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EUROPEAN PHARMACEUTICALS
I/O headache for fast-followers

Opdivo's dominance in lung cancer raises key commercial questions: The continued strength of immuno-oncology revenues moving into the Q4 2015 results reflects the ongoing rapid uptake of the class in lung cancer. BMY's Opdivo has a dominant market share of 70% in refractory squamous NSCLC and 47% in refractory non-squamous NSCLC, outselling MRK's Keytruda 20:1. The uptake of Opdivo in refractory metastatic renal cancer appears to progressing equally rapidly. In this report we provide an updated perspective of dynamics for the immuno-oncology class using proprietary data from AlphaImpactRx, discuss the challenges fast-followers such as AZN face when standard of care changes so quickly and again highlight the role of PD-L1 testing so far. For specific commentary on BMY/MRK, please refer to Geoff Meacham's Q4 previews: **BMY:** ***4Q15 Earnings Preview*** **and MRK:** ***4Q15 Earnings Preview***.

Opdivo dominant in lung cancer: Total penetration for the anti-PD-L1 class has stabilized in the mid-70%s in refractory squamous NSCLC patients, with Opdivo holding a dominant 70% market share. Opdivo penetration in refractory non-squamous NSCLC patients has risen to 47%, with Keytruda holding a modest 3% share. Just 22% of NSCLC patients were tested for PD-L1 expression over the 6 month period to Oct'15, which implies to us that Opdivo's all comers approach in refractory NSCLC is likely to support a dominant position and make it tough for fast-followers to make inroads.

Keytruda maintains melanoma leadership despite increasing pressure: Keytruda has surpassed Yervoy as the leading agent with a 31% market share across metastatic melanoma overall, but is facing competition from Mekinist/Tafinlar, Zelboraf and the Opdivo/Yervoy combination. Mekinist/Tafinlar (Novartis) and Zelboraf/Cotellic (Roche) look well placed to hold onto a majority share in first-line BRAF-mutant patients (currently circa 70%) and we do not expect the current trends to materially change ahead of emerging combo data.

Rapid change in standard of care is a headache for fast-followers: Investors have attributed a high probability of commercial success to cancer drugs particularly in the US given a positive regulatory environment with fast routes to market, strong innovation relative to existing medicines, NCCN guidelines supporting off-label usage and a positive payor environment. However we believe that the rapid shifts currently seen in the standard of care are likely to impact the market opportunity for fast-followers, forcing the adoption of higher clinical risk "make-or-break" trial designs, and could create patient cross-over issues in first-line trials with, for example, first-line NSCLC patients in the control arm who progress crossing over to Opdivo second-line.

Key questions: The roll-out of Opdivo in renal cancer and the success (or otherwise) of immuno-oncology combination approaches remains a key focus in 2016. Another key consideration is whether Keytruda will be the first anti-PD1 approved for first-line NSCLC with Keynote-024 expected to complete June 2016 (versus the Opdivo Checkmate-026 trial Nov 2016) and whether this will afford a first-move advantage.

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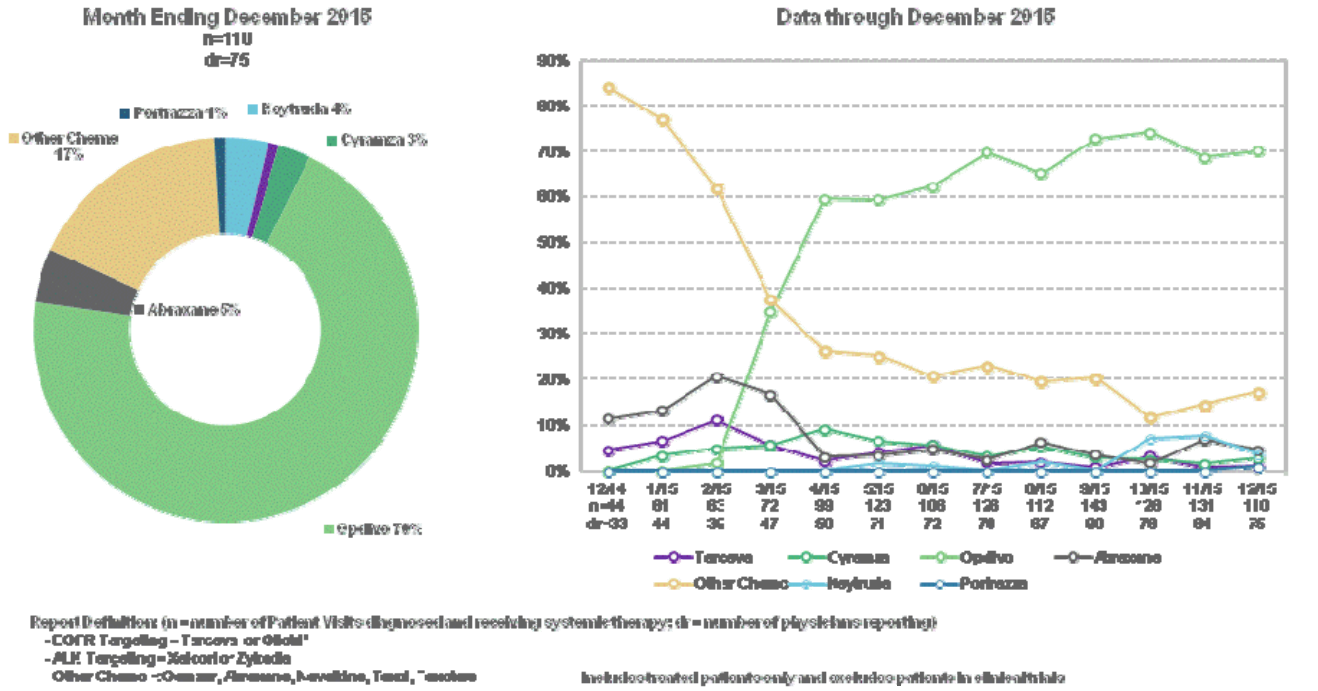
Rapid uptake in refractory NSCLC continues with Opdivo dominant

BMY reported above consensus US Opdivo forecasts of $268m for Q3 2015 and IMS data project US Opdivo revenues of >$350m for Q4 2015, driven by the continued strong uptake in lung cancer. Opdivo penetration in refractory squamous NSCLC has stabilized at 70% after appearing to plateau in the mid-60%s initially, with adoption increasing in the community hospital setting. Total penetration for the anti-PD-L1 class has stabilised in the mid-70%s in this setting following the launch of Keytruda 2 October and implies that the proportion of refractory squamous NSCLC patients with autimmune conditions who are contraindicated against anti-PD-L1 treatment could be in our projected 10% range.

