HILLIARD LYONS

American Society of Clinical Oncology Annual Meeting – ASCO 2017

A Review

We recommend this report be viewed/printed in color

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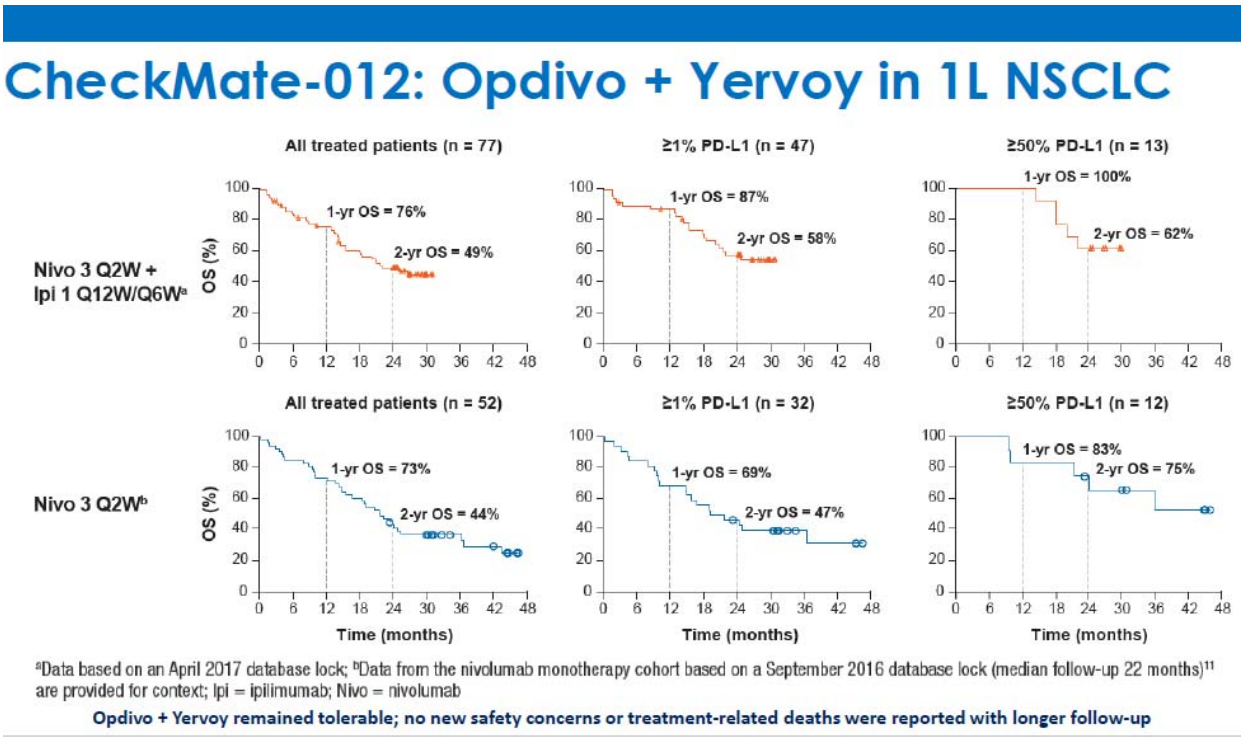
This report is not intended to be an exhaustive summary of the American Society of Clinical Oncology (ASCO) Annual Meeting. Our recap is focused on our covered names, Bristol-Myers Squibb (BMY - $54.97 – Long-term Buy, $65 PT) and Eli Lilly (LLY - $80.13 – Long-term Buy, $93 PT), as well as potential implications from competitors.

