# Bristol-Myers Squibb Company

## Opdivo/ Yervoy approval an incremental positive - ALERT

**Overweight**

**BMY, BMY US**
Price: $59.20

**30 September 2015**

**Pharmaceuticals — Major & Specialty**
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This morning, the FDA announced that it has approved Bristol's Opdivo (PD-1) in combination with Yervoy (CTLA4) for previously untreated BRAF wild-type melanoma patients. This approval follows the presentation of the -067 (Phase III) study that confirmed the results from the -069 (Phase II) trial, which was the basis of this filing. Overall, Opdivo/ Yervoy is the first I/O combo to be approved and given the risk/benefit profile we see a clear role for this combo in the frontline setting. Along these lines, we see this approval stabilizing Yervoy sales, which have been declining over the past few quarters. Reiterate OW.

- **Opdivo/Yervoy approved for frontline BRAF wild-type melanoma.** The FDA approved the Opdivo/Yervoy combo for use in patients that have not been previously treated for metastatic melanoma. Although the approval is based on results from a Phase II trial, recently a Phase III (Checkmate-067) study confirmed Opdivo/Yervoy combos ~15% improvement in ORR relative to Opdivo monotherapy. While this is a small indication, it represents the approval of the first I/O combo and we see the experience with the Opdivo/Yervoy combo will be important for refining treatment with I/O combos in different tumor types.

- **We see a role for the Opdivo/ Yervoy in frontline as the additional tox appears to be manageable.** Despite higher frequency of grade 3/4 events and treatment discontinuations relative to Opdivo and Yervoy monotherapy, the toxicity generally appeared to be manageable when established safety guidelines were followed. In our view, the risk-benefit profile of Opdivo/ Yervoy combination appears to justify the combo for frontline therapy in patients able to tolerate the additional toxicity.

- **Up Next: Multiple novel IO agents/combinations expected to enter the clinic in 2016.** In addition to watching for Opdivo trends and monotherapy data in additional tumor types such as frontline NSCLC, glioblastoma and liquid tumors, BMY expects to present clinical data from the second-generation I/O agents such as CD137, KIR and LAG-3 in 2016. In addition, multiple novel agents such as IDO, OX40 and CD73 both a single agents/ in combinations are also expected to enter the clinic by 2016.

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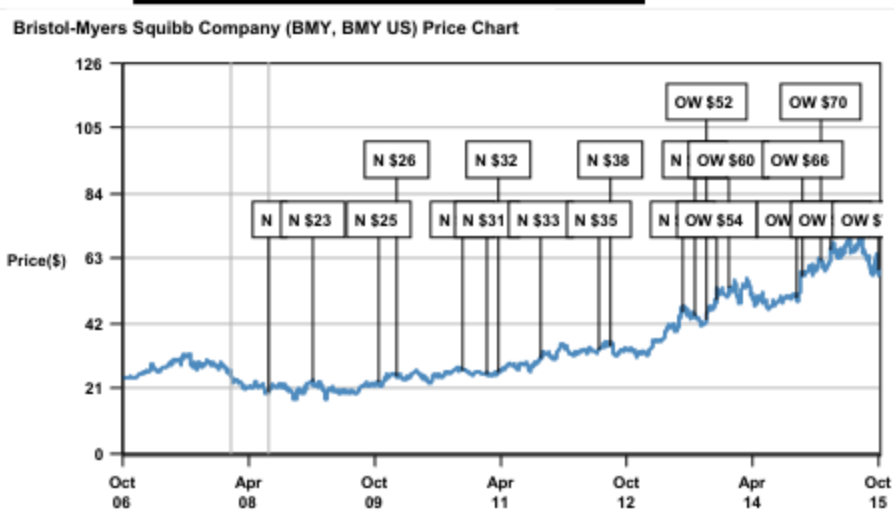


| Date | Rating | Share Price ($) | Price Target ($) |
|---|---|---|---|
| 24-Jun-08 | N | 20.23 | -- |
| 06-Jan-09 | N | 23.23 | 23.00 |
| 19-Oct-09 | N | 22.97 | 25.00 |
| 05-Jan-10 | N | 25.23 | 26.00 |
| 18-Oct-10 | N | 27.33 | 27.00 |
| 27-Jan-11 | N | 25.79 | 31.00 |
| 25-Mar-11 | N | 26.43 | 32.00 |
| 26-Sep-11 | N | 30.94 | 33.00 |
| 04-Jun-12 | N | 33.66 | 35.00 |
| 25-Jul-12 | N | 34.95 | 38.00 |
| 03-Jun-13 | N | 46.01 | 48.00 |
| 25-Jul-13 | N | 44.59 | 50.00 |
| 16-Sep-13 | OW | 43.56 | 52.00 |
| 23-Oct-13 | OW | 49.73 | 54.00 |
| 19-Dec-13 | OW | 53.84 | 60.00 |
| 10-Oct-14 | OW | 50.28 | 63.00 |
| 03-Nov-14 | OW | 57.80 | 66.00 |
| 20-Jan-15 | OW | 62.45 | 70.00 |
| 05-Mar-15 | OW | 66.05 | 75.00 |



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|---|---|---|---|---|
| 30-Sep-15 | OW | 59.20 | 78.00 | |

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