FIGURE 1
Refractory squamous NSCLC market shares

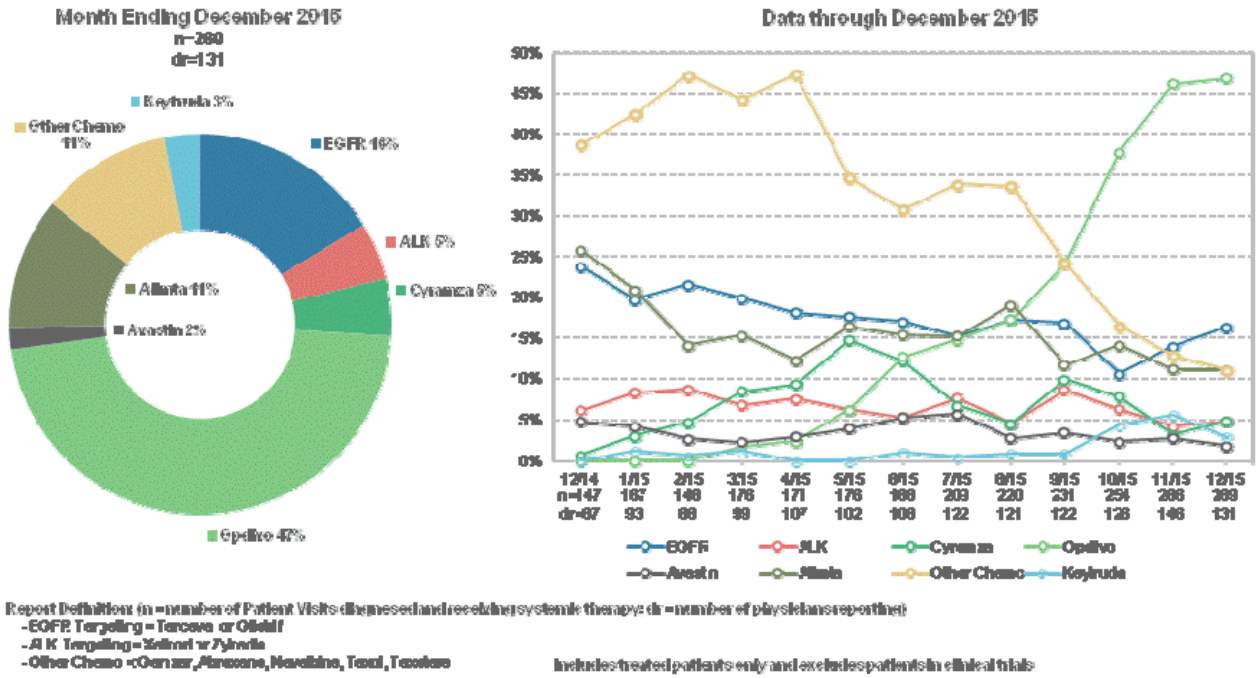


Source: Barclays Research, AlphaImpactRx

Opdivo penetration in refractory non-squamous NSCLC patients had risen to 24% in September following the presentation of the CHECKMATE-057 at ASCO in June and an NCCN guideline Category 1 recommendation. Following FDA approval in this setting 9 October, Opdivo penetration has catapulted to 47% largely at the expense of cytotoxic agents and to a lesser extent EGFR inhibitors. Keytruda has gained a modest 3% share in this setting following FDA approval 2 October and we expect the anti-PD-1 class penetration to continue to rise towards 60%.

The next key development will be the label expansion for Keytruda in PD-L1 positive refractory NSCLC based on the results of Keynote-010 which were submitted to regulators in Q4 2015. Roche still expects to be able to file atezolizumab for PD-L1-positive refractory NSCLC patients based on the BIRCH and FIR trials, although there is a risk that if Keytruda gains full approval first, Roche would have to wait for survival data from the OAK trial mid-2016. From a commercial perspective, the relative survival benefits demonstrated by Keytruda and atezolizumab in the Keynote-010 trial and OAK trials, respectively, compared to the Opdivo benchmarks will in-part determine whether Opdivo can retain its dominant market share. Off-label penetration rates for Opdivo in first-line NSCLC patients remains modest – 2% in the non-squamous setting and 12% in the squamous setting

FIGURE 2
Refractory non-squamous NSCLC market shares



Source: Barclays Research, AlphaImpactRx

Keytruda maintains leadership in malignant melanoma despite increased pressure

Immuno-oncology agents continue to hold just over 50% of the metastatic melanoma opportunity. Keytruda has surpassed Yervoy as the leading agent with a 31% market share across metastatic melanoma overall, but is facing increasing competition from Mekinist/Tafinlar as well as the Opdivo/Yervoy combination.

