Evaluate Vantage

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Snippet roundup: A small success for Galapagos and a big one for Karius

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

This week, August 7 to 11, 2017, we had thoughts on the following: caution is warranted with Galapagos's new lung disease hope; Karius gets $50m for Digital Culture; hearts pounding over Myokardia's cardiomyopathy success; even cough and cold offers no balm for Vernalis.

These snippets were previously published daily via twitter.

Caution is warranted with Galapagos's new lung disease hope

August 10, 2017

Common sense seems to have prevailed on Galapagos's idiopathic pulmonary fibrosis data – shares in the Dutch drug developer settled 8% higher after surging as much as 24%. Early signals might be promising, but caution is certainly warranted considering that the study of GLPG1690 only recruited 23 patients, 17 of whom received active treatment. Not that the company held back in promoting the phase IIa trial – a webcast of the results painted a very favourable picture of GLPG1690's profile compared with Esbriet and Ofev, the two IPF therapies to have made it to market. True, the study appeared to show a stabilisation of lung function in treated patients, while placebo patients declined as expected. But the project's mechanism of action, autotaxin inhibition, remains largely untested – inhibition of ATX leads to a reduction in lysophosphatidic acid production, which blocks signalling cascades that ultimately drive the development of fibrosis. Galapagos says it will quickly move into later-stage studies, and a look at the pipeline suggests that it will be leading the way here. Still, others could soon follow: Pharmakea, which is working with Celgene, has said it intends to put an autotaxin inhibitor into the clinic this year, while Gilead forged a deal in 2015 to support development of X-Rx's work in this space.

Targeting autotaxin

Phase	Product	Company	Notes
Phase II	GLPG1690	Galapagos	Heading to late-stage study
Phase I	Autotaxin inhibitor program	PharmAkea	Celgene option
Pre-clinical	ATX Inhibitor	X-Rx	Gilead collaboration
Related work?			
Phase II	BMS-986020 (LPA 1 receptor antagonist)	Bristol-Myers Squibb	Work in IPF presumed abandoned

Karius gets $50m for Digital Culture

August 8, 2017

Karius has secured medtech's biggest series A round for more than two years to develop and sell a test that uses a combination of machine learning, genomics algorithms and next-generation sequencing to detect more than 1,250 pathogens. The test uses the same technique as most liquid biopsies, detecting cell-free DNA in the patient's blood, but instead of picking up DNA shed by a tumour it identifies DNA fragments left by bacteria, viruses, fungi and other eukaryotes in a patient's blood, even when living organisms are no longer detectable. The Karius Digital Culture test is to be used after other diagnostics fail to find the culprit, and has a turnaround time of one day, faster than many culture tests and panels that test for a narrower range of pathogens. It is sold in the US as a lab-developed or homebrew test, and is therefore not approved by the FDA; part of the $50m funding will go towards clinical trials, though the company has not said whether this is intended to secure full FDA approval or approval in other countries.

Top 5 medtech series A rounds of 2017

Date	Company	Investment ($m)	Focus
August 7	Karius	50.0	In vitro diagnostics
June 13	Centogene	26.8	In vitro diagnostics
May 1	Lensgen	21.0	Ophthalmics
May 22	Anaconda Biomed	16.0	Neurology
March 16	Renalguard Solutions	14.5	Nephrology

Hearts pounding over Myokardia's cardiomyopathy success

August 7, 2017

Myokardia's success in a phase II hypertrophic cardiomyopathy trial is likely spurring investor speculation that the group could be a target for its partner and investor Sanofi. With Myokardia valued at just under $1bn this would be a pretty big bet on a project in heart failure/cardiomyopathy, where phase II success by no means predicts a positive pivotal outcome – witness the trouble companies like Cardiorentis, Celyad and Mesoblast have had converting promising mid-stage data into something the regulators will consider. MYK-461 (mavacamten) was able to show a statistically significant 112-point reduction in post-exercise left ventricular outflow tract gradient over baseline measurements in 10 obstructive hypertrophic cardiomyopathy patients who were treated over 12 weeks in the Pioneer-HCM trial. An 11th patient with a history of paroxysmal atrial fibrillation (AF) dropped out after a recurrence – this patient had stopped taking AF medications to participate in the trial. Myokardia shares rose 81% in early trading today. Sanofi was an early investor in the group, having put $10m into its equity under a 2014 collaboration and participation in a 2015 series B round before the company went public. On the side of Myokardia is that the condition it seeks to treat is much smaller than acute or chronic heart failure, and has a genetic component, perhaps making success more likely.

Recent late-stage setbacks in heart failure

Project	Company	Outcome	Trial ID
Ularatide	Cardiorentis	Failed in True-AHF	NCT01661634
C-Cure	Celyad	Failed in Chart-1	NCT01768702
Serelaxin	Novartis	Failed in Relax-AHF-2	NCT01870778
Rexlemestrocel-L	Mesoblast	Teva handed back rights; Dream HF-1 passed interim futility analysis	NCT02032004

Even cough and cold offers no balm for Vernalis

August 7, 2017

Investors in the UK's Vernalis have been through the wars, and today came more pain. Even the company's move into the safe and unexciting market of long-acting cough and cold medications has run into trouble, with a US complete response letter for the antitussive CCP-08. This follows last year's identical setback for the related asset CCP-007. Vernalis embarked on the cough/cold strategy through a licensing deal with Tris Pharma in 2012, but so far US approval of Tuzistra XR, for cough and upper respiratory allergy symptoms, has been its only success. Vernalis's long history has seen several incarnations, most notably as developer of the antimigraine drug frovatriptan, and the takeovers of companies including British Biotech – the UK sector's former star and most notorious blow-up. It is not clear where the setback leaves Vernalis, though for now CCP-007 and 008 remain a focus, albeit with a delay; perhaps some of British Biotech's oncology assets could find new life, though the baggage they would come with would be an obstacle. The US complete response letters likely relate to manufacturing problems at Tris, and Stifel analysts no longer see CCP-08 hitting the market in time for the 2017/18 cough/cold season.

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