

February 14, 2014 Friday

Today's Intelligence at a Glance

1. Pfizer: Competitive Dynamics Positive for Palbociclib (Breast Cancer), Multi-Year Lead Over Novartis & Lilly's CDK 4/6 Programs

JPMorgan/Schott, February 14, 2014

[HealthACE Abstract](#)

Indication: Breast

2. Pfizer: Vaccines, Oncology, and Consumer Healthcare (VOC) Business Unit Has Potential to Grow Earnings at Mid-20% CAGR, Assuming Favorable Palbociclib (Breast Cancer) Data

JPMorgan/Schott, February 14, 2014

[HealthACE Abstract](#)

Indication: Breast

3. AVEO: Astellas Ends Partnership, Signaling Effective End of Tivozanib (RCC) Clinical Development; New Strategy Needed, Most Viable Option is to Acquire New Clinical Assets

Stifel/Klein, February 14, 2014

[HealthACE Abstract](#)

Indication: Kidney

4. Genmab: Partner Janssen Likely to Move Daratumumab (MM) into Combo Trials Over Next 12-18 Months; Cost of Multi-Drug Combos a Potential Limiting Barrier, But Velcade Generics Likely to Ease Access

Deutsche Bank/Parkes, February 14, 2014

[HealthACE Abstract](#)

Indication: Hematologic

5. Genmab: Anti-CD20 to Remain a Core Component of CLL Treatment; Expanded Development Plans for Arzerra Will Read Out Throughout 2014

Deutsche Bank/Parkes, February 14, 2014

[HealthACE Abstract](#)

Indication: Hematologic

6. Synta: Recent Publication Underscores Ganetespib Potential in RAF Inhibitor Resistant, Mutant BRAF Melanoma

JMP Securities/King, February 13, 2014

[HealthACE Abstract](#)

Indication: Hematologic

7. Ariad: Iclusig Usage Expected to Increase Over Next 12 Months, Including in 2nd-Line CML Patients Without T315i Mutation

Stifel/Sendek, February 13, 2014

[HealthACE Abstract](#)

Indication: Hematologic

8. Celgene: Polymorph-Related Event (Cephalon's Nuvigil) in 1H14 Could Have Some Relevance to Revlimid's IP

PiperJaffray/Schimmer, February 13, 2014

[HealthACE Abstract](#)

Indication: Hematologic

Additional Analysis

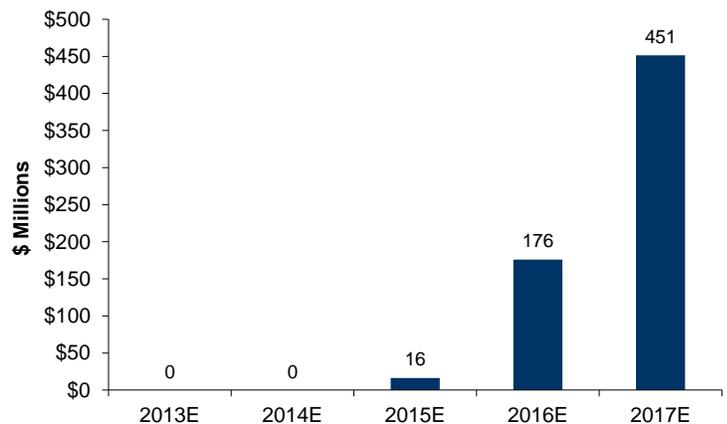
Phase III Trials for Palbociclib (Pfizer)

Study Name Design	Indication	Endpts	Estimated Completion Date
NCT01740427 PALOMA-2; +/- Letrozole	Breast Cancer 1st-Line Treatment of Postmenopausal Women with ER+/HER2-	1 ^o : PFS 2 ^o : OS, ORR, DOR	March 2016 Recruiting
NCT01942135 PALOMA-3; With Fulvestrant	Breast Cancer HR+ HER2- Metastatic, After Endocrine Failure	1 ^o : PFS 2 ^o : OS, ORR, DOR, CBR	January 2017 Recruiting
NCT02028507 PEARL; With Exemestane vs. Chemo	Breast Cancer HR+ HER2- Metastatic, Resistance to Non- Steroidal Aromatase Inhibitors	1 ^o : PFS 2 ^o : ORR, CBR, DOR, OS, Safety	January 2018 Not Yet Recruiting
NCT01864746 PENELope-B; + Standard Endocrine Treatment	Breast Cancer HR+ HER2 Normal Patients With Residual Disease After Neoadjuvant Chemo and Surgery	1 ^o : iDFS 2 ^o : DDFS, OS, Compliance and safety, QALY	November 2021 Recruiting

CBR: Clinical Benefit Response
DDFS: Distant Disease Free Survival
DOR: Duration of Response
iDFS: Invasive Disease Free Survival
ORR: Objective Response Rate
OS: Overall Survival
PFS: Progression Free Survival
QALY: Quality-Adjusted Life Years

Source: www.clinicaltrials.gov

Palbociclib - Annual Sales Projection



Sources: Company Reports; 5+ Brokerage Analyst Reports

[Back to Front Page](#)

Pfizer: Competitive Dynamics Positive for Palbociclib (Breast Cancer), Multi-Year Lead Over Novartis & Lilly's CDK 4/6 Programs

We see palbociclib as a \$5+ billion product opportunity, addressing a large segment of the breast cancer market (first-line advanced/metastatic HER2-/ER+) with few treatment options. Pfizer recently reported that the roughly 165 patient phase I/II trial (PALOMA-1) met its primary PFS endpoint and disclosed that it is planning to discuss the data with regulators. We expect full phase II results at AACR in the spring (April 5-9). Given that palbociclib has Breakthrough Designation, we believe that there is a pathway for accelerated filing and review at the FDA without phase III data if the final phase II results are even close to the interim data (26.1 mos vs. 7.5 mos for the placebo).