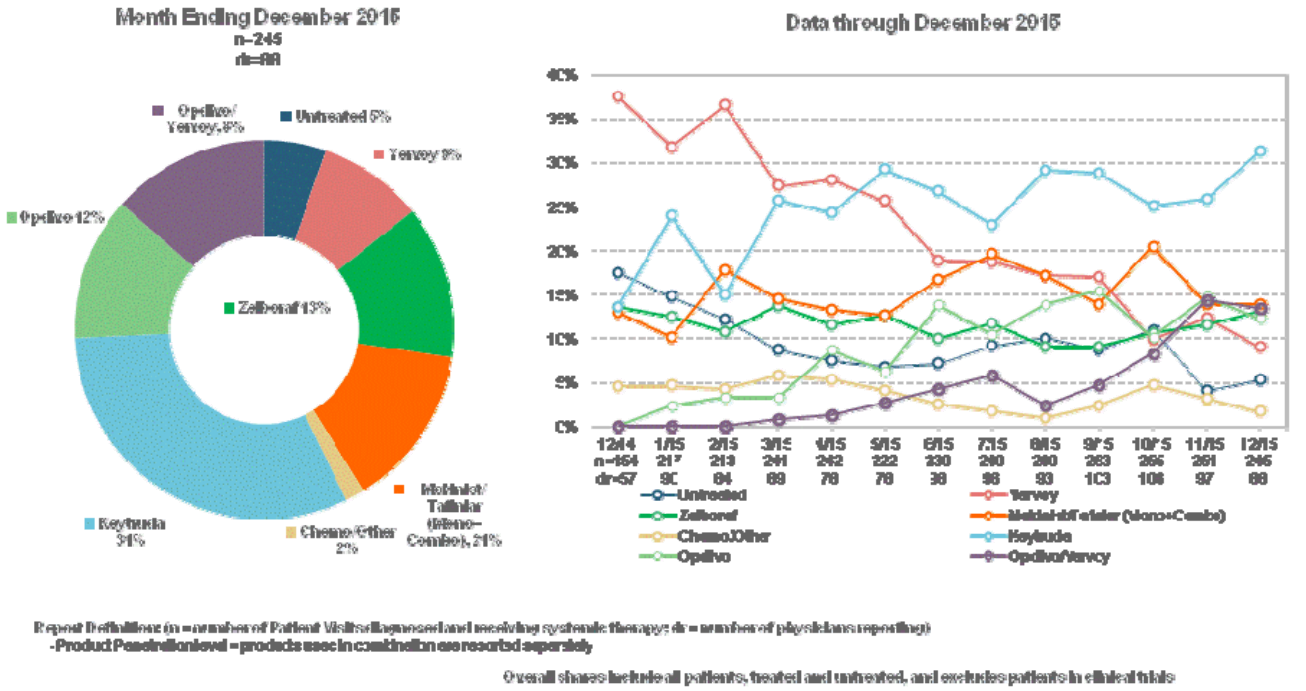
The BRAF-mutation targeted combinations Mekinist/Tafinlar (Novartis) and Zelboraf/Cotellic (Roche) look well placed to hold onto a majority share in first-line BRAF-mutant patients, with median overall survival rates of 25.1 months and 22.3 months, respectively. Combined market share in this setting has remained around 70%.

Across all first-line metastatic melanoma patients, Mekinist/Tafinlar and Zelboraf combined hold a 31% share, Keytruda a 31% share, Opdivo (including combination with Yervoy) a 25% share and Yervoy monotherapy an 11% market share. In the refractory setting, Keytruda supported by a more convenient dose regimen and earlier launch holds a reduced 39% market share compared to a 31% share for Opdivo (including combination with Yervoy).

We do not expect the current trends to materially change in the near-term. Opdivo received a complete response letter 27 November for monotherapy use in BRAF-mutant patients and received a conditional approval in combination with Yervoy in the same setting 24 January 2016. Keytruda received FDA approval in the first-line setting 18 December 2015. Merck has moved into phase 3 with Keytruda plus Incyte's IDO inhibitor epacadostat based on a 53% ORR in 19 patients (c.79% PD-L1+ve). Roche has demonstrated a 76% ORR with atezolizumab in combination with Zelboraf in first-line BRAF-mutant patients (with an impressive 20.9m duration of response), but will await phase 1b data from a trial combining atezolizumab plus Zelbora plus Cotellic before assessing next steps.

