Evaluate Vantage

January 17, 2012

Which of 2012's launches will be future blockbusters?

Evaluate Vantage

A review of the year's biggest product launches - based on analyst forecasts - reveals a bumper crop of oral small molecules approaching the market. From Biogen Idec's MS therapy BG-12 to Pfizer's RA pill tofacitinib, if all goes to plan 2012 could see some game changing medicines launched before the year is out.

The world of biotechnology is predicted to have a quieter year, with Novo Nordisk's new long acting insulin, degludec, potentially the biggest product up for approval this year. Roche's pertuzumab is also a strong contender but could slip into the class of 2013 on even a small delay. In all, eight out of the top 20 product launches of 2012 are forecast to achieve blockbuster status by 2016, according to consenus data from EvaluatePharma (see table). As ever, however, delays and setbacks can rarely be ruled out and the picture by the end of the year is likely to have shifted (*Lift off for big drug hopes of 2011, Jan 10, 2012*).

Biotech class

Forecasted to reach $1.4bn by 2016, Novo’s diabetes drugs Degludec and Degludec Plus look to be this year's biggest launches if granted European approval on April 23 and in the US on July 27, 2012. The product is important for the Danish company's growth ambitions and its ego, after its previous new insulin offering, Levemir, never really threatened the hold Sanofi's Lantus has on the market. The threat of generic insulin meanwhile further clouds the future for the product and the company.

Roche is expecting to hear on EU and US approvals by July and October, respectively, for the company’s metastatic breast cancer treatment RG1273 (pertuzumab). With Herceptin biosimilars expected to enter the market as soon as 2014, this product approval would be a welcome addition for the company.

Whether Bexsero reaches European markets this year is questionable although Novartis has told analysts recently it is confident a green light will be received at some point. The company has said it will file in the next few months, although is not anticipating a US filing until 2014.

Glaxo meanwhile will be hoping its third time lucky its meningitis vaccine Menhibrix. The company has received two complete response letters from the FDA already and in December 2011 re-submitted more information.

As potentially the first non-surgical treatment for vitreomacular adhesion ThromboGenics’ ocriplasmin has two regulatory milestones in 2012. With a European decision date in May and PDUFA in October, sales forecasts reach $409m by 2016. The company intends to build its own commercial organisation to market the product in the US and parts of Europe (*EP Vantage Interview - ThromboGenics eyeing approval success, December 23, 2011*).

In December 2011 Sanofi voluntary withdrew its US filing for Zaltrap in previously treated metastatic colorectal cancer to clear up chemistry, manufacturing and controls issues. The company plans to resubmit in early 2012, with European filing also expected at this time, so launch is feasible this year, although it looks open to delays.

This year the French company will hear on a couple of products. Sanofi has previously said it will file Lemtrada for approval in the US and Europe in the first quarter of this year and, given its fast track status it could feasibly reach the market this year. That allows for no slippage, however. And Kynamro, the antisense product it acquried with Genzyme for the treatment of homozygous familial hypercholesterolemia, is due to hear in Europe by February. A US filing is expected early 2012.

NPS pharmaceuticals' biggest growth driver Gattex has an imminent EMA decision date and a PDUFA date set for June 2012, after asking the FDA for a priority review back in December, 2011. If approved the treatment for short bowel syndrome is forecasted to reach $201m sales by 2016. Gattex has received orphan drug designation in both regions.

Osiris Prochymal remains on the list, a hangover from last year. The stem cell therapy is filed in Canada in graft vs host disease but a series of setbacks means the product has little chance of meeting what appear to

be optimistic forecasts.

Conventional class

Amarin's fish oil-based triglyceride lowering pill AMR101 is due to hear on approval by July 26; the event will also bring crucial news on whether the product has been awarded new chemical entity status by the regulator (*AHA 2011 - Amarin's patent concerns set to prevail despite more strong data, November 17, 2011*). This first approval is in a fairly limited patient population – to meet the substantial potential reflected in those lofty sales forecasts the drug would need to win later approvals in much broader and lower-risk patient population.

BG-12 meanwhile will be lucky to get to the market this year, although that is what a handful of optimistic analysts are forecasting. Others have opted for a more conservative 2013 launch. Biogen intends to file in the first half of this year so approval could happen if all goes well – but next year appears more likely. If it does make it this year the drug would certainly count as one of the most notable approvals of 2012 – its remarkable efficacy in clinical trials and oral dosage means great things are expected from the novel MS therapy.

