Evaluate Vantage

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Priority review vouchers revisited

Jacob Plieth

Among the many uncertainties in this week's surprise approval of Sarepta's eteplirsen, the FDA granting the company a paediatric priority review voucher is at least a relatively secure source of value.

How much value is a guess, however, though this has not stopped analysts from adding into their models up to $350m of cash inflow from the voucher's sale. Based on the limited evidence of other voucher transfers, the need to assume near-term blockbuster revenue to justify a knockout price, and vouchers' declining scarcity value, a lucrative sale is no dead cert (see table below).

With Sarepta's market cap putting on $850m on Monday after the FDA verdict, the potential value of the priority review voucher (PRV) was likely lost in the surge in sentiment over potential eteplirsen sales (*Sarepta, patients win – but what of regulatory oversight?, September 19, 2016*).

However, some banks immediately assumed that Sarepta would sell the PRV for a handsome amount: Leerink added a $350m cash windfall into its model, while Baird went for $250m.

It is by no means certain whether these figures are realistic, as they simply approximate to the two most lucrative disclosed PRV transfers – Asklepion's and United Therapeutics', sold in 2015 to Sanofi for $245m and to Abbvie for $350m respectively.

Scarcity value

Several changes since then have had important effects on the scarcity value of PRVs. While back then the paediatric PRV scheme was destined to end in March 2016, it is now in the process of being extended until the end of 2018.

Four PRVs are still unsold, counting Johnson & Johnson's and the two belonging to Alexion in addition to Sarepta's. Furthermore, the removal of earlier limits on the transferability of tropical disease PRVs will impinge further on the value of the rare paediatric variety; there does not seem to be a limit on the future issuance of tropical disease PRVs.

The fate of disclosed priority review vouchers					
Date sold	**Price**	**Date issued**	**Voucher type**	**Issued company**	**Action**
–	–	Apr 2009	Tropical disease	Novartis	Redeemed by Novartis in BLA for Ilaris (gout)
Jul 2014	$67.5m	Feb 2014	Rare paediatric	Biomarin	Sold to Sanofi & Regeneron
Sep 2014	Not disclosed	Sep 2015	Rare paediatric	Wellstat	Transferred to AstraZeneca in licensing deal
Nov 2014	$125m	Mar 2014	Tropical disease	Knight	Sold to Gilead
May 2015	$245m	Mar 2015	Rare paediatric	Asklepion	3rd paediatric PRV issued; sold to Sanofi
Aug 2015	$350m	Mar 2015	Rare paediatric	United Therapeutics	Sold to Abbvie
Q2 2016*	~$200m**	Jun 2016	Tropical disease	Paxvax	Likely sold to Gilead*
–	–	Dec 2012	Tropical disease	J&J	None
–	–	Oct 2015	Rare paediatric	Alexion	None***
–	–	Dec 2015	Rare paediatric	Alexion	None***
–	–	Sep 2016	Rare paediatric	Sarepta	None
*Notes: *Gilead revealed purchase of undisclosed PRV in Q2 statement; **based on Gilead disclosure of $624m increase in R&D spend, less $400m Nimbus purchase and undisclosed clinical trial progression; ***assumed, as Alexion, a listed entity, would likely have had to disclose transfer.*					

Evidence of PRV transfers suggests a rising trend of prices paid, culminating at United's $350m windfall. However, in a second-quarter report Gilead revealed that it had bought a PRV for an undisclosed amount; back-calculating from the hints it dropped about its resulting increase in spending suggests a price of $200m – a significant drop from $350m.

And, of course, any price paid will be determined by demand as well as supply. Since filing with a PRV can reduce review time from 10 months to six, a buyer needs to reckon on the net present value of an extra four months' profits of its proposed drug exceeding the amount it pays for the PRV.

Put simply, it would likely require a drug to hit blockbuster sales almost as soon as it hits the market to justify shelling out $300m on a PRV. Beyond Roche's Ocrevus, Gilead's bictegravir and Ophthotech's Fovista there are no obvious late-stage industry candidates capable of meeting this threshold.

If Sarepta does manage to sell its PRV for $300m that would give it a strong cash balance of about $420m; nevertheless it has decided to file for a $225m secondary equity offering – a logical use of this week's share price surge.

A final consideration is whether its PRV – or indeed any cash it gets for it in a sale – might be revoked in the event of eteplirsen's accelerated approval being withdrawn on the basis of lack of efficacy.

There appears to be no provision for forfeiture of a PRV in the current legislation, and on this matter, as on Sarepta's specific plans for its PRV, the fund-raising prospectus is silent.

Evaluate HQ
44-(0)20-7377-0800

Evaluate Americas
+1-617-573-9450

Evaluate APAC
+81-(0)80-1164-4754