Evaluate Vantage

September 01, 2017

Snippet roundup: The regulatory news is good for Lilly and Abbott, but bad for Acorda

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Welcome to your weekly roundup of *EP Vantage*'s snippets – short takes on smaller news items.

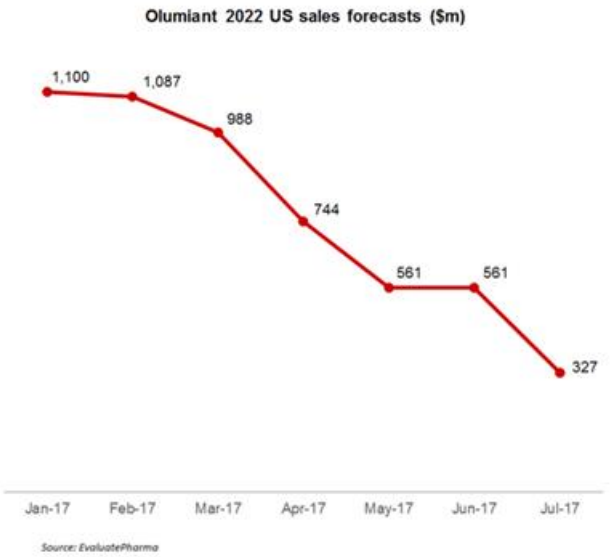
This week, August 28 to September 1, 2017, we had thoughts on the following: Lilly surprises with speedy Olumiant resubmission; US approval for Abbott's HeartMate 3 arrives right on time; Acorda stumbles in pursuit of Ampyra replacement; Astra and Takeda partner on emerging Parkinson's mechanism.

These snippets were previously published daily via twitter.

Lilly surprises with speedy Olumiant resubmission

August 30, 2017

One of the biggest regulatory blows of the year might not be quite the setback many had assumed. Lilly said today it would re-file its blockbuster rheumatoid arthritis candidate, Olumiant, before the end of January 2018, raising hopes for a green light six months later. Expectations for a launch in the US had been pushed back to 2020 in the wake of a surprise complete response letter in April, causing sales forecasts to slump. The asset was forecast to become the company's fifth-biggest product by 2022, according to *EvaluatePharma*'s consensus, but current estimates rank it at only 11. Lilly shares rose 2.5% on the news and partner Incyte jumped 8%. Lilly has apparently gathered sufficient new data since then to appease the FDA's concerns about safety and dosing, although, considering that an apparent clot risk was one of the red flags raised, it would be prudent to assume some approval risk remains.

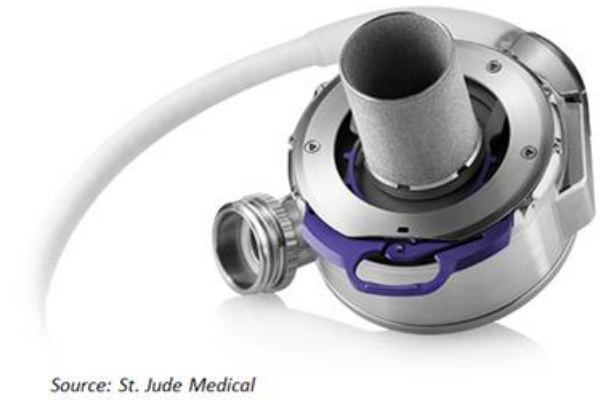


US approval for Abbott's HeartMate 3 arrives right on time

August 30, 2017

US approval of the newest iteration of the HeartMate left ventricular heart device (LVAD) will be welcomed by Abbott, particularly as the control unit for a previous model, HeartMate II, was recalled from the US market after 26 patients died when replacing it. The HeartMate 3 may be used to keep end-stage heart failure patients alive until they can receive a transplant. The new model, being smaller and posing a lower thrombosis risk than both the earlier version and Medtronic's competing HVAD product, ought to expand the overall LVAD market and help Abbott capture share. But Medtronic could fight back: the HVAD is on course to get FDA approval as a permanent implant this year. Wells Fargo analysts put Abbott's global LVAD sales at $554m for this year, rising to $628m in 2018, and say that HeartMate 3 is an important near-term growth driver for the company. Abbott is also working on other heart implants: separately, it said it was issuing a firmware update

to the implantable pacemakers and defibrillators it obtained, along with the HeartMate range, through its acquisition of St. Jude Medical. The new software is intended to improve the devices' cybersecurity and protect against unauthorised access.



