Evaluate Vantage

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Snippet roundup: Adocia fails, Nymox perseveres, FDA rejects Amgen and backs Impact

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

This week, 22-26 August 2016, we had thoughts on the following: Adocia boots foot ulcer project after trial failure; FDA knocks back Amgen's Parsabiv; Nymox still hopes to inject life into BPH space; FDA backs Impact of concussion test.

These snippets were previously published daily via twitter.

Adocia boots foot ulcer project after trial failure

26 August 2016

Adocia's phase III miss with its diabetic foot ulcer treatment is a disappointment to be sure, but it was a low-probability trial based on recent results of similarly acting projects. Last year saw the failures of two other assets, CureXcell and Aclerastide. Adocia's Biochaperone PDGF-BB hoped to improve on the main platelet-derived growth factor product in this space, Regranex, by reducing patient exposure to the protein and halving the dose to once every other day. Adocia failed to show a statistically significant improvement in wound closure at 20 weeks compared with placebo. The French group's big hope is its ultra-fast insulins, so it still has some important catalysts. Nevertheless, shares fell 6% today on news that the foot ulcer treatment had failed.

Setbacks in diabetic foot ulcer treatment		
Company	**Project**	**Outcome**
Adocia	BioChaperone PDGF-BB	Phase III failed 2016
Macrocure	CureXcell	Phase III failed 2015
Derma Sciences	Aclerastide	Phase III failed 2015

FDA knocks back Amgen's Parsabiv

25 August 2016

Amgen's lifecycle management strategy has taken a blow with a complete response letter for Parsabiv, its Sensipar follow-on, in secondary hyperparathyroidism, a complication of chronic kidney disease. Amgen did not give more details on the reasons for the FDA's rejection or say whether it needed to produce more data, but safety concerns are a possibility; a higher rate of cardiac failures was seen with Parsabiv versus Sensipar in a head-to-head trial, although the newer project did show better efficacy. Parsabiv is not Amgen's most valuable pipeline asset, but with Sensipar set to come off patent in 2018 it could have done with a positive decision.

Amgen's top five pipeline prospects			
Prjeuct	**Indication**	**Status**	**2022e sales ($m)**
ABP 501	Rheumatoid arthritis/psoriasis	Filed	810
Romosozumab	Osteoporosis	Filed	426
Parsabiv	Secondary hyperparathyroidism	Filed	404
AMG 334	Migraine	Phase III	253
ABP 980	Breast cancer	Phase III	148

Nymox still hopes to inject life into BPH space

25 August 2016

Nymox Pharmaceutical is persevering with its benign prostatic hyperplasia candidate fexapotide, but will extension data be enough to convince the FDA? The latest results, from a long-term blinded placebo crossover group – presumably from two US phase III trials that have already failed – found that fexapotide patients were significantly less likely to require surgery in the next two to three years compared with those who received conventional BPH treatments. Nymox plans to file for approval in the couple of quarters. The news sent the group's share price up 83%, putting it not far off levels in 2014 before the pivotal studies – NX02-0017 and NX02-0018 – failed to show improvements in their primary endpoints, the international prostate symptom score and the American Urological Association symptom index respectively. The mechanism behind fexapotide, also known as NX-1207, has not been fully elucidated, but some researchers believe that the project, which is injected directly into the prostate, has anti-apoptotic properties.

Top-five BPH drugs in 2022

Drug	Company	Year launched	Mechanism	2022e sales ($m)
Flomax	Boehringer Ingelheim/Astellas	1996	Alpha 1 adrenoreceptor antagonist	784
Avodart	GlaxoSmithKline	2003	Alpha 5 reductase inhibitor	341
Zalutia	Nippon Shinyaku/Lilly	2014	Phosphodiesterase V inhibitor	134
Urorec	Recordati	2010	Alpha 1 adrenoreceptor antagonist	133
Finasteride	Mylan	2006	Alpha 5 reductase inhibitor	103

FDA backs Impact of concussion test

23 August 2016

The FDA's de novo approval pathway, designed for low-risk medical devices unlike anything that has come before, has ushered another innovation onto the US market. Immediate Post-Concussion Assessment and Cognitive Testing (Impact) assesses cognitive skills such as word memory, reaction time and word recognition to help evaluate patients with suspected concussion – for example at the side of a football pitch when a player has suffered a head injury. The Impact software, sold by the Pennsylvania group Impact Applications, runs on a computer and is intended for people aged 12 to 59; a version called Impact Pediatric, which runs on an iPad and is designed for children aged 5 to 11, has also been approved. Only healthcare professionals should perform the test, the FDA said, adding that clinicians should not rely on Impact alone to rule out a concussion or determine whether an injured player should return to a game.

FDA de novo clearances by year		
Year	**Number**	**Ave time (months)**
2007	7	4.5
2008	3	6.0
2009	4	12.4
2010	3	14.4
2011	10	12.9
2012	10	15.3
2013	18	9.9
2014	28	13.7
2015	18	10.9
2016 to date	15	14.9*
**Approval time unavailable for the Impact test, so this has been excluded from this analysis.*		

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