Evaluate Vantage

January 06, 2017

Snippet roundup: J&J and Shire make some deals, but disappointments beckon for Arena and Inotek

Edwin Elmhirst

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

This week, January 2-6, 2017, we had thoughts on the following: J&J joins the Nash pack; Shire finds good home for mRNA unit; Arena admits defeat over obesity; Inotek cannot see past phase III failure; Consort's Voke deal revoked.

These snippets were previously published daily via twitter.

J&J joins the Nash pack

January 6, 2017

Johnson & Johnson has long been involved in funding early-stage research through its J&J Innovation arm – and 15 new arrangements have pushed the unit's total deals over 300 since its inception in 2013. Arguably the most interesting partnership is with Bird Rock Bio in non-alcoholic steatoheapatitis (Nash) – the company has a cannabinoid receptor 1 modulator, namacizumab, in phase I development. The Nash pipeline is crowded, but the project is the only one in the space targeting CB1, according to *EvaluatePharma*. However, rival candidates are well ahead. Meanwhile, Janssen has separately signed an agreement with Bristol-Myers Squibb to evaluate Darzalex and Opdivo in phase Ib/II studies in multiple myeloma and several solid tumour types – marking yet another combo approach for Bristol's product.

New J&J Innovation partnerships

Partner	Project	Deal type
Amorsa Therapeutics	Ketamine analogue technology for depression	Research, option and license agreement with Janssen
Aspect Biosystems	3D printed knee meniscus	Collaboration with DePuy Synthes
Bird Rock Bio	Namacizumab (cannabinoid receptor 1-targeting antibody) for Nash	Collaboration and option agreement with Janssen
Caelus Health	Microbiota-based products for cardio-metabolic disease	Joining the JLINX community
Center for Probe Discovery and Commercialization	Centyrin platform for immunotherapy drug development	Exclusive out-license by Janssen
Dendright	DEN-181 (tolerizing immunotherapy) for rheumatoid arthritis	Additional funding for R&D collaboration and option to license agreement from Janssen
eTheRNA	RNA-based immunotherapies for cancer and infectious diseases	Joining the JLINX community
Karolinska Institutet	Four projects: biomarkers in treatment-resistant depression and suicide risk; biomarkers in virus-induced type 1 diabetes through the DIA; immunological approaches in chronic hepatitis B viral infection and liver biology; and immune profiling of early prostate cancer	Funding, resources and advice from Janssen
Medicines for Malaria Venture	Long-acting injectable anti-malarial agents	Collaboration with Janssen
Octimet Oncology	MET kinase inhibitors for cancer	Joining the JLINX community
Rest Devices	Nod app for baby sleep coaching	Collaboration with J&J Consumer
S-Biomedic	Microbiome modulators for skin conditions eg, acne, eczema and rosacea	Investment from Johnson & Johnson Innovation/JJDC
Synthetic Genomics	RNA-based therapies and vaccines for infectious diseases and cancer	Collaboration with Janssen
University of Massachusetts	Cataracts and/or presbyopia therapies	Licensing agreement with Janssen
Weill Cornell Medicine	Prostate cancer therapies	Research alliance with Janssen

Shire finds good home for mRNA unit

January 5, 2017

Shire's decision to offload its messenger RNA technology MRT and its employees to the specialist private company Rana Therapeutics looks like a sensible decision. The Irish-domiciled speciality and rare-disease player has its hands full with multiple launches and late-stage clinical readouts, not to mention the likely need to defend the legacy Baxalta haemophilia A franchise from incursions by Roche's emicizumab. Shire's work in DNA and RNA therapeutics, which began in 2008, has yet to advance into the clinic. In taking a stake in Rana, the serial acquirer Shire puts itself in the pole position to license or take out Rana should the MRT projects or Rana's own proprietary pipeline bear fruit. Massachusetts-based Rana said it would continue to advance the MRT lead projects in cystic fibrosis and urea cycle disorders, aided by the transfer of Shire's MRT employees into the group's fold. Rana has raised $87m since its founding, starting with a seed capital round in late 2011.

Shire RNA & DNA therapeutics projects

Product	Pharmacological Class
Pre-clinical	
ZFP Huntington's Disease Program	CNS agent
BAX 499	Anti-tissue factor pathway inhibitor aptamer
Research project	
Santaris Pharma/Shire Genetic Disorder Program	miRNA antisense
Cystic Fibrosis Foundation/Shire Research Program	Cystic fibrosis transmembrane conductance regulator corrector