Non-Small Cell Lung Cancer (NSCLC)

First-line (1L) NSCLC continued to problematic for BMY. The company presented updated data from its Phase 1 trial, Checkmate-012, that clouds the overall survival (OS) picture. The rapid decline in survival rates and closing of the gap between the combination (Opdivo/Yervoy) and Opdivo monotherapy from year 1 to year 2 among the PD-L1 positive patients is a source of concern. While this is derived from a small data set, it definitely raises the specter of the combination not prolonging life compared to monotherapy. Even if Checkmate-227 (the Phase 3 trial testing multiple combinations) does result in a small increase in OS, some may question if it is worth the additional toxicity. Observers continue to point to response rates and progression-free survival (PFS) from Merck's (MRK - $65.07) Keynote-021 G cohort as evidence of the PD-1/ chemo combo superiority, but we caution reading too much into those imperfect surrogates for OS. Witness Roche's (RHHBY - $32.61) Tecentriq getting accelerated approval based on objective response rate (ORR) and then failing the trial for OS in 2L bladder cancer. However, defenders of the surrogates can legitimately point to therapy crossover complications for OS in Keynote-021G. We remind investors the G cohort also incorporates Lilly's Alimta.



Source: Company Presentation; nivo= Opdivo ipi= Yervoy

Regardless, the market appears to be assuming an advantage for the chemo combo. Although BMY is testing Opdivo in combination with chemo as a part of Checkmate-227, Merck will have been on the market with their combo for over a year after the accelerated approval just granted last month.

Small Cell Lung Cancer (SCLC)

BMY scored a win in 2L SCLC with strong data from the Phase 1/2 trial, Checkmate-032. Results showed over twice the response rate in the Opdivo/ Yervoy arm compared to Opdivo monotherapy. Additionally, two year OS rates were 30% and 17% for the combo and mono arms, respectively.

Renal Cell Carcinoma (RCC)

RCC is another place where we would say BMY may have experienced more harm than good. While BMY presented very little data in the space, Pfizer (PFE - $32.35) posted impressive results. Pfizer tested Bavencio (an Opdivo competitor) with its own Inlyta in 1L RCC, which resulted in an impressive ORR of 54.5%, surpassing the Opdivo/ Yervoy response rates seen in a Phase 1 trial (40.4%). We do note the Opdivo/ Yervoy trial included patients on their second line of therapy in addition to treatment-naïve patients, so comparisons aren't perfect. Additionally, both trials are early stage and tested a limited number of patients.

Colorectal Cancer

BMY presented strong results for the Opdivo/ Yervoy combo in dMMR and MSI-H (two biomarkers) positive patients in 2L. The ORR was 41% and the disease control rate (DCR, which includes responders and those with stable disease) was 78%. Merck also presented solid data, but the comparisons are difficult to make because their trial, Keynote-164, tested Keytruda in later lines of therapy.

Liver Cancer

BMY posted solid results for the Opdivo in hepatocellular carcinoma. Checkmate-040 tested the molecule in both 1L and 2L, and Opdivo generated positive data in both. The ORR in 1L was 20% and 15% in 2L, with the one-year OS of 73% and 60%, respectively. Lilly also presented data on their pipeline asset, galunisertib, combined with sorafenib in 1L. The median OS, based on immature data, was 17.9 months.

Gastric, Gastroesophageal, or Esophageal

Merck presented highly impressive data in a small arm of a Phase 2 trial, Keynote-059. Keytruda, in addition to two chemotherapy agents, resulted in an ORR of 60% and a DCR of 92%. However, we note SAEs occurred in an alarming 76% of patients. On the other hand, only 12% of patients discontinued treatment due to drug-related AEs.

Urothelial (Bladder) Cancer

Merck presented solid data from Keynote-045 in 2L urothelial cancer, with an ORR of 21.1% and median OS of 10.3 months compared to the chemo arm ORR of 11.4% and median OS of 7.4 months. Interestingly, the presentation pointed out PFS were not statistically different between the arms despite the OS improvement.