FIGURE 3

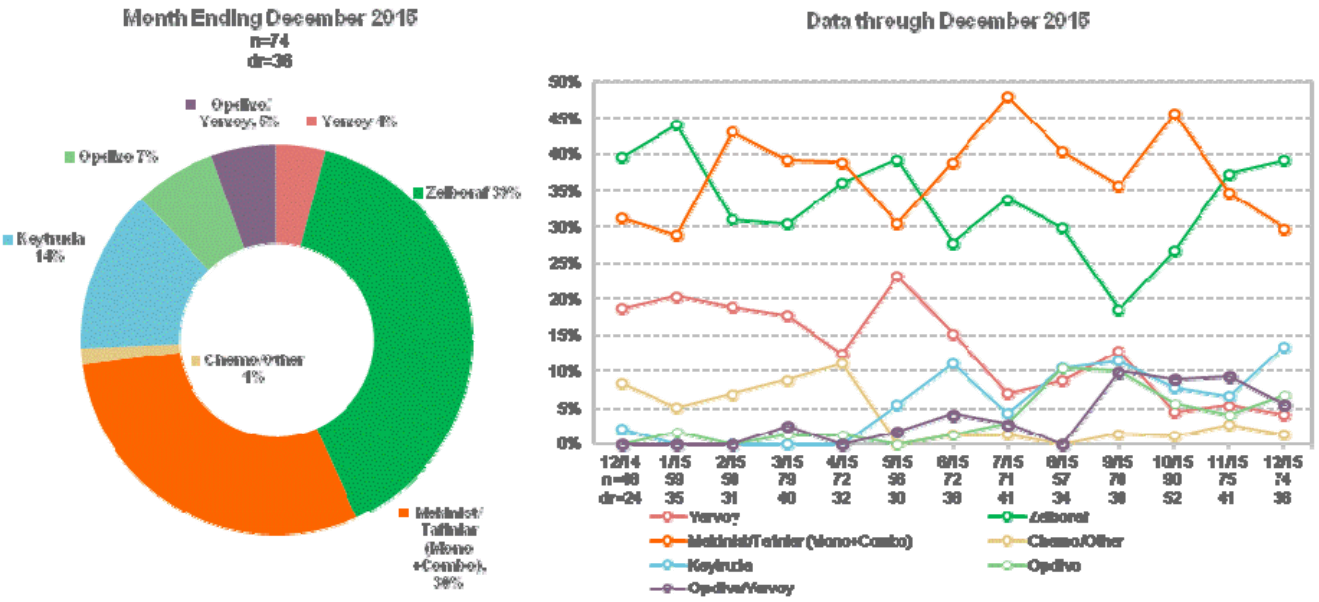
Overall metastatic melanoma shares



Source: Barclays Research, AlphaImpactRx

FIGURE 4

Metastatic melanoma shares in first-line BRAF-mutant patients



Source: Barclays Research, AlphaImpactRx

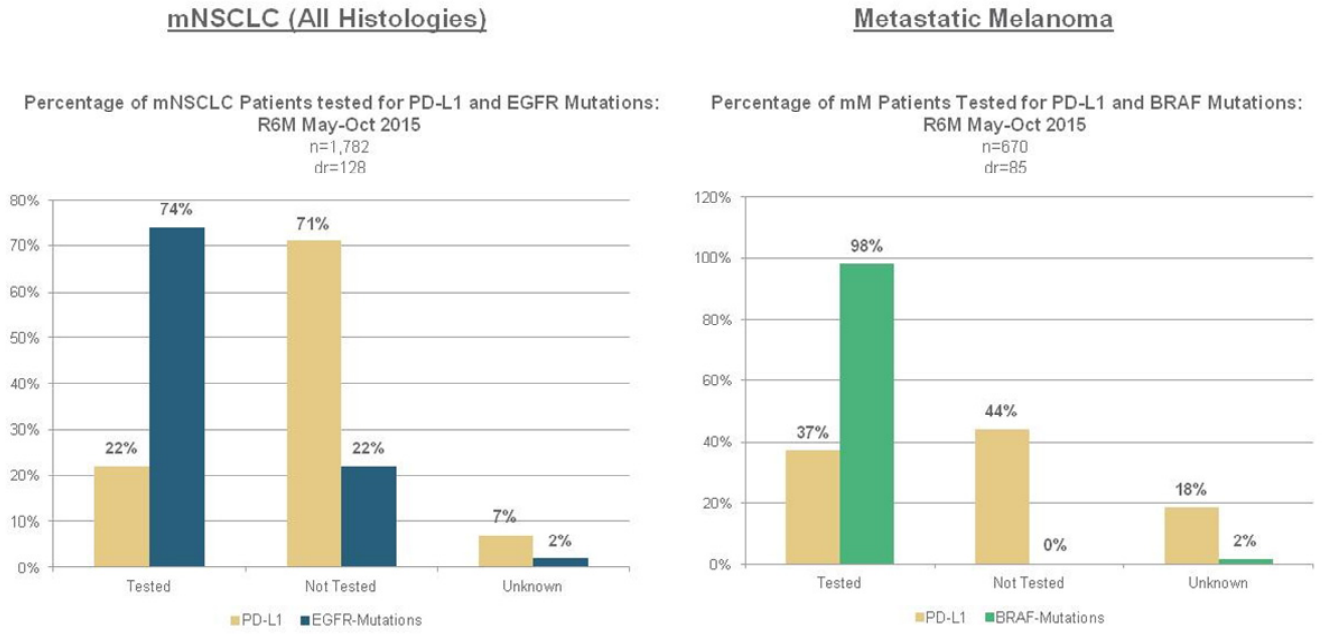
PD-L1 testing perspectives

The debate rumbles on as to whether effort should be spent on diagnostically triaging treatment of lung cancer patients who have failed on prior therapy based on PD-L1 expression. PDL-1 expression is a continuous and inducible variable, impacting its value as predictable and prognostic biomarker. However imperfect enrichment for treatment benefit can still move the field forward, altering the health economics and informing treatment prioritisation for patient subgroups compared to established standard of care.

Just 22% of NSCLC patients were tested for PD-L1 expression May through October compared to 74% of patients tested for EGFR-mutations. 37% of metastatic melanoma patients were tested for PD-L1 expression compared to 98% of patients for BRAF-mutations. Broadly half of patients treated with Opdivo and Keytruda are tested for PD-L1 expression, with around 45% testing positive. Importantly just 20% of PD-L1 testing occurs in patients who have progressed into a refractory setting. With anti-PD-1 penetration rates of 81% in refractory squamous NSCLC, 42% (and rising rapidly) in refractory non-squamous NSCLC and 43% across all malignant melanoma, PD-L1 testing does not appear to be a treatment-gating factor for the current on-label indications in the US.

FIGURE 5

Comparative testing rates for PD-L1 and established biomarkers in NSCLC and melanoma



Source: Barclays Research, BrandImpact / BrandImpactDx

PDL-1 negative patients do not seem to suffer lower efficacy compared to chemotherapy and possibly benefit from better tolerability. NCCN guidelines support the use of Opdivo refractory NSCLC and melanoma regardless of PD-L1 status, taking the debate out of the hands of payors in the US and providing patients and physicians with confidence when it comes to reimbursement.

Opdivo is expected to dominant the refractory NSCLC segment based on its all comers approach, with overall survival benchmarks of 38% in squamous and 27% in non-squamous patients. Key details of the Keytruda Keynote-010 trial by histology are not yet available, but data released so far have set overall survival benchmarks of 26% in squamous and 37% in non-squamous patients. Roche's atezolizumb has followed an all-comer approach in the OAK trial which reports mid-2016 and would have to beat the Opdivo benchmarks to gain meaningful traction in refractory NSCLC from a third entrant position.

