Evaluate Vantage

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# Snippet roundup: Adamas and Alexion score approvals and Amgen gets the price right

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

This week, August 21 to 25, 2017, we had thoughts on the following: Adamas bags approval, now comes the hard part; Finding of Amgen Repatha cost-effectiveness analysis should be little surprise; Alexion muscles in on new market; Mimedx asks for a refund; Samsung looks beyond biosimilars with Takeda deal.

These snippets were previously published daily via twitter.

**Adamas bags approval, now comes the hard part**

**August 25, 2017**

Adamas Pharmaceuticals has the world's first approved therapy for levodopa-induced dyskinesia in Parkinson's disease. Now it has to launch the product itself, no mean feat for a small company. FDA approval for the company's extended-release formulation of amantadine, ADS-5102 – now brand named Gocovri – had seemed likely after positive data from two phase III trials, but investors still sent Adamas's stock up 50% in premarket trading today. There had been some concerns about a possible delay to approval or unfavourable safety language being included in the product's label, with Mizuho analysts noting an increasingly cautious tone from the company. As it is, there is no black box warning but the label does highlight side-effects including suicidality and hallucinations. Adamas plans to formally launch Gocovri in January 2018 using its own sales organisation; the company has not yet said how much the drug will cost. The group admits it has limited commercial infrastructure and there are questions over why it has not chosen to use a contract sales force. *EvaluatePharma* consensus forecasts 2022 sales of $280m, but good execution will be vital to achieve this.

Gocovri growth

| | | Global sales forecasts ($m) | | | | | |
|---|---|---|---|---|---|---|---|
| Product | Company | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 |
| ADS-5102/Gocovri | Adamas Pharmaceuticals | 7 | 51 | 105 | 162 | 223 | 280 |

Source: EvaluatePharma.

**Finding of Amgen Repatha cost-effectiveness analysis should be little surprise**

**August 24, 2017**

Amgen beat third-party cost-effectiveness organisations to the punch with an analysis of Repatha based on long-term outcomes data in patients with arteriosclerotic cardiovascular disease. Amgen's analysis, published in JAMA Cardiology, found that at an annual price of $9,669, Repatha, a PCSK9-blocking antibody, would meet a cost-effectiveness threshold of $150,000 per quality adjusted life year (QALY) in patients with heart disease and a low-density lipoprotein (LDL) level of at least 70 mg/dL. The analysis was based on the Fourier study in this patient group, which found that Repatha treatment yielded an underwhelming 15% reduction in the risk of heart attacks, strokes, death and other complications of elevated LDL. Amgen said the $9,669 price is similar to what insurers pay for Repatha once discounts and rebates are taken into account – thus the findings from the cost-effectiveness analysis may be more than coincidental. The Institute for Clinical and Economic Review, an independent organisation, has promised a cost-effectiveness analysis based on Fourier to be delivered by the end of August. Its earlier analysis, based on less robust clinical trials, found that for heart-disease patients not achieving target LDL levels the price needed to be $7,600 for patients not at target LDL levels and $8,300 for patients intolerant to statins to achieve that $150,000 per QALY threshold.

Cost effectiveness analyses of Repatha

| Analysis | Cost-effectiveness price at $150,000/QALY |
|---|---|
| Amgen August 2017 (based on Fourier) | $9,669 |
| ICER November 2015 (pre-Fourier) | $7,600 (not at LDL targets) $8,300 (statin intolerant) |

**Alexion muscles in on new market**

**August 22, 2017**

European approval for Alexion's lead product Soliris in myasthenia gravis could increase investor confidence

ahead of its October 23 PDUFA date, but arguably more important for the company are next year's phase III data with its follow-on project, ALXN1210. The myasthenia gravis indication represents 20% of Soliris's sellside consensus forecast in 2022, but mixed results from the Regain trial have made the FDA's decision difficult to call; the latest approval supports the company's stance that the total data package will be enough for US regulators. Alexion also has phase III Soliris data coming up in neuromyelitis optica, but this is a much smaller indication – and next year attention will shift to its next-generation candidate, ALXN1210, which has three phase III trial readouts due in the two rare diseases in which Soliris is already approved: haemolytic uremic syndrome and paroxysmal nocturnal haemoglobinuria. ALXN1210 is an anti-complement factor C5 MAb like Soliris but is given via intravenous infusion every eight weeks, versus Soliris's once-fortnightly schedule. With its new chief executive, Ludwig Hantson, playing down the rest of Alexion's pipeline to focus on ALXN1210, the company needs the upcoming trials to succeed.

