Evaluate Vantage

February 28, 2019

Go or no go? Johnson & Johnson awaits Spravato nod

Madeleine Armstrong

Others hoping to get FDA approvals include Sage Therapeutics and Novartis, but hopes look dimmer for Lexicon and Sanofi.

The first US approval slated for March is also set to be the biggest. Johnson & Johnson expects the go-ahead by next week for its brightest pipeline hope, the depression project Spravato (esketamine), after a surprising positive panel vote earlier this month.

Sage's Zulresso is also odds-on to get the nod for postpartum depression. While sales expectations are more muted, given that it is delivered via a 60-hour intravenous infusion, approval should help Sage establish a commercial presence as it takes its promising oral depression candidate Sage-217 through late-stage development.

Things do not look so rosy for Lexicon and Sanofi's SGLT1/2 inhibitor Zynquista, which is under review for type 1 diabetes. A January adcom was split 8-8 on whether the project should be approved, with panellists voicing concerns about the risk of diabetic ketoacidosis (*Ketoacidosis worries could scupper Lexicon, January 18, 2019*).

Notable March first-time approval decisions			
Project	**Company**	**PDUFA date**	**Product NPV ($m)**
Spravato (esketamine)	Johnson & Johnson	Mar 4	4,993
Roclatan	Aerie	Mar 14	532
Zulresso (brexanolone)	Sage	Mar 19	813
Ryaltris	Glenmark	Mar 21	-
Zynquista (sotagliflozin)	Lexicon/Sanofi	Mar 22	2,850
Meloxicam	Recro Pharma	Mar 24	153
Mavenclad	Merck KGaA	Mar 29* (2nd review)	4,450
Midazolam nasal spray	UCB	Mar 29	9
Duaklir	Astrazeneca/Circassia	Mar 31	282
Mayzent (siponimod/BAF312)	Novartis	March	4,526
**Estimate based on filing date.*			

There are big expectations attached to two multiple sclerosis projects with approval decisions due in March: Merck KGaA's Mavenclad and Novartis's Mayzent. However, these look optimistic given the pricing pressure in the MS market.

This is particularly the case for the ageing Mavenclad, which the FDA rejected in 2011; the drug, which is used in relapsing MS, is approved in various other territories including Europe and Canada. Meanwhile, Novartis believes that its candidate, Mayzent, could become a blockbuster. The Swiss group used a priority review voucher to hasten a decision in secondary progressive MS, a population in which it claims Mayzent is the only drug proven to work.

March is an important month for Aerie, which hopes to get approval for Roclatan, the follow-on to its glaucoma drug Rhopressa. And Recro Pharma will hope that a resubmitted NDA for its pain candidate intravenous meloxicam will address the questions that spurred the FDA to issue a complete response letter last May.

Circassia could complete its transformation from an allergy to a respiratory player with decisions due on two Astrazeneca-partnered COPD projects: a first-time approval for Duaklir and expanded approval for Tudorza to include new data on cardiovascular safety and the reduction of COPD exacerbations.

Supplements

There are several other important product expansions on the horizon. Notably, Regeneron and Sanofi expect approval of Dupixent in adolescent atopic dermatitis, to add to its existing use in adults with the skin disorder. Regeneron estimates the prevalence in adolescents to be about half of that in adults, with around 150,000-200,000 teenagers suffering from the disease.

And Roche's PD-L1 inhibitor, Tecentriq, could also get a couple of new indications next month. The drug could become the first checkpoint inhibitor to bag approval in triple-negative breast cancer.

In small-cell lung cancer Bristol-Myer's Squibb's Opdivo is already approved, albeit for third-line disease with a controversial accelerated approval. Roche could also steal a march on another rival, Merck & Co, here: Merck's Keytruda is not due an approval decision in SCLC until June, and that is in third-line disease.

After a couple of quiet months on the approvals front, and as fears of another US government shutdown recede, it looks like March could see a return to business as usual for the FDA.

Supplementary approvals and other notable regulatory decisions for March			
Product	**Company**	**Event type**	**Date**
Herceptin SC	Roche	PDUFA on Herceptin SC for breast cancer	Mar 1
Dupixent	Regeneron/Sanofi	sNDA/BLA for Dupixent for atopic dermatitis in adolescents (aged 12-17)	Mar 11
Tecentriq	Roche	sNDA/BLA for Tecentriq + Abraxane for 1st-line triple-negative breast cancer	Mar 12
		sNDA/BLA for Tecentriq + chemo for 1st-line SCLC	Mar 18
Tudorza Pressair	Astrazeneca/Circassia	sNDA/BLA for Tudorza Pressair for COPD	Mar 31
Gattex	Takeda	sNDA/BLA for Gattex for pediatrics (aged 1-17) with short bowel syndrome	March

The entry for Mavenclad has been updated.