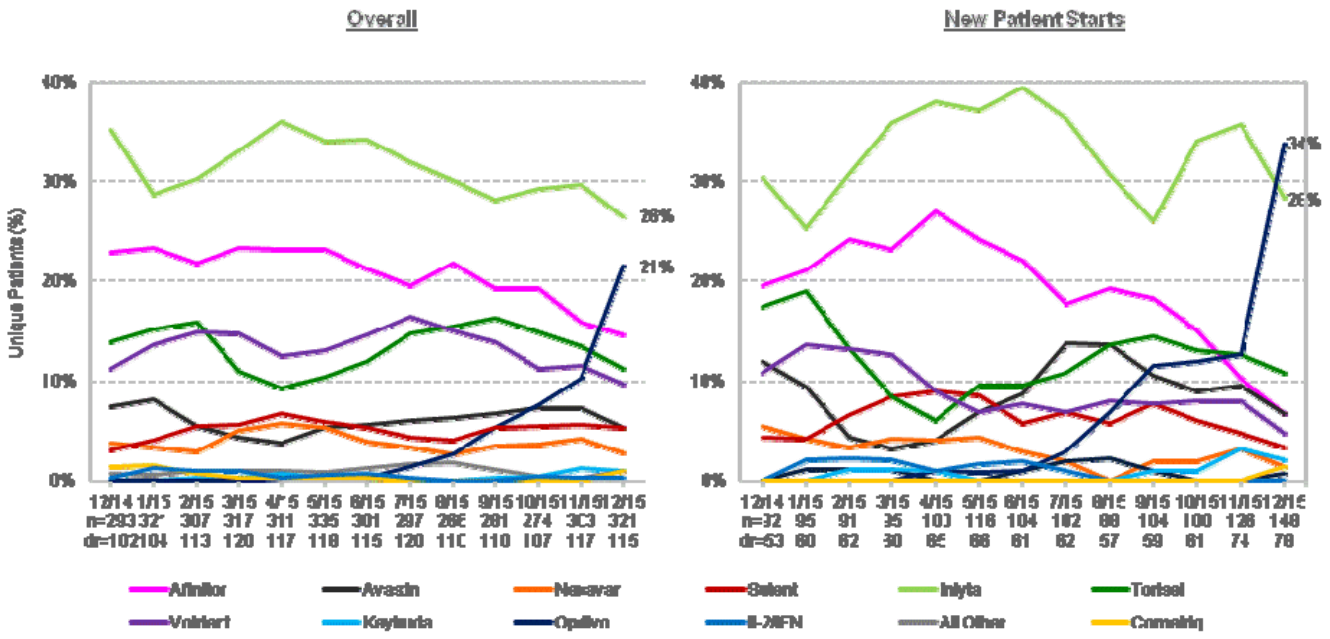
Rapid changes in standard of care raises commercial risk in oncology

Investors have attributed a high probability of commercial success to cancer drugs particularly in the US given a positive regulatory environment with fast routes to market, strong innovation relative to existing medicines, NCCN guidelines supporting off-label usage and a positive payor environment. However we believe that the rapid shifts currently seen in the standard of care are likely to limit the market opportunity for fast-followers such as AZN's durvalumab and force these players to design clinically higher risk head-to-head trials to achieve commercial success.

As detailed above, Opdivo plus Keytruda have captured a combined mid-70% patient share in refractory squamous NSCLC just 10 months after the approval of Opdivo in this setting. Within 3 months of FDA approval in refractory non-squamous NSCLC, Opdivo plus Keytruda had captured circa 50% patient share. Whilst patient share in melanoma is shared equally between BMY (Yervoy, Opdivo) and MRK (Keytruda), BMY has a dominant position in refractory NSCLC where Opdivo retains a mid-90% share of the anti-PD-1 class. Rolling three month data from AlphaImpactRx in refractory metastatic renal cancer show that Opdivo has already catapulted to a leading position following FDA approval 23 November at the expense of Pfizer's Inlyta and Novartis' Affinitor.

FIGURE 6

Refractory metastatic renal cancer market shares (3 months rolling period ending December 2015)



Report Definition: (n = number of Unique Patients diagnosed and receiving some type of drug therapy; dr = number of unique physicians reporting)

Source: Barclays Research, AlphaImpactRx

Such a rapid shift in standard of care presents a number of challenges especially for fast-follower companies such as AZN and PFE/Merck kGaA.

- Firstly, it can potentially remove fast to market strategies, eg AZN's 3L NSCLC trial ATLANTIC.
- Second, it could create patient cross-over issues, with patients progressing in first-line NSCLC crossing over to Opdivo and blunting the overall survival benefit. (Psuedo)-progression occurs relatively early with anti-PD(L)-1 agents relative to the overall survival benefit demonstrated, compounding the cross-over issue.

- Third, it puts pressure on having to show a clinically meaningful step-up in efficacy against a rapidly evolving standard of care.
- It means that fast-followers have to design higher clinical risk, potentially higher-commercial reward "make-or-break" trials.
- Product life-cycles could potentially be shortened, eg Rova-T from StemCentRx could replace I/O approaches as the standard of care in SCLC.

Where does this leave AstraZeneca in I/O?

AZN projects anti-PD-L1 durvalumab to capture peak sales of $6.5bn, with $3.5bn alone driven by NSCLC. The key focuses on the AZN side have been: (1) the potential for durvalumab plus tremelimumab to be a better tolerated combination treatment than BMY's Opdivo plus Yervoy (are anti-PD-L1's better tolerated than PD-1s in combination?); (2) the potential for the durvalumab plus tremelimumab combination to have differentiated efficacy in PD-L1 negative patients; (3) a fast-follower on areas of promise, eg the Roche PD-L1 chemotherapy combination approach in first-line NSCLC.

