Evaluate Vantage

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Snippet roundup: Fresh oncology questions for Astra and Bristol

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

This week, January 30 - February 3, 2017, we had thoughts on the following: Astrazeneca keeps mum on treme as Mystic moves closer; Sprycel patent loss another hit to Bristol oncology; Pfizer's firepower scrutinised for hints of next big deal; Gore streets ahead with Viabahn approval; Novan's spotty acne performance hurts shares.

These snippets were previously published daily via twitter.

Astrazeneca keeps mum on treme as Mystic moves closer

February 2, 2017

Don't worry – the Mystic trial isn't binary. Or so claimed Pascal Soriot today, in the run up to Astrazeneca's most crucial clinical read out for years. Technically the Astra CEO is correct, as there are more than two possible outcomes from the first-line lung cancer study, but for investors the only relevant win would be efficacy in patients who do not express high levels of PD-L1. Confidence that Astra's immuno-oncology crown jewels – durvalumab and tremelimumab – can achieve this has been rattled in the wake of Bristol-Myers Squibb's decision not to seek early approval of Opdivo plus Yervoy, its rival combination of these mechanisms. On an earnings conference call today Astra execs were keen to push their interpretation of BMS's cold feet – essentially that an open-label trial would never have been enough to convince regulators to grant approval. But doubts about the data cannot be ruled out, and Astra's refusal to reveal anything further on tremelimumab – on which very little has been published – will do nothing to calm fears while the market waits for Mystic.

Valuing the crown jewels

Product	NPV	% of Astra's market cap
Durvalumab	$12.4bn	18%
Tremelimumab	$4.9bn	7%

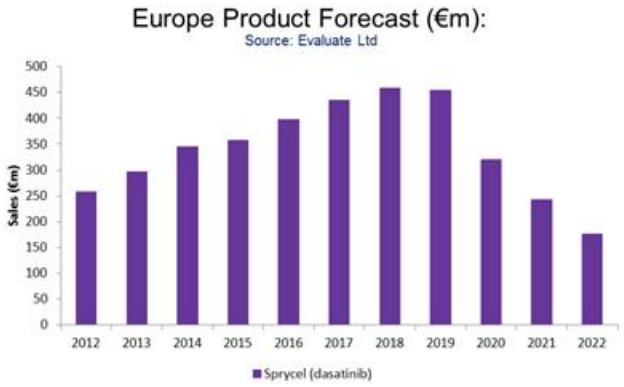
Source: EvaluatePharma

NPV based on consensus sell-side sales forecasts

Sprycel patent loss another hit to Bristol oncology

February 2, 2017

Bristol-Myers Squibb's loss of European exclusivity of Sprycel is not the oncology disaster that its failed Opdivo Checkmate-026 trial was, but it is far from good news. The European Patent Office has ruled that the leukaemia drug's composition of matter patent is invalid, clearing the way for generic competition as early as mid-year. Loss of protection puts at risk 2017 sales of €435m ($470m), which was expected to continue rising to a peak of €459m in 2018, according to *EvaluatePharma's* European drug forecast. The kinase inhibitor had been forecast to peak at $2bn in worldwide sales in 2019 before losing US patent protection in 2020, but those figures will likely need to be revised. Evercore ISI analyst Mark Schoenebaum said if the company did not change the 2017 guidance it issued in October, which assumed no European generic competition for Sprycel, it might need to impose tighter cost control to meet this guidance.



Pfizer's firepower scrutinised for hints of next big deal

January 31, 2017

Pfizer was peppered by questions on tax reform and business development on its fourth-quarter conference call, as analysts attempted to gauge the likelihood of another big deal from the serial acquirer. Executives freely admitted that access to overseas cash would be useful – Pfizer is thought to have about 60% of its cash outside the US – but stressed that tax reform alone would not shift its appetite for deal making, pointing to other considerations like creating shareholder value. Considering that the pharma giant is big enough to do pretty much any deal it wants, questions of access to capital are probably moot in most circumstances. What analysts were really interested in was gauging Pfizer’s appetite for a really big deal, namely Bristol-Myers Squibb, which is looking vulnerable in the wake of its immuno-oncology missteps. Analysts at Bernstein reckon Pfizer would be unlikely to make a move until the first late-stage trials testing various I-O combinations read out later in the year. But if Pfizer is really interested – history tells us it probably is – a strike sooner rather than later cannot be ruled out.

