

Which of 2013's launches will become blockbusters?



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With the exception of Roche's highly anticipated breast cancer antibody conjugate trastuzumab-DM1, 2013 will be the year of the small molecule. A review of the biggest forecast drug launches of the coming year shows that T-DM1 is the sole biotech product expected to attain blockbuster status. By contrast, six conventional drugs are expected to meet this mark.

2013's biggest fish by far is Biogen Idec's multiple sclerosis therapy BG-12, expected to do \$3.7bn of revenue within five years of its debut in March. And the two leaders point to another trend: drugs for chronic disorders – not just cancer and MS, but COPD, diabetes and hypertension – look likely to sell like hot cakes (see table).

Chronic

BG-12's presence in the top spot is hardly unexpected ([Biogen and Gilead top tables with most valuable R&D assets, August 8, 2012](#)). It has initially been forecast to be launched last year, and is still expected to sail through FDA review and swiftly establish itself as the front-line MS treatment thanks to excellent efficacy in clinical trials and its oral administration. EU approval, already overdue, will doubtless see it attain the same position in Europe.

The other MS product – this one an antibody, Sanofi's Lemtrada – also suffered a delay to its market entry in the US, which is now scheduled for the end of this year ([Lemtrada knock-back rebounds onto BTG, August 29, 2012](#)). EU approval, expected in the second quarter, should ease Sanofi's patient cliff worries as well as MS patients' symptoms. That said, with Lemtrada's patent expiring in 2017, the respite will be brief.

The anticancer charge is led by T-DM1 and Bayer's Alpharadin, intended to treat castration-resistant prostate cancer patients with bone metastases. Hopes are rising that the latter could gain approval for use before chemotherapy, and sales forecasts are rising with them. Alpharadin, a radiopharmaceutical, is expected to sell \$1.1m in 2018.

As for TDM-1, the difference between the expectations for Roche's cytotoxic Herceptin conjugate and the next-highest biotech product is intriguing in itself: TDM-1 is forecast to rake in \$1.4bn, more than twice as much as the number two, Heparin. This may be attributed to the large survival benefit the conjugate showed over Tykerb and Xeloda in phase III and, consequently, its accelerated approval schedule ([Roche finds success in trial failure over Herceptin, October 2, 2012](#)).

Metabolic

With the world's population getting older and fatter, it is unsurprising that many companies are targeting metabolic diseases: type 2 diabetes, hypertension and hyperlipidaemia are all represented.

The type 2 diabetes therapy albiglutide, previously licensed from Human Genome Sciences by GSK and acquired outright through the hostile takeover last summer, is in a three-horse race with Sanofi's Lyxumia and Lilly's dulaglutide to be the next glucagon-like peptide-1 agonist to market. Conversely, Johnson & Johnson's type 2 diabetes drug canagliflozin, now known as Invokana, ought to reap the benefits of becoming the first drug of its class to reach the US market after putting in a decent showing at an FDA panel ([Adcom backing gives canagliflozin a chance at an open diabetes field, January 11, 2013](#)).

COPD is also a popular choice. GSK's Breo Elipta is awaiting approval in the EU and the US, as well as EU sanction for asthma, which should see it net 2018 sales of \$1.2bn. Licensed from Theravance, the LABA-steroid combo is seen as risky by analysts owing to its varying phase III results and LABA dose concerns ([Midcap players ask Europe to bring it on in 2013, December 24, 2012](#)). With GSK's Advair ruling both the COPD and asthma markets, it will be an interesting launch to watch.

Elsewhere, Novartis's LABA/LAMA combination QVA149 should just squeak into blockbuster territory five years hence.

Going viral

Another dominating feature is the number of antivirals making the list. While some of this is a function of the continued interest in hepatitis C, there are other drug categories that stand to make their developers healthy profits in 2013.

Once again forecasts for biologics lag those for their small-molecule colleagues, with the star graduate from the Pfizer and GlaxoSmithKline's ViiV collaboration, dolutegravir, leading the way. The HIV drug is only one of a handful of integrase inhibitors in development and is expected to not only provide Gilead's combination drugs with some competition – finally – but also rack up \$1.36bn in sales by 2018.

