Evaluate Vantage

December 01, 2016

Approvals of novel molecules set to plunge in 2016

Amy Brown

With only a month of the year to go, it is clear that 2016 will register a big drop in the number of novel molecules approved by the FDA. This prompts an important question: were the last two years of astonishing R&D productivity actually a blip?

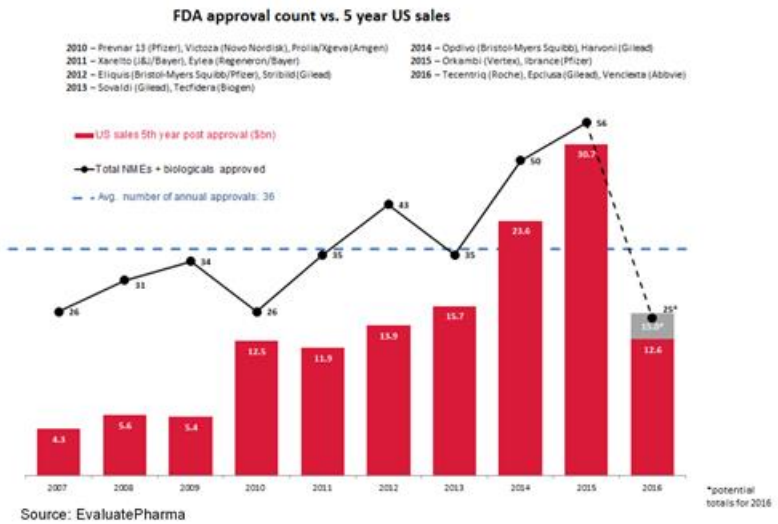
If this proves to be the case those expecting the industry's output to remain at historically high levels will be disappointed, although realistically a return to more sustainable levels was very likely to happen. Any sign that productivity is dropping further, however, to levels last seen 10 years ago, would rightfully cause concern (see graph).

The analysis below points to the approval of 25 novel small molecules and biologics this year – this assumes that Roche's Ocrevus and Cempra's Solithera both get a green light in December.

Roche's MS therapy Ocrevus promises to be one of 2016's biggest approvals, certainly in commercial terms; it has a PDUFA date of December 28 and few expect a knockback.

Safety concerns around Solithera, a macrolide antibiotic, make its approval chances much shakier despite the indisputable need for novel medicines to fight dangerous bacterial infections *(Panel nod gives Cempra little solace, November 7, 2016).*

The oral and IV forms have PDUFA dates of December 27 and 28 respectively.



Source: EvaluatePharma

Still, should a knock back come Cempra will certainly not be alone. Several of 2016's notable contenders have received complete response letters; anecdotally it looks like the FDA has taken issue with a lot of filings this year, although *EP Vantage* has not conducted a quantitative analysis to see whether this has happened more than usual.

One of the most notable was Sanofi's sarilumab earlier this month, delayed on manufacturing concerns; the rheumatoid arthritis therapy becomes one to watch in 2017. The fear is that these issues will also impact the approval of dupilumab, a dermatitis antibody which is predicted to become a much bigger product and that is also up for approval in March next year. If this worst case scenario unfolds, the French pharma giant will come under a lot of pressure.

Above and below

The stellar years of 2014 and 2015 that saw the arrival of huge blockbusters like Opdivo, Harvoni and Ibrance were always going to be hard to repeat. For as the analysis above shows, not only did these years see the

arrival of some huge commercial drugs – as measured by fifth year US sales – the sheer number of approvals was also well above the 10 year average.

Even if Ocrevus and Solithera win FDA endorsement, 2016 will still be running well below the average number of approvals for the last 10 years. Maybe this does not matter too much when considering that on commercial terms 2016 is not looking too bad. Fifth year sales are running about average – seven potential blockbusters have been approved this year, including Tecentriq, Epclusa and Venclexta, a respectable run on this measure.

Of course the industry's output of novel molecules is only one measure of productivity. And there are many reasons why this analysis should not be viewed in isolation. For example it makes no consideration of the time or money put into creating these new medicines. A straightforward count also understates some of these agents' broad utility across various illnesses – although the inclusion of fifth year sales attempts to address this.

As such, although this year's approval tally looks similar to 2007, comfort can be taken from the fact 2016's drug launches are forecast to be considerably more valuable.

Next year no one will want to see another contraction. Even if 2014 and 2015 were outlier years, the improvements in productivity witnessed from 2010 must be maintained. A return to the R&D doldrums of the middle of last decade would be a disaster for the sector.

To contact the writer of this story email Amy Brown in London at AmyB@epvantage.com or follow @AmyEPVantage on Twitter.