Will a significant number of PD(L)-1 combination approaches move into pivotal trials during 2016, putting pressure on AZN's durvalumab plus tremelimumab strategy, or will toxicity limit the number of combination approaches and conversely strengthen AZN's competitive position?

There are currently over 30 targets, including both immune-oncology and non-I/O targets, being investigated in combination with the various anti-PD(L)-1 agents. Despite some phase 1/2 combination trial programs having run for approaching two years now, only BMY's Yervoy, AZN's tremelimumab. Incyte's IDO1 inhibitor epacadostat (in melanoma) and marketed agents such as Avastin and chemotherapy have moved into pivotal combination trials. We believe (unexpected) toxicity remains a key challenge, alongside trying to identify which subgroups of patients benefit from a combination approach. It remains to be seen whether targets such as OX40, LAG3, anti-GITR, anti-CD137, CSF1 and IDO (beyond melanoma) will move forward into pivotal combination trials over the next 12 months or whether AZN's tremelimumab is more likely to face competition from traditional chemotherapy and its emerging immune-modulatory role.

Will AZN's durvalumab opportunity in lung cancer, head & neck cancer and gastric cancer move increasingly out of reach over the next 24 months?

Durvalumab will generate phase 2 single-arm data in second-line head and neck cancer in 2016, whereas Opdivo will generate phase 3 overall survival data in the same indication. In gastric cancer, there is pressure on the durvalumab plus tremelimumab arm of the phase 2 second-line trial reporting end 2017 to demonstrate a clinically differentiated signal compared Keytruda which will generate over survival data versus standard of care (SoC) chemotherapy shortly afterwards.

Front-line NSCLC data are expected as early as June 2016 (Keytruda KN-024) and November 2016 (Opdivo CM-026), with Roche's extensive chemotherapy combination dataset and BMY's large CM227 trial exploring the combination of Opdivo with both Yervoy and chemotherapy reporting 2017. This makes the MYSTIC trial a "make-or-break" opportunity for durvalumab, putting pressure on the durvalumab plus tremelimumab arm to demonstrate a clinically differentiated safety/efficacy signal compared to Opdivo plus Yervoy and atezolizumab plus chemotherapy.

FIGURE 7

Competitor data puts pressure on the durvalumab plus tremelimumab combination in lung, head & neck and gastric cancer

	Opdivo	Keytruda	atezolizumab	durvalumab
2016				
Lung cancer	CM026 1L PDL-1+ 535pts PFS (Nov)	KN024 1L PDL-1+ 300pts PFS (June)	OAK 2L all-comers 1225pts OS	na
Head & neck	CM141 2L 360 patients vs SoC OS (Oct)	KN055 3L 150pts ORR (May)	na	HAWK phase 2 single arm 2L PD-L1+ 112pts ORR (H2)
Gastric	na	KN059 1/2L 223pts ORR (Sep)	na	na
2017				
Lung cancer	CM227 1L PDL-1+ &-ve 1980pts PFS/OS Yervoy & chemo combos (Jan'18)	KN042 1L PDL-1+ 1240pts OS (June'18)	Impower 110, 111, 130, 131; 1L trials mono and chemo combo; 3,750 patients PFS	MYSTIC 1L 675pts mono vs treme combo vs chemo PFS
		na		PACIFIC Stage III unresectable 702pts mono OS (Q2'17)
		na		ARCTIC 3L 702pts mono vs treme vs combo vs SoC; PFS/OS (Q1'17)
Head & neck		KN048 1L 750pts mono vs chemo combo vs SoC; PFS (Nov)		CONDOR phase 2/3 2L PD-L1-ve 240pts mono vs treme vs combo ORR (Dec)
		KN040 2L 600pts mono vs SOC; PFS/OS (Apr)		
Gastric	3L 480pts mono OS (Aug)	KN061 2L 720pts vs chemo PFS/OS (May'18)		Phase 2 trial 2L+ 174pts mono vs treme vs combo ORR (Nov)

Source: Barclays Research, company data, clinicaltrials.gov

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We, Mark Purcell, Michael Leuchten and Olivia Capra, hereby certify (1) that the views expressed in this research report accurately reflect our personal views about any or all of the subject securities or issuers referred to in this research report and (2) no part of our compensation was, is or will be directly or indirectly related to the specific recommendations or views expressed in this research report.

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AstraZeneca (AZN.L, 26-Jan-2016, GBP 44.16), Equal Weight/Neutral, A/C/D/J/K/L/M/N

Roche (ROG.VX, 26-Jan-2016, CHF 265.70), Overweight/Neutral, A/D/E/J/K/L/M/N

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Bristol-Myers Squibb (BMY, 26-Jan-2016, USD 62.69), Equal Weight/Positive, A/C/D/J/K/L/M/N

Merck & Co. (MRK, 26-Jan-2016, USD 51.45), Overweight/Positive, C/D/J/K/L/M/N/O

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IMPORTANT DISCLOSURES CONTINUED

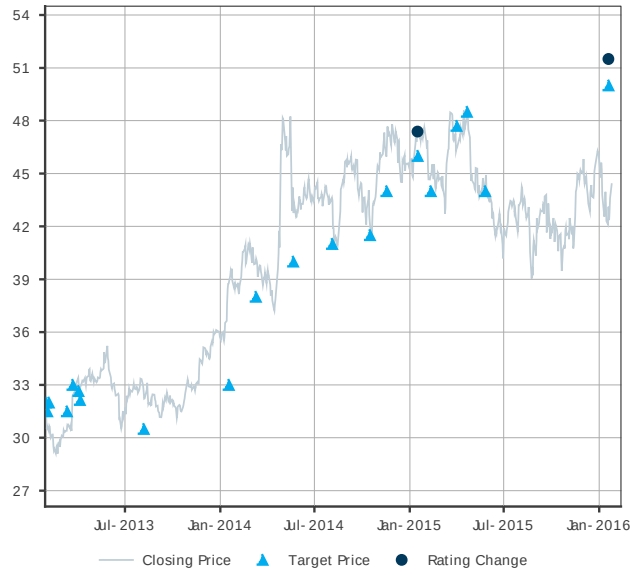
AstraZeneca (AZN LN / AZN.L)