Competition will also be an issue for Medivir's Johnson & Johnson-partnered protease inhibitor, simeprevir, which last year impressed in phase III trials with its ability to treat patients infected with the tricky genotype 1 of the virus. What the drug needs now is a first pass at approval given the number of all-oral interferon-free treatments currently in development ([Medivir gets good hep C news, but can it keep up with all-oral combos?](#), December 20, 2012).

Although Dynavax's hepatitis B treatment Heplisav has been included in the list, it is highly unlikely that it will be launched this year. The drug received a big knockback in November after members of an FDA advisory board narrowly voted against approval over concerns that there was not enough data to prove safety, despite its strong efficacy. The FDA has to make a decision by February 24, but the odds must be heavily stacked against Heplisav getting approval without a larger trial ([Efficacy little solace as Dynavax faces yet another delay](#), November 16, 2012).

Few issues are expected around the approval of Merck & Co's successor to Gardasil, VS03. The HPV drug is a 9-valent vaccine, giving it the potential to offer wider protection than the quadrivalent Gardasil. So far, despite its superiority, sales in 2018 are only forecast to be \$458m; Gardasil's 2012 sales are expected to be \$1.47bn. Merck will almost certainly be looking to move patients over to V503 ahead of Gardasil's 2019 patent expiry.

Conventional

Lastly, the well-travelled orphan disease pathway is represented by BioMarin's Morquio syndrome therapy GALNS. The company intends to file for approval this quarter, making for regulatory decisions in the US in the fourth quarter and in the EU in the second quarter of 2014 ([BioMarin primes the market for a year of wait and see](#), December 7, 2012). The data are believed to be robust enough to secure approval; with an expected price tag of around \$330,000 per patient per year, its 2018 sales are set to hit half a billion dollars.

But GALNS – and Otsuka's schizophrenia therapy Abilify Depot and Novo Nordisk's anti-haemophilia A drug turoctocog alfa – is a minority concern. The story of 2013 launches is one of conventional therapies for conventional diseases.

Biggest expected product launches in 2013*						WW annu sales (\$m)	
Biotechnology	Rank	Product	Pharmacology class	Company	Status	2013	2018
	1	Trastuzumab-DM1	Anti-HER2 (ErbB-2) MAb-DM1 maytansinoid conjugate	Roche	Filed	66	1,4
	2	Heplisav	Hepatitis B vaccine	Dynavax Technologies/Undisclosed Partner Sales	Filed	21	59
	3	GALNS	N-acetyl-galactosidase-6-sulfatase	BioMarin Pharmaceutical	Phase III	7	50
	4	V503	HPV vaccine	Merck & Co	Phase III	9	45
	5	Turoctocog alfa	Anti-fibrinolytics	Novo Nordisk	Filed	8	39
	6	Kynamro	Anti-hyperlipidaemics	Sanofi	Filed	117	34
	7	Lemtrada	MS Therapies	Sanofi	Filed	67	34
	8	Albiglutide	GLP-1 agonist	GlaxoSmithKline	Phase III	5	32

<i>Total biotech products</i>						299	4,3
Conventional	1	BG-12	Nuclear factor erythroid 2-related factor (Nrf2) pathway activator	Biogen Idec	Filed	378	3,7
	2	Dolutegravir	HIV integrase inhibitor	GlaxoSmithKline	Filed	54	1,3
	3	Simeprevir	Hepatitis C NS3/4A protease inhibitor	Johnson & Johnson	Phase III	15	1,2
	4	Breo Ellipta	Beta 2 adrenoreceptor agonist & corticosteroid	GlaxoSmithKline	Filed	24	1,2
	5	Alpharadin	Radiotherapy agent	Bayer	Filed	55	1,1
	6	QVA149	LAMA & LABA	Novartis	Filed	39	1,0
	7	Abilify Depot	5-HT1A (serotonin) & dopamine D2 partial agonist & 5-HT2 (serotonin) antagonist	Otsuka Holdings	Filed	44	94
	8	Riociguat	Guanylate cyclase activator	Bayer	Phase III	19	93
	9	Invokana (canagliflozin)	SGLT2 inhibitor	Johnson & Johnson/Mitsubishi Tanabe Pharma	Filed	21	91
	10	Opsumit	Endothelin receptor antagonist	Actelion	Filed	9	83
<i>Total conventional products</i>						658	13,3

* 2018 sales above \$100m

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