Evaluate Vantage

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FDA’s flashing green light boosts novel drug approvals

Amy Brown

No slowdown at the FDA, as regulator remains on track to approve at least 43 new drugs this year.

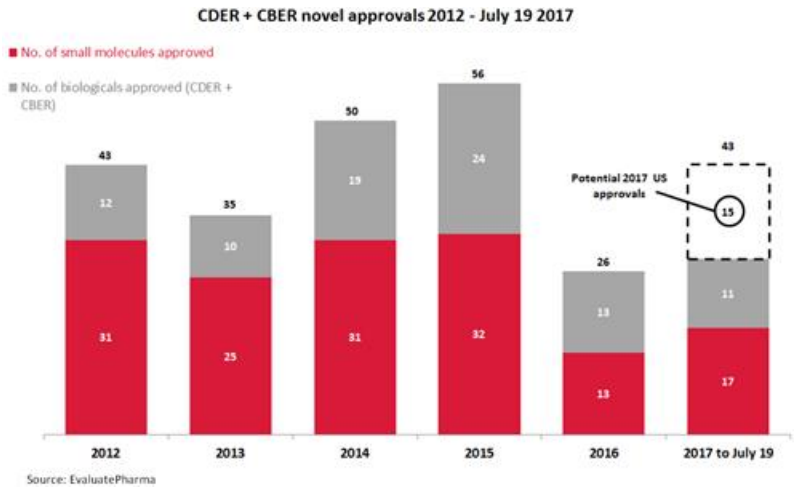
This week's approvals for Puma and Gilead mean that the US FDA has given the green light to more novel drugs this year than across the whole of 2016. Fears of a regulatory slowdown, which arose in the wake of last year’s drop-off, can be firmly put to bed.

The apparent dip now looks like a benign timing issue, which should be confirmed in the coming months as more drugs pass regulatory muster. Astrazeneca’s asthma antibody benralizumab, Pfizer’s antibody-drug conjugate Besponsa and of course the first CAR-T therapies are awaiting the FDA's verdict; *EP Vantage* estimates that another 15 novel medicines could receive approval by the end of the year.

Should these occur 2017’s tally would come in at 43 new chemical or biological approvals. Unlike some other analyses of the FDA’s data, *EP Vantage* includes drug approvals by the regulator’s biologicals division CBER, as well as the more widely followed CDER unit.

So, for example, our count of the year so far includes the approval of Alk-Abello’s dust mite allergy tablet Odactra.

Nods this week for Puma’s breast cancer drug Nerlynx and Gilead’s new hepatitis C triplet Vosevi – which contains the novel molecule voxilaprevir – take the year’s endorsements to 28, our analysis reveals. The result means that 2017 should well outstrip 2016’s 26, with approvals heading back towards levels more commonly seen over the past five years.



The biggest approval so far this year – in terms of sales potential – is Sanofi and Regeneron's atopic dermatitis treatment Dupixent, although Roche's MS therapy Ocrevus is not far behind. By 2022, both should be selling around $3bn in the US, *EvaluatePharma's* sellside consensus predicts.

Other big sellers that have already received a green light include Astrazeneca's anti-PDL-1 antibody Imfinzi, Novartis's breast cancer pill Kisqali and Tesaro's Parp inhibitor Zejula. In fact this year is looking good for potential blockbusters – should Novo Nordisk's once-weekly diabetes treatment semaglutide and Kite's CAR-T contender win through, eight products with the potential to generate US sales of $1bn will have gained FDA approval this year.

Huge sales potential is not the only yardstick of success, of course. Drugs like Novartis's Rydapt and Biomarin's Brineura are notable for being the first to reach the market to treat rare forms of leukaemia and Batten disease.

Delays are inevitable of course. Big setbacks this year include knockbacks for Lilly and Incyte's RA pill Olumiant and Astrazeneca's ZS-9, for hyperkalaemia, and only this week Amgen received a complete response letter for its osteoporosis candidate romosozumab, now branded Evenity.

Biotech watchers are now focused on the big regulatory events of the year: decisions on Novartis's CTL019 and Kite's KTE-C19. Verdicts on these groundbreaking CAR-T therapies are due by October 3 and November 29 respectively, though it is not inconceivable that Kite will be called in front of an advisory committee before then.

Given the positive tone of Novartis's committee review last week, few are expecting any holdups for that project (*Novartis's CAR speeds towards approval with panel nod, 13 July 2017*). The biopharma sector has enjoyed a notable return to favour over the course of the year, so swift regulatory success for these highly innovative, living therapies would only brighten the mood further.

Five year approval run				
Year	**No. of small molecules approved**	**No. of biologicals approved (CDER + CBER)**	**Total approvals**	**% YoY chg in total new products**
2017 to Jul 19	17	11	28	8%
2016	13	13	26	(54%)
2015	32	24	56	12%
2014	31	19	50	43%
2013	25	10	35	(19%)
2012	31	12	43	n/a

To contact the writers of this story email Amy Brown or Edwin Elmhirst in London at news@epvantage.com or follow @ByAmyBrown or @EdwinElmhirst on Twitter