Snippet roundup: Merck gets Tecos knockback, Gottlieb moves towards FDA hotseat

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

This week, April 3 to April 7, 2017, we had thoughts on the following: US FDA tells Merck to try again on Tecos; Gottlieb nomination moves to full Senate; Jazz trumpets Xyrem’s stay of execution; Fantom haunts Europe; no checkmate this time as Opdivo comes up short in brain cancer; Paratek delivers again; Genmab punished for Darzalex failure.

These snippets were previously published daily via twitter.

US FDA tells Merck to try again on Tecos
April 7, 2017

The US FDA has rejected Merck & Co’s bid to include cardiovascular safety data from the Tecos trial on the labels of its sitagliptin-containing diabetes pills Januvia, Janumet and Janumet XR. The New Jersey-based big pharma group did not disclose the objections outlined by the regulator in its complete response letter. Tecos, one of several cardiovascular outcomes studies recently completed on diabetes drugs, found that Januvia did not pose a greater cardiovascular risk than placebo – patients were allowed to take additional hyperglycaemic agents to keep blood glucose under control. While the Tecos data would not have helped give a marketing edge as the Empa-Reg Outcome data for Boehringer Ingelheim and Lilly’s Jardiance have done, they would have helped put physicians’ and patients’ minds at ease that there is no danger of cardiovascular complications or death from taking Januvia. Januvia is forecast to tumble from the top-selling diabetes drug in the world to fifth place in 2022, while Jardiance will be at the top of the table, according to EvaluatePharma’s consensus of sellside forecasts.

Gottlieb nomination moves to full Senate
April 6, 2017

Confirmation of Scott Gottlieb as the next US FDA commissioner looked on track after questioning from members of the Senate Health, Education, Labor and Pensions Committee. At a panel hearing yesterday, Mr Gottlieb, a scholar at the American Enterprise Institute, faced extensive questioning on his pharmaceutical industry ties, including board seats, investments and position as venture partner at New Enterprise Associates. How to address opioid addiction was a top priority of numerous senators. He struck a moderate note by emphasising the FDA’s importance in encouraging pharmaceutical innovation but also recognising that both regulations and career staff have a role to play in promoting innovation. Asked specifically about the purported links between vaccines and autism, Mr Gottlieb said that he believes the evidence disproves those links. The full Senate will not vote to confirm Mr Gottlieb until after it returns from a recess between April 10-21.
Jazz trumpets Xyrem’s stay of execution
April 6, 2017

Jazz Pharmaceuticals has been working hard to reduce its dependence on Xyrem, though judging by yesterday’s post-market settlement with Hikma the narcolepsy drug remains key to its fortunes. Hikma is the first generic filer, and will now launch an authorised copy in 2023 on which Jazz will collect a royalty. Jazz stock was up 7% in today’s premarket, which is strange since according to ISI Evercore’s Umer Raffat the buyside had expected a 2024/25 settlement date. However, the key to broad genericisation lies not in Hikma but in settlements with four other filers. Jazz could thus enjoy relatively steady Xyrem revenue for a couple of years after 2023, though sellside consensus has sales starting to plateau next year. A bigger factor in the stock’s rise could be the poison pill Jazz also implemented yesterday, which might have sent out the signal that the group had received takeover approaches against which it needs to defend itself. Still, it is not 2014 anymore, and companies need to do more than just domicile in Ireland and fit the speciality model to ensure being taken out.

Fantom haunts Europe
April 5, 2017

Better late than never. Reva Medical’s Fantom has become the fourth bioresorbable vascular scaffold to reach the market in Europe after its predecessor, called ReZolve2, was shelved. Reva will now compete with the much larger groups Abbott and Biotronik, as well as the smaller private company Elixir Medical. The device is made from a proprietary polymer, desaminotyrosine polycarbonate, which unlike polylactic acid is radiopaque, allowing cardiologists to track the implant’s placement. In studies the device had a low rate of major adverse cardiac events (MACE) – 2.1% – but this was at the six month time point, and it is MACE rates at much later time points that have caused problems for Abbott’s device, Absorb. Last month the FDA issued a warning about the 11% MACE rate with Absorb two years after implantation. But these were higher than Fantom’s at six months, too – around 5% – so perhaps Fantom can keep its reputation for safety. Boston Scientific has an exclusive option on distribution rights for Fantom both in Europe and worldwide; US approval is not expected before 2019.

No checkmate this time as Opdivo comes up short in glioblastoma
April 4, 2017

Opdivo’s failure to treat recurrent glioblastoma is not the first disappointment in this space, and is unfortunately unlikely to be the last. But it was the first time that a checkpoint inhibitor had been tried in a late-stage randomised trial in this setting, and there were hopes that a new approach would yield much-needed positive results. In the end, in the Checkmate-143 trial the Bristol-Myers Squibb drug proved less effective than Avastin. Bristol is not giving up, however, and two more first-line clinical trials, Checkmate-498 and Checkmate-548, are continuing. The studies will test a combination of Opdivo and radiotherapy with or without chemotherapy. Bristol is not alone in its pursuit of a breakthrough using checkpoint inhibitors in glioblastoma: Merck & Co and Astrazenca both have ongoing phase II trials.

Paratek delivers again
April 4, 2017

Paratek’s good run continues, with positive data with its antibiotic omadacycline in community-acquired bacterial pneumonia coming just a week after its acne project sarecycline also succeeded in phase III. The acne data sent shares up 9%, and they opened up 31% in early trading today. The phase III Optic study met all pre-specified primary and secondary endpoints, and the overall rates of treatment-emergent adverse events were lower for omadacycline than the comparator, moxifloxacin. The company plans an NDA filing in the first quarter of next year and submission to the EMA later in 2018. A study in acute bacterial skin and skin structure infections is due to readout in June. Sales are forecast to reach $331m by 2022, according to consensus from EvaluatePharma, a figure that assumes that omadacycline is partnered at some point. With Allergan already on board with sarecycline, the trial success raises hopes for a second partnering deal.

Genmab punished for Darzalex failure

April 3, 2017

It was back to the drawing board for the blood cancer treatment Darzalex, after the drug failed to pass futility tests as monotherapy in relapsed/refractory non-Hodgkin’s lymphoma, halting its phase II study. It was always going to be hard to get a result in NHL, given the difficulty in treating the disorder and Darzalex’s previous form as a solo agent. And, while few analysts had forecasts for NHL sales, shares in Genmab have fallen by 10% since the news was announced. Partner J&J is continuing to explore use of the drug in its lead indication of multiple myeloma (MM) in the hope of moving it up even further up the treatment schedule. This is no bad thing as earlier lines of treatment represent a much larger market, complete with longer treatment durations. The market leading and first-line MM drug Revlimid last year clocked up sales of $6.97bn. What could now assist Darzalex in meeting some of the lofty sales expectations attached to it is a subcutaneous version and expansion into solid tumours. The next big share inflection for Darzalex will be readout of the Alcyone study in first-line MM expected in the third quarter. Given the recent share price reaction, the drug cannot afford to disappoint again.

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