Pharma's offshore assets

Company	Offshore cash ($bn)	Total cash, equivalents and marketable securities ($bn)	% total assets held offshore
J&J	38.2	38.4	99%
Amgen	29.0	31.3	93%
Bristol Myers-Squibb	7.2	8.9	81%
Eli Lilly	7.1	10.6	67%
Gilead	15.7	26.2	60%
Pfizer	13.2	23.2	57%
Biogen	3.5	6.2	57%
Merck	11.4	26.5	43%
Mylan	0.4	1.5	24%

All figures as of YE15; Source: Company filings

Gore streets ahead with Viabahn approval

January 31, 2017

W.L. Gore’s balloon expandable stent graft has become the first such device approved by the FDA for use in the iliac artery. The Viabahn VBX is approved to treat *de novo* or restenotic lesions in iliac arteries, including those at the aortic bifurcation. These are tricky to reach, and until now could only be treated via off-label use of devices approved for elsewhere in the body. Naturally Gore is playing up the economic advantages of the graft, saying that as the artery does not need to be predilated, the procedure needs fewer balloons, and because the Viabahn comes in a range of lengths multiple stents need not be used for longer lesions. Though Gore has extensive operations outside healthcare, in medtech it is a specialist, making devices solely for cardiologic indications. It will be the seventh-largest cardiology company in 2022, according to *EvaluateMedTech*, with sales just shy of $10bn.

Top 10 cardiology groups in medtech

	WW sales ($bn)		
Company	2016	2022	CAGR
Medtronic	10.6	13.5	4%
Abbott Laboratories	2.7	9.9	24%
Boston Scientific	5.4	7.4	6%
Edwards Lifesciences	3.0	4.7	9%
Terumo	2.2	3.0	7%
Johnson & Johnson	1.8	2.6	3%
W. L. Gore & Associates	1.6	2.1	5%
Asahi Kasei	1.4	1.9	7%
Getinge	1.4	1.6	2%
Abiomed	0.4	1.5	23%

Source: EvaluateMedtech

Novan's spotty acne performance hurts shares

January 30, 2017

We are living in markets where no company can afford to slip up. As such, the mixed phase III data Novan Therapeutics revealed on Friday was enough to cause shares in the North Carolina-based company to plummet 78%. A fundamental mismatch between two identical phase III studies, that saw one trial of its nitric oxide-based acne treatment SB204 meet all its endpoints and the second only one, wiped more than $221m off the value of Novan. Wedbush analysts, who attributed the failure to inconsistencies in responses to nitric oxide-based therapy, lowered their rating from outperform to neutral. Novan declined to confirm whether it would press on with future studies – most acne products are approved on the basis of two successful trials. The uncertainty will come as little comfort to shareholders who have seen what initially looked like a good investment turn sour. Novan floated at the end of last year, raising $52m, but its cash runway is only expected to last until the end of this calendar year. Saving itself the expense of running more phase III trials is most probably the most pragmatic solution because the recent share price falls ensure that it will be exceptionally hard to get shareholders to dip their hands in their pockets again.

Topline Results from SB204 Phase 3 Pivotal Trials

	NI-AC301	NI-AC302
Non-Inflammatory Lesion Reduction		
SB204, 4%	39%*	42%*
Vehicle	34%	34%
Inflammatory Lesion Reduction		
SB204, 4%	46%	51%*
Vehicle	43%	41%
IGA Success		
SB204, 4%	13.4%	18.6%*
Vehicle	13.8%	14.3%

**p<0.05, Source: Novan.com*

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