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Week of good Yervoy news boosts BMS fortunes

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If there has been any bad news lately for Bristol-Myers Squibb's Yervoy, you would be hard-pressed to find it. Last week it got the all-clear signal from US regulators for all late-stage melanoma patients, a wider population than the New York group tested the antibody on, and reported positive pivotal results in a first-line population.

With additional reports that the price will be greater than what analysts were expecting, more than double in some cases, forecast upgrades are likely for the product known also as ipilimumab. That helps to explain the jump in BMS shares, which rose 3% to $27.29 on Friday on word of the FDA approval.

Good signs

As the FDA had dispensed with an advisory committee for 'ipi', approval in the population BMS studied in the pivotal 020 trial – advanced patients who had failed on previous treatment - appeared to be a *fait accompli* (*Event - BMS readies for two big ipi events, March 3, 2011*). What surprised, given the regulator's increasing safety caution, was the approval in all inoperable or metastatic disease.

The company announced it will be pricing Yervoy at $30,000 a dose, increasing the likely annual cost from $45,000-$50,000 to around $100,000, based on three to four doses per year, although a cap on total patient expenditures of $120,000 will be placed on the medication.

As such, substantial forecast upgrades are likely, well in excess of what would normally be seen when a drug is approved; analysts from UBS increased their 2015 estimates from $760m to $1.45bn. They write: "At mid-day the question was is ipi a $1bn or $2bn drug. We think the discussion now shifts to if ipi is a $2bn or a $3bn drug." Likewise, analysts from Leerink Swann added $400m to their 2016 forecast, putting sales at $1.23bn.

EvaluatePharma's current forecast puts 2016 sales at $879m, giving it a non-risk-adjusted net present value of $3.43bn. Should all of the analysts in that consensus add similar figures, we can expect those numbers to increase, making BMS' $2.4bn buyout of Medarex look like one of the few great M&A bargains of recent history (*Bristol-Myers gets its antibody deal at last, July 23, 2009*).

Key product

Ipi's non-risk-adjusted NPV represents 7.5% of BMS' market capitalisation – making it as important as Abilify is to total company value – and is currently ranked as the fifth largest growth driver. As such, good news clearly has been welcomed by investors who are looking over one of the steepest patent cliffs in the industry, with $8.2bn, or 58% of its portfolio, at risk in the next three years (*Pfizer patent cliff dwarfs peers as loss of Lipitor looms, February 1, 2011*).

And if the data released earlier last week are borne out, the numbers may only continue to rise. BMS published data on the 024 trial testing ipi in combination with darcabazine in first-line treatment of metastatic melanoma. That trial found the combination extended survival in this previously untreated population when compared to dacarzabine monotherapy, although the company did not release full data as it plans to submit an abstract for ASCO in June.

Off-label first-line use is likely to make its way into the market in advance of any regulatory approvals, so it is not clear what the impact of the 024 trial will be. UBS analysts estimate a 2.5% market share penetration for ipi this year and 10% next year without a regulatory approval; the likely earliest we could expect a first-line approval would be in the first half of 2012 assuming a regulatory submission in the second half of this year.

For a drug that had been written off two years ago, ipi now seems to be key to BMS' patent cliff strategy. Thus investors last week clearly underscored the need for continued good news.