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Key regulatory events for the next six months

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The hype and excitement around Biogen Idec's treatment BG-12 for multiple sclerosis is set to come to a head with widely expected fourth quarter approval in both the US and Europe. Although BG-12 is set to be one of the biggest drug launches this year, there are also others in the midcap world expecting decisions that could have an even greater an impact on their shares and future

The other big events include Medivation and Astellas Pharma's US approval of prostate cancer drug enzalutamide (MDV3100); Amarin getting a decision in the US on cholesterol treatment AMR101 that would help its patent position; and both European and US approval of linaclotide from Ironwood Pharmaceuticals and Forest Laboratories, two companies under pressure and in desperate need of some good news (see table).

Moving to the front

Big things are predicted for BG-12, which is not only the biggest growth driver at Biogen, but also the group's most valuable product, with a NPV of $11bn. Sales are expected to hit $3.42bn by 2018 (*Confirm shows BG-12 potential, October 26, 2011*).

If the drug is approved by the December 28 PDUFA action date in the US, the big debate will be at which stage of the disease BG-12 will be used. Some in the industry are expecting doctors could move it straight to frontline treatment. Whatever stage it is used, with its superior efficacy it is almost certainly going to erode sales of current oral incumbent Gilenya, which has been hit by safety scares following unexplained cardiovascular deaths.

For most companies securing approval is the end of their troubles; for Amarin, this is just one more bridge crossed before it can finally relax. The FDA is set to rule on the group's triglyceride-lowering drug, AMR101, by July 26, but for Amarin the most important task is strengthening the intellectual property around the fish oil treatment (*Event – US filing is only part of the Amarin puzzle, July 06, 2012*). What Amarin will most desire is that the FDA decides AMR101 is a new molecular entity, a ruling expected a month after the PDUFA decision and one that should give AMR101 and its shaky patents three to five years of protection from generic competition.

Forest in particular will be hoping that all goes well when its drug for irritable bowl syndrome with constipation, linaclotide, is up before the US regulators on September 7. Forest is currently reeling from a the patent expiry of anti-depressant Lexapro, that has forced it to cut its growth forecasts for the year and on Tuesday report a 79% fall in quarterly earnings. But the PDUFA date, which was delayed by three months, may not save Forest's board, which is under attack from activist shareholder Carl Icahn. A showdown is expected at the August 15 annual board meeting.

Share price rise

Growing expectations about prostate cancer drug and US marketing authorisation in the fourth quarter are behind the more than doubling of Medivation shares since the beginning of the year. The drug has shown impressive results in clinical trials, leading to the early halt of its phase III Affirm trial (*Medivation roars back to life as prostate cancer drug delivers, November 3, 2011*). Despite the stop the drug is believed to have clear survival benefits. Sales for partner Astellas are forecast to reach $1.12bn fueled by its efficacy and the fact that unlike its nearest competitors it is a monotherapy.

Having been another victim of the FDA's decision to extend the review time of their drug, Relistor, Progenics Pharmaceuticals and Salix Pharmaceuticals are expecting to find out by July 27 if their oral version of opioid induced constipation drug Relistor will pass muster. If the oral formulation is approved it would continue the turnaround for Progenics, which was sparked by the release of positive top line data in December (*Progenics' Relistor moving nicely through trial success, December 21, 2011*). Approval would also open up a new and much bigger patient population in the form of patients with chronic non-cancer pain.

The table below highlights some of the biggest regulatory decision facing the industry, outside of big pharma.

