggers a €3m payment with potential additional milestones of €300m plus royalties.

Immunology deals

In addition to this and in keeping with the industry fashion, Sanofi has ventured into immuno-oncology with Evotec / Apeiron Biologics. This revisit to oncology follows downsizing and reorganisation and moves Sanofi into next generation therapies which are anticipated to complement the current checkpoint inhibitors in development. As a strategic collaboration it is fairly risk sparing and accesses Apeiron's immunological expertise; no financial terms were disclosed other than the deal headline value of €200m plus substantial research payments and royalties.

AstraZeneca

As for virtually all of our Deal Watch tables, the acquisitions dominate the top headline values, but AstraZeneca [MedImmune] topped the table for the biggest headline value licensing deal with Inovio at $727m. This was the fifth deal* announced by AstraZeneca/Medimmune in the month under which the company gained access to INO-3112 a cancer vaccine which targets cancers caused by human papilloma virus. INO-3112 generates killer T-cell responses to HPV 16 and 18 driven tumours and is in phase 1 / 2 clinical studies for cervical and head and neck cancers. MedImmune has paid $27.5m upfront, with a further $700m in milestones and double digit tiered royalties.

**Two deals did not report financial terms so are not included in the main table.*

AstraZeneca deals	Subject	Headline $m
Inovio	Cancer vaccines	727
Heptares	HTL 1071 and A2A receptor blocking compounds	510
Isis	Antisense drugs for CVS metabolic and renal disease	65
Mirati Therapeutics	Immuno-oncology combinations in lung cancer	Not disclosed
Peregrine Pharmaceuticals	Combination clinical trials	Not disclosed

Staying in oncology, AstraZeneca closed an exclusive global licence with Heptares [owned by Sosei] securing a headline value of $510m. Under the terms of the deal, AstraZeneca gains access to HTL-1071, a small molecule which blocks A2A receptors with a further collaboration in this field. The deal brings an upfront of $10m to Heptares with a further $500m and tiered double digit royalties.

Building on the existing antisense relationship that was forged through its original deal with Isis [for 5 cancer targets] signed in December 2012 [see DW 30] AstraZeneca invested further with an upfront fee of $65m. Antisense oligonucleotides target RNA and the new collaboration will extend into renal diseases, cardiovascular and metabolic fields.

The last two deals completed by AstraZeneca did not disclose financial terms but both were therapeutic combination approaches. AstraZeneca will collaborate with Peregrine on a non-exclusive basis looking at the combination of bavituximab and durvalumab [MEDI4736] in solid tumours. Looking at another combination, AstraZeneca entered into a clinical trial collaboration this time with durvalumab in combination with Mirati Therapeutics' investigational spectrum-selective histone deacetylase (HDAC) inhibitor, mocetinostat. No financial terms were disclosed but Mirati will conduct and fund the initial phase 1/2 clinical trial [due to start in 2016] with MedImmune supplying durvalumab.

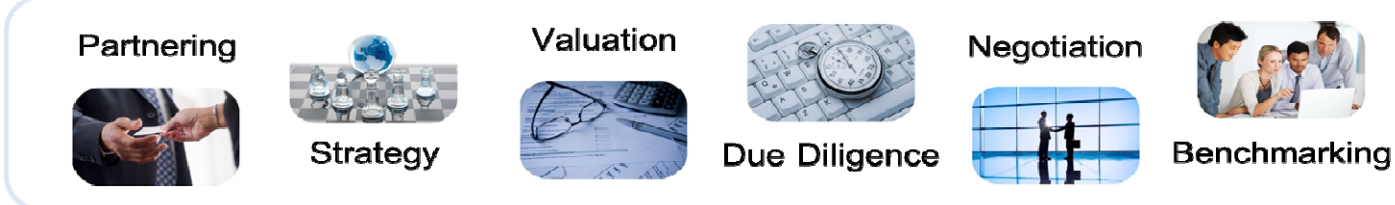
Other Immunology Activity

Although the weather patterns were fairly mixed during this holiday month – the UK not surprisingly getting a good deal of rain - it was still very hot on the oncology/immuno-oncology front with 12 deals being reported. In addition to those noted above from Sanofi and AstraZeneca, J&J closed a deal with Alligator Biosciences for a headline value of $700m [no upfront fee was disclosed]. Late to join the immuno-oncology race, ADC 1013 is a CD40 targeting antibody in phase 1 clinical studies; J&J assumes development responsibilities when the phase 1 studies are completed.