Melanoma

A substantial amount of data was presented in melanoma, so we will attempt to stick to the most interesting data points. A combination of Keytruda and Yervoy in 1L melanoma generated a one-year OS rate of 89%, with 15% of patients obtaining a complete response. BMY presented data that suggests they may have yet another immunotherapy agent to help combat cancer. In patients whose tumors expressed any level of LAG-3, BMS-986016 (an anti-LAG-3 molecule) combined with Opdivo generated an ORR of 20% with a nice safety profile. The trial focused on patients who failed to respond and/or progressed on immunotherapy, so success with this drug could reopen 2L to BMY in many different cancer types. The 2L opportunity is narrowing in many cases because most 2L Opdivo approvals are for treatment after chemo, and immunotherapies are rapidly displacing chemotherapy in 1L. However, we urge caution in optimistic assumptions, as this data was based on a very small patient set, and it is unclear it will progress to approval.

Breast Cancer

Eli Lilly presented compelling data from the MONARCH-2 trial, testing its abemaciclib in combination with fulvestrant in second-line (2L) HR+/HER2- patients. Patients on the abemaciclib regimen had a median PFS of 16.4 months compared to 9.5 months for the fulvestrant+placebo arm. The ORR was 48.1% for the abemaciclib arm versus 21.3% for the placebo arm. Further, safety events were very reasonable, in our view. For example, diarrhea, which had been a source of concern among investors, only registered an SAE in 13.4% of patients, and Lilly's investor presentation showed how quickly that could be resolved for most patients with simple over-the-counter medications. Only 1.6% of patients (after they lowered the tested dose) discontinued treatment as a result of severe diarrhea. Neutropenia was an SAE in 26.5% of patients. For comparison, 65% of patients in the PALOMA-3 trial experienced an SAE of neutropenia. PALOMA-3 is the clinical trial testing Pfizer's (PFE - $32.51) Ibrance in combination with fulvestrant in 2L HR+/HER2- patients. Cross trial comparisons are difficult and sometimes inappropriate to make, but that spread in safety is worth mentioning in our opinion. This is particularly true considering Ibrance patients must take a week off in treatment, a dosing schedule designed to help with neutropenia. Patients on abemaciclib are able to continuously dose, a factor Lilly believes will be a differentiator. We do note Lilly was more selective (no prior chemotherapy patients permitted, for example) than Pfizer in their patient selection for these 2L trials. The most recent efficacy data for PALOMA-3 was far less mature than the MONARCH-2 ASCO presentation, so efficacy comparisons are inappropriate in our view. However, abemaciclib's strong showing in MONARCH-2 gives reason to think the molecule could be best-in-class; Lilly stated they believe this is the longest ever reported PFS in the patient group that progressed on prior endocrine therapy.

Concluding Thoughts

We view this ASCO as a solid positive for Lilly. Due to the trial having to continue after the interim look, we were initially concerned about efficacy and hesitant to be bullish on the drug. However, after seeing the MONARCH-2 data, our opinion on abemaciclib has undoubtedly improved. MONARCH-2 isn't likely to enable abemaciclib to have a substantial commercial impact, as Ibrance is shrinking that market by getting the FDA approval for 1L over two years ago. Thus, we await more detailed data from MONARCH-3 (the 1L trial) before significantly altering estimates or opinion. As a reminder, Lilly recently announced the success of this trial, but data will be revealed in the second half of the year. We are more bullish on abemaciclib now but note that without superior data, Lilly still faces an uphill commercial battle taking share from the much more established Ibrance.

With concerning data in the large addressable NSCLC market and new competitive threats, particularly in RCC, we would chalk this ASCO up as a net "loss" for BMY. The rapid decline in OS for the Opdivo/ Yervoy combo in NSCLC was worrisome and, although this was expected, the conference served as a stark reminder of the fierce competition forming. Nevertheless, we believe the market has overreacted to developments in NSCLC and tends to forget how segmented the market will be. Due to this segmentation, we believe the Opdivo/ Yervoy combo will still play a prevalent role in the intermediate term, although we believe Yervoy will ultimately be displaced by other Opdivo combinations longer term.