GBP 44.16 (26-Jan-2016)

Stock Rating: **EQUAL WEIGHT**

Industry View: **NEUTRAL**

Rating and Price Target Chart - GBP (as of 26-Jan-2016)



Currency=GBP

Date	Closing Price	Rating	Adjusted Price Target
19-Jan-2016	43.13	Equal Weight	50.00
26-May-2015	43.74		44.00
21-Apr-2015	48.55		48.50
01-Apr-2015	46.41		47.70
10-Feb-2015	44.88		44.00
16-Jan-2015	47.15	Underweight	46.00
17-Nov-2014	45.97		44.00
16-Oct-2014	42.25		41.50
04-Aug-2014	43.63		41.00
21-May-2014	44.20		40.00
10-Mar-2014	39.90		38.00
17-Jan-2014	38.75		33.00
06-Aug-2013	32.72		30.50
05-Apr-2013	32.83		32.15
02-Apr-2013	33.40		32.65
22-Mar-2013	32.36		33.00
11-Mar-2013	30.39		31.50
04-Feb-2013	30.41		32.00
01-Feb-2013	30.69		31.50
29-Jan-2013	31.68		32.00

Source: Thomson Reuters, Barclays Research

Historical stock prices and price targets may have been adjusted for stock splits and dividends.

Source: IDC, Barclays Research

Link to Barclays Live for interactive charting

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Valuation Methodology: We value AstraZeneca through a DCF valuation assuming a risk-free rate derived from the yield curve, an equity risk premium of 5%, an asset beta of 0.9, pre-tax cost of debt based on CDS spreads and a target debt ratio of 25%. Beyond our explicit forecast period we assume returns fade to cost of capital in the long term and we adjust AZ's reported capital base by capitalising and expensing R&D over an assumed 12-year asset life. These assumptions result in our price target of GBP50.00.

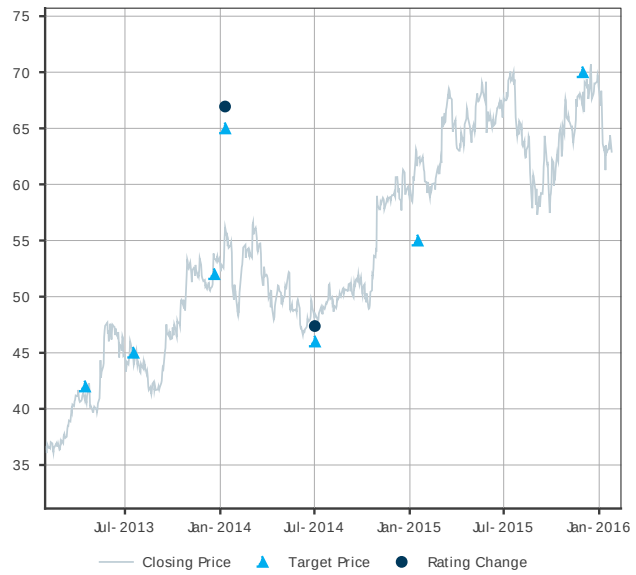
Risks which May Impede the Achievement of the Barclays Research Valuation and Price Target: Risks and opportunities relate to outcomes for development pipeline projects, especially oncology assets such as durvalumab, tremelimumab and acalabrutinib which account for over half our pipeline forecasts. Commercial success of Brilinta (acute coronary syndromes), Farxiga (diabetes) and the respiratory franchise (Symbicort, PT003/PT010) are also important drivers.

IMPORTANT DISCLOSURES CONTINUED

Bristol-Myers Squibb (BMY / BMY)

Stock Rating	Industry View
USD 62.69 (26-Jan-2016)	**EQUAL WEIGHT**	**POSITIVE**

Rating and Price Target Chart - USD (as of 26-Jan-2016) **Currency=USD**



Date	Closing Price	Rating	Adjusted Price Target
30-Nov-2015	67.01		70.00
16-Jan-2015	62.31		55.00
02-Jul-2014	48.24	Equal Weight	46.00
10-Jan-2014	56.18	Overweight	65.00
20-Dec-2013	53.37		52.00
17-Jul-2013	44.51		45.00
15-Apr-2013	40.75		42.00

Source: Thomson Reuters, Barclays Research

Historical stock prices and price targets may have been adjusted for stock splits and dividends.

Source: IDC, Barclays Research

Link to Barclays Live for interactive charting

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Valuation Methodology: We value BMY on a price/growth basis using the 2017 peer group average, which we view as appropriate given BMY's pivot into specialty drug and biotechnology markets. Based on the mid-teens earnings growth outlook, applying the group average price/growth multiple of 2.0x implies a value of $70 per share.

Risks which May Impede the Achievement of the Barclays Research Valuation and Price Target: As BMY's growth prospects increasingly depend on the delivery of its immuno-oncology pipeline, any setbacks or delays could pose risk to the stock. The field of immuno-oncology is getting increasingly competitive and BMY's leadership is being challenged by other major players. Any competitive disadvantage in terms of clinical development or regulatory timelines could put pressure on the stock.

