Evaluate Vantage

November 01, 2017

Astra wins a speedy nod as US novel drug approvals swell

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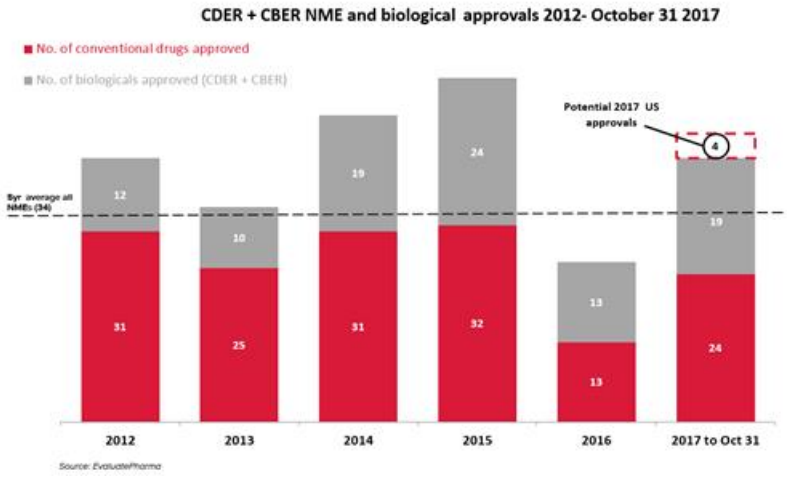
FDA back in business after 2016's fall in drug approvals.

The green light for Astrazeneca's new lymphoma therapy, Calquence, is the 43rd novel drug approval from the US regulator so far this year. With two months of 2017 remaining, this year looks like a return to form for the FDA after 2016's worrying dip in output.

This now appears to have been nothing more than a benign timing issue, and drug developers can remain confident that the US agency is primed to push through innovative medicines quickly. Calquence is a case in point: its approval came a mere three months after the filing was accepted (see tables below).



Astrazeneca is now free to sell its BTK inhibitor to treat mantle cell lymphoma patients who have already failed on one previous line of therapy. The FDA granted accelerated approval based on an overall response rate of 80%, which was generated in an open-label trial of 124 patients.

Calquence, which contains the active ingredient acalabrutinib, is unlikely to rank as one of the biggest new products to reach the market this year, based on future sales potential. But, as only the second BTK inhibitor to be approved, its entry is significant. Its main competitor is the hugely successful Imbruvica, but in mantle cell lymphoma Calquence arguably looks more efficacious, the caveat of across-trial comparisons notwithstanding.

Imbruvica's label cites an ORR of 66%, which was generated in a study very similar to Calquence's.

More common cancers are where the real sales potential lie, however, and Imbruvica is ahead of the game here, with six indications already on its label. Analysts reckon it will be generating $7.6bn in sales for Abbvie and Johnson & Johnson by 2022, versus $811m for Calquence.

The table below shows that several other 2017 approvals have fifth-year sales potential in excess of Calquence's forecast – Sanofi and Regeneron's Dupixent and Roche's Ocrevus being probably the two most notable new arrivals this year.

Top five approvals of 2017 to date (to October 31)

Product	Pharma class; indication	Company	US sales 2022 ($bn)
Dupixent	Anti-IL-4 & IL-13 MAb; atopic dermatitis	Sanofi	3.0
Ocrevus	Anti-CD20 MAb; multiple sclerosis	Roche	2.8
Imfinzi	PD-L1 MAb; bladder cancer	Astrazeneca	1.5
Verzenio	CDK 4 & 6 inhibitor; breast cancer	Lilly	1.1
Mavyret	Hepatitis C anti-viral	AbbVie	0.8

Source: EvaluatePharma.

EP Vantage's investigations reveal four more novel prospects that could receive a green light from the FDA this year, adding further to this tally. Most keenly awaited is the verdict on Novo Nordisk's new diabetes contender, semaglutide, though a unanimously positive advisory committee vote in October means that a positive outcome is widely expected (*Snippet roundup: Insulet, Dexcom and Gilead try clever pricing strategies, 20 October 2017*).

By the end of the year Astra should hear about another candidate, its asthma antibody benralizumab, while Merck & Co and Pfizer will receive the verdict on a new SGLT2 inhibitor, ertugliflozin, that they have been jointly developing in diabetes.

Perhaps the company with the most at stake is Ultragenyx, which will find out whether it gets its first approval in the coming weeks. Vestronidase alfa is an enzyme-replacement therapy for the rare lysosomal storage disease MPS7, and while its sales potential might be relatively small the event will show whether the company is capable of navigating regulatory pathways. This is important because a much more valuable asset, burosumab, faces a US approval decision in April.

The dip in 2016 notwithstanding, the FDA has notched up several strong years for novel drug approvals, and 2017 looks set to continue this trend. New initiatives to help bring important novel medicines to patients more quickly have had a lot to do with this productivity surge. With the regulatory climate so fertile, it is up to industry to keep delivering the innovation.

Potential approvals of 2017

Product	Pharma class; indication	Company	Approval guidance	US sales 2022 ($m)
Semaglutide	GLP 1 agonist; type II diabetes	Novo Nordisk	By December 5th	1,422
Benralizumab	Anti-IL-5 MAb; asthma	Astrazeneca	Q4 2017	424
Ertugliflozin	SGLT 2 inhibitor; type II diabetes	Merck & Co/ Pfizer	December	348
Vestronidase alfa (rhGUS)	Lysosome enzyme therapy; MPS 7	Ultragenyx	By November 16th	19

Source: EvaluatePharma.

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