Another game-changing novel therapy that is much more likely to reach the market this year is tofacitinib, Pfizer's RA drug. The company is due to hear in Europe by mid year and in the US in August and while its novelty is likely to prompt the regulators to tread carefully, no serious hiccups are anticipated.

April will be a big month for Vertex, when it is due to hear EU and US regulators' opinions on cystic fibrosis drug Kalydeco (*Vertex's cystic fibrosis candidate exceeds hopes, February 24, 2011*). As the first disease modifying therapy, albeit only for 5% of patients that carry a specific gene mutation, its approval would be a landmark for treatment of the disease.

Mid-year should bring news for Gilead's new Quad HIV pill. Although the drug's commercial potential is not completely clear given impending generic competition to certain of its components, analysts still reckon it should bring in useful revenues for the company (*Superiority just out of reach for Gilead's Quad, September 20, 2011*).

Vivus' obesity agent Qnexa meanwhile is certainly one of the biggest unknowns of this group. Whether regulators can be convinced the drug's benefits outweigh its risks remains unknown, although many are turning more positive on the product's chances of reaching the market.

Linaclotide could be lining up to provide some relief to the under served irritable bowel syndrome with constipation market, with a US decision due in July.

Medivation and Astellas might squeeze in approval of prostate cancer drug MDV3100 this year as some analysts forecast, if they get a move on with a filing. The drug received fast track status from the FDA in November, following knock-out phase III data (*Medivation roars back to life as prostate cancer drug delivers, November 3, 2011*).

The chances of dapagliflozin - partnered with AstraZeneca - receiving approval are pretty low following a rough ride from an adcom last year and a predictable three month delay (*Dapa doubts validate Bristol-Myers decision to share the risk, July 20, 2011*).

Carfilzomib went to the FDA with a high hope of receiving priority review in multiple myeloma only to receive word that its application would undergo a standard 10-month consideration; a decision is due from the FDA in July (*Carfilzomib shifting to the slow lane, December 12, 2011*).

Biggest expected product launches in 2012						**W sa**
Biotechnology	**Rank**	**Product**	**Pharmacological Class**	**Company**	**Status**	**201**
	1	DegludecPlus/Degludec	Insulin	Novo Nordisk	Filed	58
	2	RG1273 (pertuzumab)	Anti-HER2 (ErbB-2) MAb	Roche	Filed	63
	3	Bexsero	Meningococcal B vaccine	Novartis	Filed	13
	4	Microplasmin	Plasmin	ThromboGenics	Filed	3
	5	Menhibrix (HibMenCY-TT)	Hib & meningococcal C & Y vaccine	GlaxoSmithKline	Filed	10

	6	Zaltrap	VEGFr kinase inhibitor	Sanofi	Filed	47
	7	Gattex	Glucagon-like peptide 2 (GLP-2) agonist	NPS Pharmaceuticals	Filed	11
	8	Kynamro	Apolipoprotein B-100 (ApoB-100) antisense	Sanofi	Filed	7
	9	Prochymal	Mesenchymal stem cell	Osiris Therapeutics	Filed	3
	10	Lemtrada	Anti-CD52 MAb	Sanofi	Phase III	4
Total biotech products						*36*
Conventional	1	AMR101	Omega-3 fatty acid	Amarin/Undisclosed Partner Sales	Filed	10
	2	BG-12	Fumarate	Biogen Idec	Phase III	15
	3	Tofacitinib	Janus kinase-3 (JAK-3) inhibitor	Pfizer	Filed	68
	4	Qnexa	Adrenoreceptor agonist & anti-convulsant	VIVUS	Filed	44
	5	Kalydeco	CFTR potentiator	Vertex Pharmaceuticals	Filed	78
	6	Quad	Nucleoside reverse transcriptase inhibitor (NRTI), HIV integrase inhibitor & CYP3A inhibitor	Gilead Sciences	Filed	34
	7	Linaclotide	Guanylate cyclase type-C receptor agonist	Ironwood Pharmaceuticals/Forest Laboratories/Almirall	Filed	69
	8	MDV3100	Androgen receptor antagonist	Astellas Pharma	Phase III	19
	9	Dapagliflozin	Sodium-glucose cotransporter-2 (SGLT2) inhibitor	Bristol-Myers Squibb	Filed	18
	10	Carfilzomib	Proteasome inhibitor	Onyx Pharmaceuticals	Filed	15
Total conventional products						*45*

Evaluate APAC
+81-(0)80-1164-4754