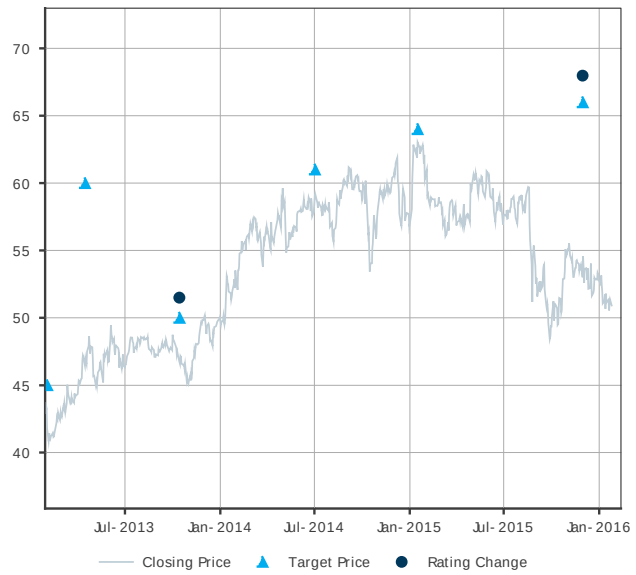
IMPORTANT DISCLOSURES CONTINUED

Merck & Co. (MRK / MRK)

Stock Rating	Industry View
OVERWEIGHT	**POSITIVE**

USD 51.45 (26-Jan-2016)

Rating and Price Target Chart - USD (as of 26-Jan-2016)



Source: IDC, Barclays Research

Currency=USD

Date	Closing Price	Rating	Adjusted Price Target
30-Nov-2015	53.01	Overweight	66.00
16-Jan-2015	63.03		64.00
02-Jul-2014	59.05		61.00
14-Oct-2013	46.75	Equal Weight	50.00
15-Apr-2013	46.46		60.00
01-Feb-2013	41.83		45.00

Source: Thomson Reuters, Barclays Research

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Valuation Methodology: Our $66 price target reflects the blended average of a global peer group valuation comparison using the average 2017E P/E multiple, which implies a value of $62 per share, and our DCF, which assumes a risk free rate of 2.00%, ERP of 6.00%, equity beta of 0.93, pre-tax cost of debt of 3.03%, and tax rate of 22.75% that results in a WACC of 6.77% and terminal growth of 1.50%, which implies an intrinsic value of $69 per share.

Risks which May Impede the Achievement of the Barclays Research Valuation and Price Target: Greater than expected pressure on Remicade from biosimilars, slow uptake of Keytruda, and declines in Januvia from SGLT-2s would significnatly affect MRK's projected revenue growth. Also, any setback in clinical development of key pipeline assets could cause concerns over long term growth.

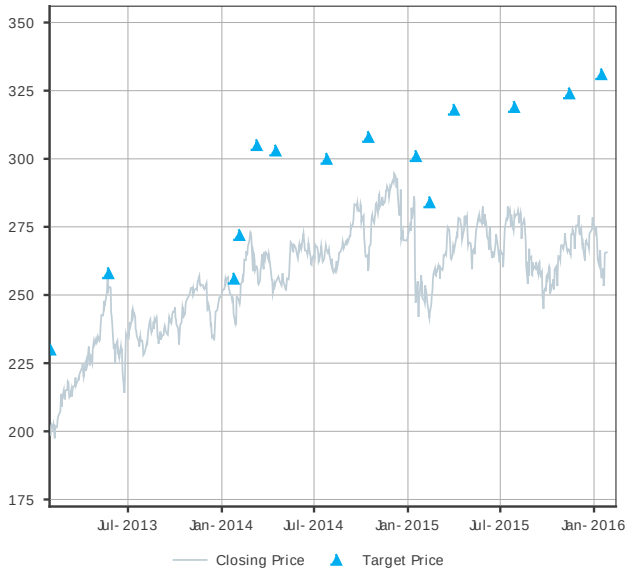
IMPORTANT DISCLOSURES CONTINUED

Roche (ROG VX / ROG.VX)

CHF 265.70 (26-Jan-2016)

Stock Rating	Industry View
OVERWEIGHT	**NEUTRAL**

Rating and Price Target Chart - CHF (as of 26-Jan-2016)



Source: IDC, Barclays Research

Currency=CHF

Date	Closing Price	Rating*	Adjusted Price Target
15-Jan-2016	256.50		331.00
13-Nov-2015	266.60		324.00
28-Jul-2015	276.70		319.00
01-Apr-2015	267.40		318.00
12-Feb-2015	241.70		284.00
16-Jan-2015	247.20		301.00
15-Oct-2014	258.90		308.00
25-Jul-2014	267.00		300.00
16-Apr-2014	254.20		303.00
10-Mar-2014	260.50		305.00
04-Feb-2014	247.50		272.00
24-Jan-2014	243.30		256.00
23-May-2013	250.70		258.00
29-Jan-2013	201.40		230.00

Source: Thomson Reuters, Barclays Research

Historical stock prices and price targets may have been adjusted for stock splits and dividends.

*The rating for this security remained Overweight during the relevant period.

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Valuation Methodology: We value Roche on a DCF basis applying a risk-free rate derived from the yield curve, a 5% risk premium, an asset beta of 0.9, cost of debt derived from the CDS curve and a target debt ratio of 10%. This yields a dynamic cost of capital. In the long-run we are feeding incremental ROCE back towards the company's long term cost of capital. This approach yields our price target of CHF331.

Risks which May Impede the Achievement of the Barclays Research Valuation and Price Target: Risks to our stance near term include R&D failures and more aggressive than anticipated margin pressure. The key downside risk to long-term forecasts and the defensive perception of Roche's future cash flows remains biosimilar competition to Rituxan and Herceptin.

Other Material Conflicts: Barclays Bank and or its affiliate is advising GeneWEAVE BioSciences Inc in relation to their potential acquisition by Roche (SIX:ROG.) The ratings, price targets and estimates on Roche (SIX:ROG) do not incorporate this transaction.

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