Evaluate Vantage

September 29, 2017

Snippet roundup: CDK4/6 inhibitors jostle for market share, and so do heart pumps

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

This week, September 25 to 29, 2017, we had thoughts on the following: subtleties emerge as third CDK4/6 inhibitor gets US green light; Medtronic gets closer to its heart pump destination; Shandong Weigao looks outside China with Argon buy; sirukumab won't figure in J&J growth picture as it heads back to the clinic; Elekta puts unity before Unity with IBA deal; Allergan adds FDA letter to weekend blues.

These snippets were previously published daily via twitter.

Subtleties emerge as third CDK4/6 inhibitor gets US green light

September 29, 2017

Yesterday's approval of Lilly's abemaciclib shows again what a tight contest lies in store against two already marketed CDK4/6 inhibitors, Pfizer's Ibrance and Novartis's Kisqali. However, subtle differences are starting to emerge, and Lilly has at least initially declined to undercut its rivals, pricing its drug, now trademarked Verzenio, on a par with its competitors at roughly $11,000 per patient per month. All are approved for HR-positive, Her2-negative breast cancer, but while Ibrance and Kisqali have a first-line label Verzenio's is for second-line use, based on the Monarch-2 trial. Front-line use depends on Lilly's Monarch-3 study, which at Esmo revealed similar efficacy to Ibrance and Kisqali. One key difference is safety: Lilly's drug causes more diarrhoea than its rivals, and less neutropenia – though neutropenia is a warning on its label. Verzenio's label also recommends liver function monitoring, as does Kisqali's – but not Ibrance's. Evercore ISI's Umer Raffat additionally points to Lilly's phase III Juniper trial in lung cancer, which is flying under investors' radar but could give Verzenio a unique indication with no competition from its rivals.

Selected trials of Lilly's Verzenio (abemaciclib)

Study	Indication	Trial ID	Data
Monarch-2	2nd-line HR+ve Her2-ve breast cancer (with fulvestrant)	NCT02107703	Reported at Asco 2017
Monarch-3	1st-line HR+ve Her2-ve breast cancer (with letrozole or anastrozole)	NCT02246621	Reported at Esmo 2017
Juniper	3rd-line Kras+ve stage IV NSCLC	NCT02152631	Due Nov 2017

Medtronic gets closer to its heart pump destination

September 28, 2017

With FDA approval as a destination therapy, Medtronic's HVAD heart pump should now be better able to compete with a rival product from Abbott. Previously, the latter's Heartmate II was the only left ventricular assist device (VAD) with this label while the HVAD, originally developed by Heartware, could only be used as a bridge to transplantation. Medtronic, which paid $1.1bn for Heartware last year, will hope that the latest approval, as well as the HVAD's small size, will help it grab more of the $800m global VAD market. However, Abbott has already moved on, and in August got the FDA green light for its next-generation pump, Heartmate 3. In this device the rotor is "suspended" by magnetic forces rather than bearings, which Abbott claims reduces damage to patients' blood cells. The development of Heartware's own follow-up pump, the miniature VAD or MVAD, stalled in 2015 amid reports of pump thrombus. Aside from the suspended MVAdvantage trial, there are no other studies of the project listed on Clinicaltrials.gov, and it is unclear whether Medtronic plans to push forward with the device – but surely it will need to if it wants to keep up with Abbott, and justify the price it paid for Heartware.

Shandong Weigao looks outside China with Argon buy

September 26, 2017

Chinese medtech companies have long sought growth by buying groups based outside this country, but Shandong Weigao Group Medical Polymer's $850m purchase of Texas-based Argon Medical Devices is the biggest such deal yet. Shandong Weigao said it was aiming to expand its product portfolio and diversify its revenue stream by increasing the contribution of sales from overseas markets. It also intends to grow its sales within China, by adding Argon's products, including single-use vascular access and pressure-monitoring devices to its own lines, which include orthopaedic and blood-purification products. Argon, a private company, had sales of $225m last year. Shandong Weigao made the acquisition through a joint venture with an unnamed private equity-backed firm, which will control 10% of the JV. The deal will be funded with debt to the tune of $420m. The value of the acquisition eclipses that of Singapore-based Biosensors by the Chinese private equity shop Citic in 2015, and since then, 10 more Chinese companies have bought non-Chinese medtechs, spending a total of $2.2bn.