Licensor Acquired	Licensee Acquirer	Product / Technology	Deal Type	Headline ($m)
Baxalta	Shire	Complementary therapeutic areas including gene therapy	Bid to acquire the company	30600
Therakos	Mallinckrodt	Approved cell therapy platform for the palliative treatment of cutaneous T-cell lymphoma [CTCL]	Acquisition - company	1300
Promedior	BMS	PRM 151 recombinant pentraxin-2 protein for idiopathic pulmonary fibrosis and myelofibrosis*	Option to acquire	1250
GSK	Novartis	Arzerra [ofatumumab] anti CD20 monoclonal antibody in oncology indications	Acquisition of remaining rights	1034
Sprout Pharmaceutical	Valeant	Addyi [flibanserin] approved for hypoactive sexual desire disorder	Acquisition - company	1000
Scioderm	Amicus	Galafold [migalastat] for Fabry's disease*	Acquisition - company	847
Inovio	AZ/Medimmune	INO-3112 vaccine in P1/2 for cervical and head & neck cancer	Licence	727
Alligator Bioscience	J&J	ADC 1013 in solid tumours in P1	Licence	700
BioMarin	Medivation	Talazoparib a PARP inhibitor in P3 for BRCA mutated breast cancer	Acquisition – asset	570
Heptares [Sosei]	AZ	HTL 1071 immuno-oncology small molecule and other A2A receptor blocking compounds	Exclusive global licence	510
Genmab	Novo Nordisk	Bispecific antibody candidates outside oncology indications	Licence	502
Tripex	Raptor	Quinsair inhaled fluoroquinolone for adult Pseudomonas aeruginosa in cystic fibrosis	Exclusive global licence	452
GeneWEAVE	Roche	Innovative clinical microbiology diagnostics	Acquisition - company	425
Twelve	Medtronic	Acquisition brings transcatheter mitral valve technology	Acquisition - company	408
United Therapeutics	AbbVie	Received on approval of Unituxin for neuroblastoma	Acquisition of Priority Review Voucher	350
Evotec	Sanofi	Beta cell modulating treatments for diabetes	Collaboration extension	330
Aveo	Novartis	AV 380 antibody for alleviation of cachexia	Licence	326
Foresight Biotherapeutics	Shire	Includes FST 100 for conjunctivitis P2	Acquisition - company	300
Aperion Biologics Evotec	Sanofi	To develop small molecule immuno-therapies	Collaboration	219
Relypsa	Vifor Fresenius	Patiromer oral suspension in treating hyperkalemia	Exclusive commercial licence	165
Cytos Biotechnology	Checkmate Pharmaceuticals	CYT 003 and VLP [virus like particle] platform in oncology	Exclusive licence	90
Isis	AZ	Addition to Dec 2012 collaboration to develop antisense drugs in oncology	Collaboration extension	65

All deals global unless otherwise stated

*orphan designated



Sharon Finch, the founder of Medius, has extensive business development experience working both in industry and for over 20 years with Medius. Sharon works primarily on partner searches and transactions.

She is the Editor of the Business Development and Licensing Journal and is the Course Director for the PLG MSc in Pharmaceutical Business Development & Licensing run by the University of Manchester.

Another early stage deal [opportunities do not seem to hang around long!] was that between Novartis and Aveo where Novartis paid an upfront fee of $15m to secure rights to AV 380 which will be used to treat cachexia, a wasting disease seen in cancer patients. AV 380 is in preclinical development and targets growth differentiation factor 15 [elevated levels are associated with cachexia].

Options and other trends

Options have been a much seen feature in Deal Watch during 2015 but of course options always carry the possible downside of the option not being exercised. This situation occurred when Genentech/Roche elected not to go further with their option to acquire the epigenetics drug discovery company, Constellation Pharmaceuticals. Originally reported in Deal Watch 19 [January 2012] the Genentech deal brought in $95m to Constellation plus funding for a three year collaboration. Constellation will now need to find another partner or funds to go further with development.

Keeping with the option trend, BMS entered into a deal which gives it the right to acquire Promedior bringing with it the rights to PRM 151 which has both fast track designation [US] and orphan status [US and Europe]. PRM 151 is under development for the treatment of idiopathic pulmonary fibrosis. The price tag of up to $1.25bn includes payments for the option to acquire, the option exercise fee, as well as the usual milestone payments.

Introduced by the FDA in 2007, a priority review voucher (PRV) is an incentive for companies to invest in treatments for neglected tropical diseases. PRVs can be used to speed up a future filing (for example from ten months down to six). In 2012 the PRV programme was extended to include rare pediatric diseases and the emergence of trading in PRVs was noted in our last Annual Deal Watch report. Keeping this trend, United Therapeutics has sold a PRV to AbbVie for a headline value of $350m. This follows previous PRV deals, such as the Knight Therapeutics /Gilead deal where the PRV was sold for $125m [November 2014]. More recently Retrophin sold its PRV to Sanofi for $245m, so it looks as though values are definitely on the rise!

Finally, no Deal Watch monthly review is complete without a mention of Valeant! This month the deal was the purchase of Sprout Pharmaceuticals for $1bn cash in two instalments of $500m bringing the recently approved product Addyi (flibanserin) which is used for hypoactive sexual desire disorder in women. As the first approved product for this disorder the US launch is expected in October.

medius associates

Tel: +44 (0) 20 8654 6040
dealwatch@medius-associates.com