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At least 11 future blockbusters await launch in 2015

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As money continues to flow readily into pharma and biotech, what are drug developers pumping out at the other end? This year it could be at least 11 future blockbusters, according to *EvaluatePharma* data, a healthy haul that helps explain ongoing investor support for the sector.

The cholesterol-lowering anti-PCSK9s from Sanofi and Amgen, a heart failure pill from Novartis and Vertex's follow-on cystic fibrosis therapy represent the class of 2015's biggest hopes. However several other novel products are attracting substantial commercial expectations, raising the pressure on the likes of GlaxoSmithKline, AbbVie and Synageva to deliver (see tables below).

The analysis is based on consensus forecasts from equity analysts, and extracts the top 10 biotechnology and small-molecule drugs likely to reach the market this year.

Some are more likely to make it than others, of course, and Novartis's novel psoriasis treatment Cosentyx looks unlikely to disappoint – it received European backing earlier this week, and a US decision is due by the end of the month; an FDA panel already gave it unanimous backing.

Dead certs include AstraZeneca's PARP inhibitor, which won both US and European backing at the very end of 2014, and Merck's newly acquired Zerbaxa, which won approval shortly after the Cubist acquisition in December.

However, the list also reflects the best-case scenario that the sellside tends to reflect, particularly when it comes to assets still in phase III.

One example is Bristol-Myers and AbbVie's multiple myeloma therapy elotuzumab, which has yet to report pivotal data. Results from a phase III trial called Eloquent-2 are due in the first half testing the project in combination with Revlimid in refractory patients. The anti-SLAMF7 antibody has breakthrough designation in this use, so a successful readout followed by swift filing could see launch this year.

In a similarly tight situation is AbbVie's venetoclax (ABT-199). Data from a phase II trial in relapsed chronic lymphocytic leukaemia patients with the p17 deletion – a high-risk and hard-to-treat group – are due in the coming months and could be submitted to regulators for review.

The biggest products slated for launch in 2015 - biotechnology drugs					
				Global sales ($m)	
Project	**Therapy area and/or pharma class**	**Company**	**Status**	**2015**	**2020**
Praluent (alirocumab)	Anti-hyperlipidaemic; anti-PCSK9 MAb	Sanofi	Filed	43	2,109
Evolocumab	Anti-hyperlipidaemic; anti-PCSK9 MAb	Amgen	Filed	77	1,839
Toujeo	Long-acting insulin	Sanofi	Filed	135	1,637
Bosatria	Bronchodilator; anti-IL-5 MAb	GlaxoSmithKline	Filed	27	1,124
Cosentyx	Psoriasis treatment; anti-IL-17A MAb	Novartis	Approved	133	1,099
Dengue Vaccine	Dengue fever vaccine	Sanofi	Phase III	23	969
Kanuma	Enzyme therapy; LAL deficiency	Synageva BioPharma	Filed	4	775
Asfotase Alfa	Enzyme therapy; hypophosphatasia	Alexion	Filed	54	762
Basal Insulin Peglispro	Long-acting insulin	Eli Lilly	Phase III	14	726
Elotuzumab	Multiple myeloma therapy; anti-SLAMF7 MAb	Bristol-Myers Squibb	Phase III	4	631

A look at the biggest expected launches from the biotech world shows just how neck and neck it is between Sanofi, partnered with Regeneron, and Amgen with the anti-PCSK9 antibodies.

Evolocumab has a US PDUFA date of August 27 and should hear in the EU in the same timeframe, while Sanofi should hear around mid-year from the FDA and later in Europe. It is almost inconceivable that the US FDA will consider these applications without consulting an advisory committee. The timing of this has yet to be confirmed, so together with the novelty of this drug class these could easily face delays.

The biotech world could also see a couple of novel long-acting insulins debut this year, from Sanofi and Lilly. However, FDA caution in this space means a wait can also not be ruled out.

And demonstrating just how big a year this could be for Sanofi, the French drug maker is also set to seek approvals in several endemic countries for its Dengue fever vaccine.

For GlaxoSmithKline, Alexion and Synageva, the decisions pending on novel biologics are all big events. This is more obvious for Synageva and Alexion – representing their first and second product launches respectively. But even Glaxo will be keen for a green light for its treatment for severe asthma; the struggling respiratory giant needs to prove that it is still an innovative player in this market.

The biggest products slated for launch in 2015 - conventional drugs					
				Global sales ($m)	
Project	**Therapy area and/or pharma class**	**Company**	**Status**	**2015**	**2020**
VX-809 + Kalydeco	Cystic fibrosis; CFTR corrector + potentiator	Vertex	Filed	575	4,744
LCZ696	Heart failure; AT1 antagonist & ARNI	Novartis	Phase III	259	4,057
Ibrance	Breast cancer; CDK 4 & 6 inhibitor	Pfizer	Filed	281	3,078
Uptravi	PAH; Prostacyclin agonist	Actelion	Filed	17	1,210
Venetoclax	CLL; Bcl-2 inhibitor	AbbVie	Phase III	8	1,058
Brexpiprazole	Anti-psychotic; 5-HT1A & D2 agonist & 5-HT2 antagonist	Otsuka Holdings	Filed	88	1,023
Zerbaxa	Antibiotic; Cephalosporin & beta-lactamase inhibitor	Merck & Co	Approved	59	735
Nuplazid	Anti-psychotics; 5-HT2A antagonist	Acadia Pharmaceuticals	Phase III	25	696
Odanacatib	Osteoporosis; Cathepsin K inhibitor	Merck & Co	Phase III	37	658
Lynparza	Breast cancer; PARP inhibitor	AstraZeneca	Approved	28	585

This year pharma will underline how conventional, small-molecule technology is still a crucial drug-generating engine, even if biotechnology seems to grab more headlines. Six products are forecast to reach blockbuster status by 2020, two of which, Novartis's heart failure pill LCZ696 and Vertex's cystic fibrosis combination, look set for particularly bright futures.

With half of the Vertex product already on the market in the shape of Kalydeco, a green light for VX-809 should open up the F508 homozygous market to Vertex, implying a 28,000-patient pool versus the 3,700 that can be targeted with standalone Kalydeco. A US decision is expected by July 5.

Novartis has yet to confirm completing filing LCZ696 in the US, although previously it said this would be done by the end of 2014. An EU filing early this year has also been flagged. Both regions have agreed to fast track their reviews, meaning decisions could come by year end, and with so much at stake progress here will be a key focus for investors.

Meanwhile, Pfizer will hear from the FDA on its breast cancer pill Ibrance in April, and Otsuka on the anti-psychotic brexpiprazole in July; Actelion submitted Uptravi late last year.

Acadia and Merck had already pushed back filings of Nuplazid and odanacatib to this year – meaning both will need a fair wind to reach the market in 2015. Therefore these seem ripe for missing analysts' expectations, although nothing can ever be ruled out of the regulatory process, for any novel drug.

With a healthy number of potential big launches to watch this year, however, investors should be delivered plenty of good news to reward their ongoing loyalty to the sector. How companies then perform on meeting these sales expectations is another analysis entirely.

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