Top 10 takovers by Chinese groups of non-Chinese medtechs, 2015-17

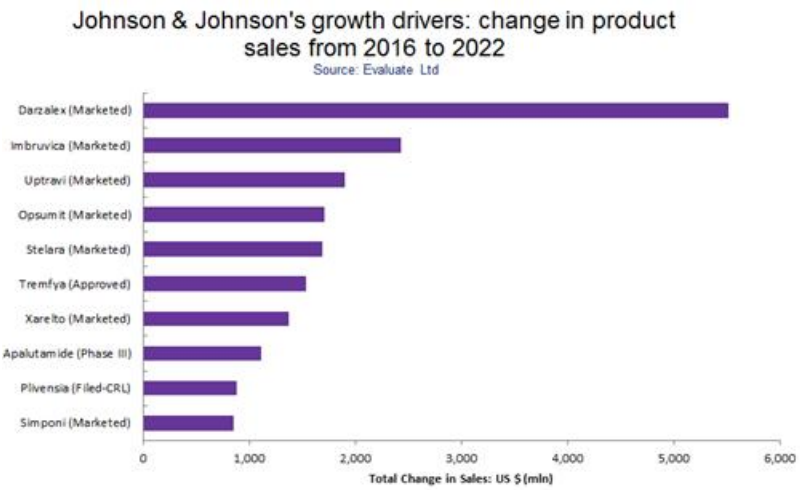
Announcement Date	Acquirer	Target	Target country	Value ($m)
September 25, 2017	Shandong Weigao Group Medical Polymer	Argon Medical Devices	USA	850
November 4, 2015	Citic (private equity)	Biosensors International	Singapore	817
May 25, 2017	Humanwell Healthcare Group	Sexual Wellness business of Ansell	Australia	600
June 18, 2015	XIO Group (investor group)	Lumenis	Israel	510
June 19, 2013	MicroPort Scientific	OrthoRecon business of Wright Medical Group	USA	290
May 2, 2016	Sinocare	PTS Diagnostics	USA	200
July 20, 2017	Ossen Innovation	San MediTech	China	181
August 31, 2016	Andon Health	eDevice	France	105
September 2, 2016	Shanghai Genext Medical Technology	Lifeline Scientific	USA	88
July 7, 2015	Mindray Medical International	Wuhan Dragonbio Surgical Implant	China	70

Sources: EvaluateMedTech, news reports

Sirukumab won't figure in J&J growth picture as it heads back to the clinic

September 25, 2017

With Plivensia's rejection by the US FDA, Johnson & Johnson looks like it will have to wait years before seeing meaningful income from a project that now has serious safety concerns to address. This will put more pressure on its already marketed products to perform, as none of the big pharma group's major growth drivers are pipeline assets. *EvaluatePharma*'s consensus of sellside analysts now forecasts Plivensia sales of $875m in 2022, a figure that has tumbled from $1.5bn in February, and will almost certainly fall further. The complete response letter probably comes as no surprise given a negative adcom vote last month over an imbalance in cardiovascular events, and now J&J faces a difficult go/no-go decision. A trial to clarify the cardiovascular risk would likely take at least a year, pushing launch out to 2019 or 2020 in a best-case scenario – and Plivensia, which contains the active ingredient sirukumab, has already been in the clinic since 2007. This is a sign of a difficult year for big pharma developers of rheumatoid arthritis drugs, after Lilly's Olumiant was knocked back in April.



Elekta puts unity before Unity with IBA deal

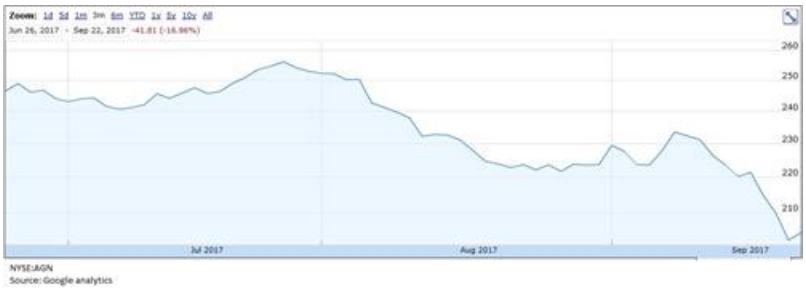
September 25, 2017

It is perhaps surprising that Elekta has signed a co-marketing agreement with the proton beam therapy developer Ion Beams Application just a couple of months before the expected European approval of its new Unity radiotherapy system. Elekta has invested heavily in Unity, and the system is expected to follow its CE marking with US approval in early 2018. But, despite the odd timing, the IBA agreement – this is a memorandum of understanding, but Jefferies expects it to morph into a full collaboration – has much to recommend it. It helps both companies compete with their rival Varian, whose bundling of radio- and proton therapy is a threat to IBA in particular. The agreement will also see the groups tweak Elekta's software to include new functionality for proton treatment, which ought to appeal to comprehensive radiotherapy departments. Lastly, each company will co-market the other's technology – quite a change for Elekta, which has in the past considered proton therapy a threat to conventional radiotherapy and has, according to Jefferies, actively discouraged adoption amongst its customer base.

Allergan adds FDA letter to weekend blues

September 25, 2017

If last Friday were not bad enough for Allergan with its underwhelming Nash data, the speciality pharma group has seen the US FDA slap it with a refusal to file letter, dashing hopes of extending the use of the antipsychotic drug Vraylar into negative symptoms of schizophrenia. While the news was not as discouraging as the seeming lack of progress in Nash, it is another disappointment for a company whose shares have slid 17% over the past three months and which today launched a $2bn share buyback to prop up the stock. Although not one of Allergan's largest products, Vraylar is forecast to become its second-biggest growth driver, according to *EvaluatePharma*, notching up sales of $807m in 2022 – and such additional sales would have been welcome. A green light from the FDA would also have provided evidence of the group being able to execute clinically, especially as there are questions about some of its other pipeline stars, including inflammation concerns with its wet AMD product abicipar.



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