Source: St. Jude Medical

Acorda stumbles in pursuit of Ampyra replacement

August 29, 2017

Acorda received a surprise refuse-to-file letter from the US FDA for Inbrija (CVT-301), its inhaled levodopa, over an inspection date for its manufacturing plant and the submission of the drug master production record. The New York-based group called the issues cited by the FDA "addressable", and said it would seek a type A meeting with the agency, which would result in a meeting within 30 days of receiving the request, to resolve the questions. Shares tumbled 26% in early trading today as resubmission of the Parkinson's disease drug might not happen until the end of 2017, meaning little hope of seeing new revenue in 2018, when Acorda's lead product, Ampyra, loses market exclusivity. This setback also puts pressure on the company to generate positive data from the phase III trial of a second Parkinson's disease agent, tozadenant, due to read out early next year.

Acorda's outlook

		Annual Sales WW - Sales ($m)							
Product	Indication	2016	2017	2018	2019	2020	2021	2022	WW Phase (Current)
Inbrija	Anti-Parkinson's agent	-	-	50	113	183	250	321	Filed
Tozadenant	Anti-Parkinson's agent	-	-	-	1	45	115	186	Phase III
Ampyra	MS Therapy	493	537	445	216	188	193	128	Marketed
rHIgM22	MS Therapy	-	-	-	-	2	7	14	Phase I

Source: EvaluatePharma

Astra and Takeda partner on emerging Parkinson's mechanism

August 29, 2017

Alpha-synuclein is not a new target for Parkinson's disease research, but work has been slow. However, if today's deal between Takeda and Astrazeneca is anything to go by, interest remains high – the new partners look set to put the fourth antibody into the clinic in this space. The theory behind this mechanism echoes work in Alzheimer's – alpha-synuclein proteins can misfold and aggregate in so-called synucleinopathies, of which Parkinson's is the best known; dementia with Lewy bodies and multiple system atrophy are other examples. By targeting aberrant forms of the protein, it is hoped that neurodegeneration can be disrupted. Roche looks set to provide a thorough test of this hypothesis with the large Pasadena trial, which it started in July. For its part, Astrazeneca claims that MEDI1341 is differentiated by its high affinity, high selectivity and lower interaction with the immune system, which gives it the potential to achieve a better efficacy and safety profile than other alpha-synuclein antibodies.

Targeting synuclein in Parkinson's disease

Product	Pharmacological Class	Company	Study details	Deal details
Phase II				
RG7935	Anti-alpha synuclein MAb	Roche/Prothena	Pasadena trial ongoing, seeking 300 pts, data 2019	2013 WW licensing deal over pre-clinical candidate; $30m up front.
Phase I				
UCB1332	Alpha-synuclein aggregation inhibitor	UCB/Neuropore	PI complete, on-going activity unclear	2015 WW licensing deal over pre-clinical candidate; $20m up front.
BIIB054	Anti-alpha synuclein MAb	Biogen/NeuroImmune	PI on-going, data 2017	2010 acquired asset with three other pre-clinical candidates for $32.5m up front.
PD01	Alpha-synuclein vaccine	AFFiRiS	PI data expected in Q4	-
PD03	Alpha synuclein vaccine	AFFiRiS	PI data expected in Q4	-
NPT088	Beta-amyloid, tau & alpha-synuclein aggregation inhibitor	Proclara Biosciences	PIb data in Alzheimer's expected in 2018, which could support a move to PII in Parkinson's.	
Selected pre-clinical candidates				
MEDI1341	Anti-alpha synuclein MAb	Takeda/AstraZeneca	PI to begin in 2017	2017 development and commercialisation deal, milestones to reach $400m.
PBT434	Alpha-synuclein inhibitor	Prana Biotechnology	PI to begin in 2017	-
BAN0805	Anti-alpha synuclein MAb	AbbVie/BioArctic	Development plans unclear	2016 collaboration; terms undisclosed.
Ge98-5	Alpha-synuclein inhibitor	Roche/Genmyd	Development plans unclear	2010 collaboration over PD and AD candidates; milestones to reach €500m.
Cu AFB2422	Anti-alpha synuclein MAb	Lundbeck/Genmab	Development plans unclear	2010 CNS antibody collaboration.

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