From a macro perspective, it is difficult not to be enthralled with the progress in oncology, and ASCO 2017 may be remembered as the coming out party for the second wave of immunotherapies. Although excitement was already there, mechanisms such as IDO from Incyte (INCY - $124.03) and CAR-T seemed to gain steam. Fascinating early research into the role of the gut microbiome was on display as well. We do not expect the wave of new cancer drugs to come to a stop in the near future.

Analyst Certification

I, Kurt A. Kemper, CFA, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject company(ies) and its (their) securities. I also certify that I have not been, am not, and will not be receiving direct or indirect compensation in exchange for expressing the specific recommendation(s) in this report.

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Buy - We believe the stock has significant total return potential in the coming 12 months.
Long-term Buy - We believe the stock is an above average holding in its sector, and expect solid returns to be realized over a longer time frame than our Buy rated issues, typically 2-3 years.
Neutral - We believe the stock is an average holding in its sector, is currently fully valued, and may be used as a source of funds if better opportunities arise.
Underperform - We believe the stock is vulnerable to a price set back in the next 12 months.

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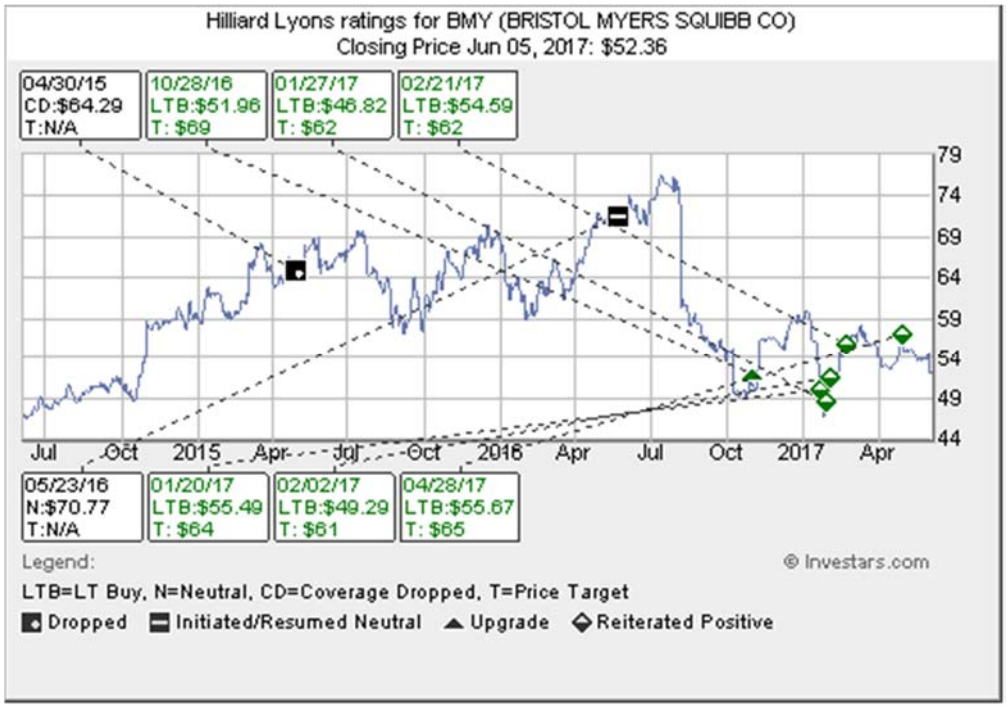
1. A large cap, core holding with a solid history.
2. A historically secure company which could be cyclical, has a shorter history than a "1" or is subject to event driven setbacks.
3. An above average risk/reward ratio could be due to small size, lack of product diversity, sporadic earnings or high leverage.
4. Speculative, due to small size, inconsistent profitability, erratic revenue, volatility, low trading volume or a narrow customer or product base.



	Hilliard Lyons Recommended Issues		Investment Banking Provided in Past 12 Mo.	
Rating	# of Stocks Covered	% of Stocks Covered	Banking	No Banking
Buy	32	26%	13%	88%
Hold/Neutral	79	64%	8%	92%
Sell	12	10%	0%	100%

As of 8 May 2017

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