Source: EvaluatePharma

Arena admits defeat over obesity

January 5, 2017

After more than a decade of proclaiming the revolutionary benefits of its anti-obesity pill Belviq Arena Pharmaceuticals has lost the faith. The product has been handed over to its global partner, Eisai, for $23m in cash and over $80m in cost clawback, while Arena will continue to receive royalties and potential sales-related milestone payments. These payments are unlikely to come close to covering the years of development costs incurred – a 12,000-patient cardiovascular safety study demanded by regulators still has several years to run – and it is hard to escape the conclusion that Belviq was a blunder from the beginning, the huge commercial opportunity notwithstanding. Still, this is Eisai's problem now; it would not be surprising if the Japanese company was waiting for the readout of this trial, called Camellia-Timi 61, to make its own call on the future of the project. Like the other oral fat fighters launched around the same time Belviq has proved a commercial flop – Takeda exited its US marketing deal for Orexigen's rival pill Contrave in mid-2016. Unless the Camellia heart safety study uncovers something quite remarkable, it is hard to see Belviq continuing to make commercial sense for Eisai.

Marketed obesity products

		WW sales ($m)	
Product	Company	2015	2022e
The three oral rivals…			
Qsymia	VIVUS	54.6	87.1
Belviq	Eisai	36.7	55.3
Contrave	Takeda	56.0	*
Other products…			
Saxenda	Novo Nordisk	27.9	808.4
Kybella	Allergan	7.3	490.8
Alli	GlaxoSmithKline	207.7	167.5
XLS-Medical	Perrigo	37.6	53.0
Bofutsushosan	Tsumura	20.8	35.6
Meridia	AbbVie	37.3	32.1
Reduxin	Pharmstandard	14.7	28.7
Oblean	Takeda	6.9	17.3

** consensus not available*

Source: EvaluatePharma

Inotek cannot see past phase III failure

January 3, 2017

Shares in Inotek Pharmaceuticals tumbled 70% in market trading following announcement that the phase III trial of glaucoma project trabodenoson failed to significantly reduce intraocular pressure when compared with placebo. The eyedrop, which aims to relieve intraocular pressure (IOP) via the trabecular meshwork as in healthy eyes, was tested four times a day during days 28, 42 and 84 of treatment, but did not show an IOP benefit at all 12 timepoints. The company said the failure was driven by better than expected IOP readings at the 8am test in patients taking placebo. Not all is lost for Inotek, as it has a second glaucoma candidate – however, as that project combines latanoprost with trabodenoson, today's announcement should cast doubt on its promise.

Inotek outlook, pre-phase III data

	WW sales ($m)				
Product	2018	2019	2020	2021	2022
Trabodenoson Plus Latanoprost	-	-	6.9	83.4	187.6
Trabodenoson	1.1	44.3	97.1	126.9	155.9

Source: EvaluatePharma

Consort's Voke deal revoked

January 3, 2017

Consort Medical has played down the termination of its agreement with British American Tobacco for its Voke nicotine inhaler, pointing to its remaining 15 asset-strong pipeline. But Voke was once one of its big hopes, with sales forecasts of £15-20m ($18-25m) per year at the time of its UK approval in September 2014. The company had planned to sell Voke to smokers who wanted to quit and as an alternative to e-cigarettes, but it never launched the product – the reason BAT gave for walking away. The long delay meant that some analysts

had already removed it from their estimates, and Consort said the end of the deal should not affect this year's financial performance. Even so, the UK group's stock was down around 6% this morning. It will hope for better news for the rest of its pipeline – including DEV610, the generic version of Advair developed with Mylan, which has a GDUFA date of March 28.

Consort Medical's major programmes

Project	Description	Customer	Status
INJ570	Auto-injector	UCB	EMA approval received. Launched Oct 2016 in UK
VAL100	Metered dose inhaler valve/actuator	Astrazeneca	Product approved, awaiting launch
DEV610	Generic Advair	Mylan	GDUFA date 28 March 2017
VAL310	Easifill primeless valve	US pharma	Awaiting regulatory approval
INJ600	PatchPump infusion system for Treprostinel	Steadymed Therapeutics	NDA submission planned H1 2017
POC010	Point-of-care test cartridge	Atlas Genetics	CE marking granted for Chlamydia; combined Chlamydia/Gonorrhoea test cartridge development progressing
IDC300	Oral integrated dose counter	Pharma company	Launch now expected H2 2018
VAL020	Metered dose inhaler valve	Global pharma	Stability trials complete; customer progressing towards approval and launch
NAS020	Nasal device	Global generic	Formulation change; brief under review
NAS030	Nasal device	Pharma company	Early stage programme
INJ650	Auto-injector	Global generic	Continuing progress; early stage
INJ700	Lila Mix injector	Pharma company	Development programme on track
VAL050	Metered dose inhaler valve/actuator	Aeropharm	Development contract ongoing
OCU050	Ocular device/ formulation/filling	Oxular	Early stage programme
SYR075	Syrina/Vapoursoft auto-injector	Global biopharma	Newly completed master development agreement

Source: Company press release December 6

To contact the writers of this story email news@epvantage.com or follow @EPVantage on Twitter