Alexion's upcoming events

| Event | Date | Notes |
|---|---|---|
| FDA decision on Soliris in myasthenia gravis | Oct 23, 2017 | $923m 2022 sales in indication* |
| Phase III results with Soliris in neuromyelitis optica | Primary completion Dec 2017 | Trial ID: NCT01892345; $153m 2022 sales in indication* |
| Phase III results with ALXN1210 in aHUS | Primary completion Dec 2017 | Trial ID: NCT02949128 |
| Phase III results with ALXN1210 in treatment-naive PNH | Primary completion Dec 2017 | Trial ID: NCT02946463 |
| Phase III results with ALXN1210 in treated PNH | Primary completion Mar 2018 | Trial ID: NCT03056040 |

*EvaluatePharma sellside consensus. aHUS: atypical haemolytic uremic syndrome; PNH: paroxysmal nocturnal haemoglobinuria.

**Mimedx asks for a refund**

**August 22, 2017**

Have you ever bought something, got it home and realised it wasn't quite what you wanted? Wound care company Mimedx is selling its bone graft subsidiary Stability Biologics back to Stability's former shareholders just a year and a half after buying it from them. Mimedx paid $10m for Stability Biologics – 60% cash and 40% stock – and also assumed the group's debt, as well as arranging a two-year earn-out. The acquisition brought it technologies including bone grafts and demineralised bone matrix, as well as skin products for burns and trauma. Now Mimedx says it wants to refocus as a biopharmaceutical company, though it does not develop drugs: instead its core technology is human amniotic membrane allografts. These use human placental tissue to repair burns and wounds, as well as for surgical, orthopaedic and sports medicine applications. Mimedx might make a loss on the deal: it said that in exchange for returning Stability to its original owners it expects to gain $8-10m. Mimedx will receive a promissory note for $3.5m and a waiver by the former stockholders of Stability of all claims to the earn-out consideration. The experience does not seem to have put Mimedx off future acquisitions, with the company saying it believes there might be better investment opportunities in biopharma.

Mimedx

| | WW sales ($m) | | | | |
|---|---|---|---|---|---|
| Segment | 2016 | 2018 | 2020 | 2022 | CAGR |
| Surgical & Sports Medicine | 61 | 102 | 143 | 184 | 20% |
| Wound Care | 184 | 262 | 336 | 409 | 14% |
| Total Company Revenues | 245 | 364 | 478 | 593 | 16% |

Source: EvaluateMedTech

**Samsung looks beyond biosimilars with Takeda deal**

**August 22, 2017**

Samsung Bioepis has quickly become a player to be reckoned with in biosimilars, and it now hopes to do the same in novel biologics, helped by a co-development deal with Takeda. The companies have not given many details apart from saying they will jointly develop multiple biologics for umet medical needs, starting with TAK-671 for severe acute pancreatitis. The compound is not shown on Takeda's pipeline, so presumably it is at an early stage of development. If the collaboration succeeds the companies could make a mark in the untapped acute pancreatitis market – current therapies include painkillers and intravenous fluids, followed by treatment of the underlying causes, usually gallstones or alcohol consumption. Takeda has gone through a restructuring and cost-cutting programme since its first non-Japanese leader, Christophe Weber, was appointed chief executive in 2015, but its pipeline is still looking thin. Given Samsung's track record, perhaps Takeda believes the South Korean group will be able to progress TAK-671 faster than it could alone.

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