Regulatory decisions		

Product	Company	Pharmacological Class	Event	Indication	Date	Product NPV ($m)	N M
BG-12	Biogen Idec	Fumarate	EU and US approval	MS	Q4	9,148	
Eylea	Regeneron Pharmaceuticals	VEGFr kinase inhibitor	EU and US approval	Wet AMD (EU), CRVO (US)	Q3, 23 Sep	6,312	
AMR101	Amarin	Omega-3 fatty acid	US approval	Hypertriglyceridemia	26 Jul	2,776	
MDV3100	Medivation	Androgen receptor antagonist	US approval	Prostate cancer	Q4	2,472	
MDV3100	Astellas Pharma	Androgen receptor antagonist	US approval	Prostate cancer	Q4	2,016	
Kyprolis	Onyx Pharmaceuticals	Proteasome inhibitor	US approval	Multiple myeloma	27 Jul	2,305	
Qsymia (Qnexa)	VIVUS	Adrenoreceptor agonist & anti-convulsant	EU approval	Obesity	Q4	2,157	
Adcetris	Seattle Genetics	Anti-CD30 MAb-auristatin E conjugate	EU approval	Hodgkin lymphoma and systemic anaplastic large cell lymphoma	Q3	1,765	
Linaclotide	Ironwood Pharmaceuticals	Guanylate cyclase type-C receptor agonist	EU and US approval	IBS	Q3, 7 Sep	1,130	
Linaclotide	Forest Laboratories	Guanylate cyclase type-C receptor agonist	US approval	IBS	7 Sep	1,083	
Linaclotide	Almirall	Guanylate cyclase type-C receptor agonist	EU approval	IBS	Q3	114	
Gattex	NPS Pharmaceuticals	GLP-2 agonist	US approval	Short bowel syndrome	30 Sep	987	
Omontys	Affymax	Erythropoietin stimulator	EU approval	Anemia	Q3	854	
Ocriplasmin	ThromboGenics	Plasmin	Ad Com, EU and US approval	VMA	26 Jul, Q4, 17 Oct	755	
Relistor	Progenics Pharmaceuticals	Mu opioid antagonist	US approval	Opoid induced constipation	27 Jul	733	
Lyxumia	Zealand Pharma	GLP-1 agonist	EU approval	Diabetes	Q4	649	
Cabozantinib	Exelixis	VEGFr2, RET & Met tyrosine kinase inhibitor	US approval	Thyroid cancer	Q4	618	

IPX066	IMPAX Laboratories	Dopamine precursor & dopa decarboxylase inhibitor	US approval	Parkinson’s disease	Q4	581
Kynamro	Isis Pharmaceuticals	Apolipoprotein B-100 antisense	EU approval	Familial hypercholesterolaemia	Q3	538
Eklira	Forest Laboratories	LAMA	US approval	COPD	30 Jul	308
DR Cysteamine	Raptor Pharmaceutical	Lysosomal transport modulator	EU and US approval	Nephropathic cystinosis	Q4	297
Budesonide MMX/Uceris	Cosmo Pharmaceuticals	Corticosteroid	EU and US approval	Ulcerative colitis	Q3, Q4	194
Budesonide MMX/Uceris	Santarus	Corticosteroid	US approval	Ulcerative colitis	Q4	174
Lomitapide	Aegerion Pharmaceuticals	Microsomal triglyceride transfer protein inhibitor	EU approval	Homozygous familial hypercholesterolemia	Q4	135
UT-15C Sustained Release	United Therapeutics	Prostacyclin analogue	US approval	PAH	27 Oct	124
Selincro	Lundbeck	Opioid antagonist	EU approval	Alcohol dependence	Q3	72
Crofelemer	Salix Pharmaceuticals	CFTR channel & calcium-activated chloride channel blocker	US approval	HIV-associated diarrhea	5 Sep	54
Zaltrap	Regeneron Pharmaceuticals	VEGFr kinase inhibitor	EU and US approval	Colorectal cancer	Q3	21
Scenesse	Clinuvel Pharmaceuticals	Melanocortin receptor agonist	EU approval	Erythropoietic protoporphyria	Q3	-
Selincro	Biotie Therapies	Opioid antagonist	EU approval	Alcohol dependence	Q4	-

Data source: EvaluatePharma's Calendar of Events.

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