Evaluate Vantage

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Snippet roundup: Anika and Valeant feel the pain, but Novo scores another oral sema win

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

This week, June 18-22, 2018, we had thoughts on the following: Anika still feels pain as osteoarthritis drug fails; Novo shows that oral sema's placebo beat was no fluke; CRL shows reduced significance of Valeant's pipeline hope.

These snippets were previously published daily via twitter.

Anika still feels pain as osteoarthritis drug fails

21 June

Fortune is not currently smiling on Anika Therapeutics. Fresh from a product recall that has cost it about $1.1m, yesterday Anika Therapeutics lost more than a third of its value following the failure of one of its biggest pipeline hopes. Cingal, an injectable combination therapy of a lubricating gel and steroids, failed to show any improvement over steroids (triamcinolone hexacetonide) in patients with osteoarthritis of the knee. The heavy fall might have been due to Cingal passing muster in a previous phase III trial where it was up against placebo, and that fact the latest trial was a key part of the group's filing for US approval. While Cingal is approved in Canada and Europe, as with most small companies US approval was the ultimate prize. The question now is whether the FDA will be prepared to approve the product on such a mixed dataset or if Anika will have to stump up for another phase III trial. Whatever happens Cingal's expected mid-2019 launch is now a thing of the past. Anika executives' attempts to accentuate the fact that the combo had some effect in pain relief across the duration of the study cut no ice with investors who, judging from the share price, appear to have made up their minds on Cingal's US approval prospects.

Novo shows that oral sema's placebo beat was no fluke

21 June

Results of two more active comparator trials of Novo Nordisk's key growth driver, the oral GLP-1 antagonist semaglutide, have shown that placebo-controlled data were no fluke, and allayed doubts raised when the first active-control study read out last month. That somewhat mixed readout, against Lilly/Boehringer's Jardiance, caused a market wobble, but investors breathed a sigh of relief today, with shares opening up 4%. The latest two trials, Pioneer 4 and 7, compared oral sema against Novo's injectable GLP-1 agonist Victoza and Merck & Co's oral DPP-IV inhibitor Januvia respectively. Pioneer 4 is commercially vital for Novo, showing sema to be at least as good as Victoza at HbA1c lowering and better at weight reduction – with the added convenience of oral dosing. In addition to intent-to-treat results Novo also presented per-protocol data, showing numerical superiority on the HbA1c endpoint versus Victoza. This again hints at patients discontinuing sema because of nausea. Ultimately it will come down to what the regulators allow to be included on the label, but for now the suggestion is that if patients can stick with oral sema they stand to benefit significantly.

Oral semaglutide phase III trials

			Results (intent-to-treat basis)		
Study	Setting	Enrolment	HbA1c reduction	Weight loss	Trial ID
Pioneer 1	Vs placebo	703	Statistically superior for all 3 doses	Superior for highest dose only*	NCT02906930
Pioneer 2	Vs Jardiance	816	Statistically superior	Not statistically superior**	NCT02863328
Pioneer 3	Vs Januvia	1,860	Data due Q2 2018		NCT02607865
Pioneer 4	Vs Victoza	690	Non-inferior***	Statistically superior	NCT02863419
Pioneer 5	Vs placebo; moderate renal impairment	324	Data due Q3 2018		NCT02827708
Pioneer 6	CV outcomes	3,176	Data due Q4 2018		NCT02692716
Pioneer 7	Flexible dose adjustment vs Januvia	500	Statistically superior	Statistically superior	NCT02849080
Pioneer 8	Vs placebo in insulin-treated patients	720	Data due Q4 2018		NCT03021187
Pioneer 9	Vs placebo or Victoza; Japanese patients	240	Data due Q4 2018		NCT03018028
Pioneer 10	Vs Trulicity, combination study in Japanese patients	455	Data due Q3 2018		NCT03015220

*Numerical superiority on a per-protocol basis for all 3 doses; **statistical significance hit at 52 weeks, but not at 26 weeks; ***numerical superiority on a per-protocol basis.

CRL shows reduced significance of Valeant's pipeline hope

19 June

On the surface the 12% share price fall over the complete response letter Valeant received yesterday for its

psoriasis drug Duobrii looked like a total overreaction – especially as the product was only forecast to have sales of $157m by 2024. But earlier this year Duobrii was wheeled out by the heavily indebted company as one of its "significant seven" – one of the seven drugs it had identified to help it achieve a combined $1bn of annual revenue within five years. So, rather than being about the value of Duobrii, investor displeasure is firmly about Valeant's inability to deliver on its turnaround promises. Recently Valeant has given itself some breathing space in servicing its enormous $30bn debt mountain, but this grace period was supposed to be filled with getting successful products to the market. It is not clear how long Duobrii will be delayed, but Valeant, which changed its name to Bausch Health Companies in May to distance itself from its chequered past, can ill afford the delay or any more slip-ups if this is how the market reacts.

Valeant's Significant Seven

Product	Indication	WW sales 2024 ($m)
Duobrii	Psoriasis	157
Relistor	Opioid-induced constipation	157
Vyzulta	Glaucoma	261
Lumify	General eye disorders	70
Bausch+Lomb Ultra	Contact lenses	-
Siliq	Psoriasis	289
Jemdel	Psoriasis	52

Source: EvaluatePharma

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