Competitive Dynamics: Pfizer Leads Novartis and Lilly. From a competitive standpoint, we believe that Pfizer holds a multi-year head start over Novartis and Lilly, which both have CDK-4/6 inhibitors in development. On one hand, we see this competition as a potential competitive threat to this very important asset for Pfizer. That said, Novartis and Lilly have highlighted their CDK 4/6 programs as their highest priority mid-stage pipeline assets, which we believe further validates the drug's mechanism.

Late in 2013, Novartis moved its CDK-4/6 inhibitor into phase III trials directly from phase I. Although we have not seen much data from this drug, we note that the phase III trial looks at PFS and OS and will likely enroll over the next 18 months. In addition, Eli Lilly has a CDK-4/6 in phase II development and Lilly believes its agent may ultimately differentiate from Pfizer with regards to its tolerability as well as its ability to effectively cross the blood brain barrier. We expect Lilly to announce top-line results and phase III decisions by mid-2014 and estimate that Lilly remains approximately three years behind Pfizer, assuming a filing off of phase II data for palbociclib.

In an Upside Case, Palbociclib Targets A \$10+ billion Market. We see palbociclib as a multi-billion product opportunity, addressing a large segment of the breast cancer market (HER2-/ER+) with few treatment options. In our view, this initial market alone (1L advanced/metastatic HER2-/ER+ breast cancer) could generate peak sales of \$5+ billion per year. In addition, we see a meaningful upside case to estimates to the extent palbociclib usage moves into the adjuvant setting, similar to what happened with Herceptin in HER2+ breast cancer. We note that Pfizer's PENELOPE-B studies palbociclib in the adjuvant setting and is expected to complete in 2019-2020.

By way of comparison, Herceptin generated over \$6 billion of sales in its 1L and adjuvant HER2+ breast cancer indications in 2013. Given that HER2+ accounts for approximately 20% of breast cancer patients and HER2-/ER+ accounts for approximately 60%, we estimate that palbociclib has the blue sky potential to generate \$10+ billion of sales over time.

Source: JPMorgan/Schott, February 14, 2014

Oncology Indication: Breast

Keyword: Clinical Trials/Pipeline

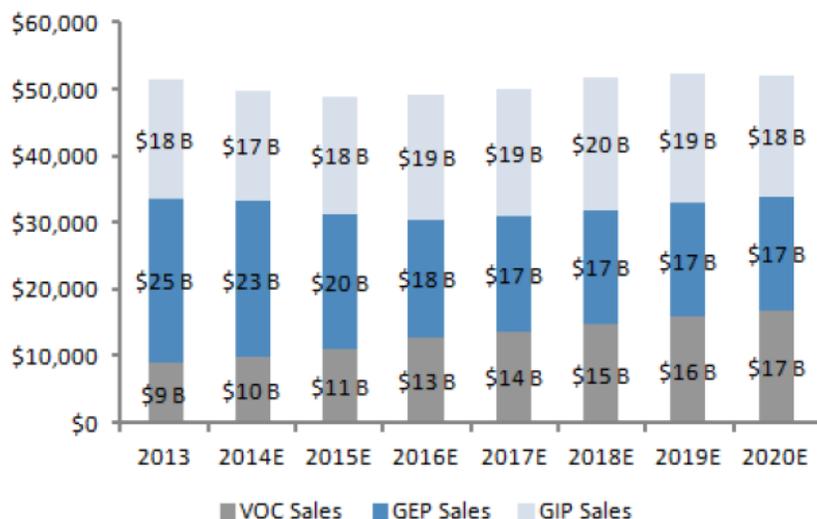
[Back to Front Page](#)

Pfizer: Vaccines, Oncology, and Consumer Healthcare (VOC) Business Unit Has Potential to Grow Earnings at Mid-20% CAGR, Assuming Favorable Palbociclib (Breast Cancer) Data

Pfizer recently split its commercial operations into three segments: Vaccines, Oncology, and Consumer Health (VOC); Global Innovative Products (GIP); and Global Established Products (GEP). VOC includes Pfizer's vaccines, oncology, and consumer assets, each of which operates as a distinct business. GIP includes the company's assets that are expected to have exclusivity beyond 2015 in areas including Inflammation/Immunology, CV/Metabolic, Neuro/Pain, Rare Diseases and Women's/Men's Health. GEP includes both off-patent products and mature patent-protected products expected to lose exclusivity through 2015, as well as biosimilars and established products collaborations. As Pfizer shifts to this new three business unit structure, our work continues to suggest upside to valuation as we consider the growth and strategic potential of these units.

Figure 1: Pfizer 2014E-2020E Sales by Business Units

\$ in millions



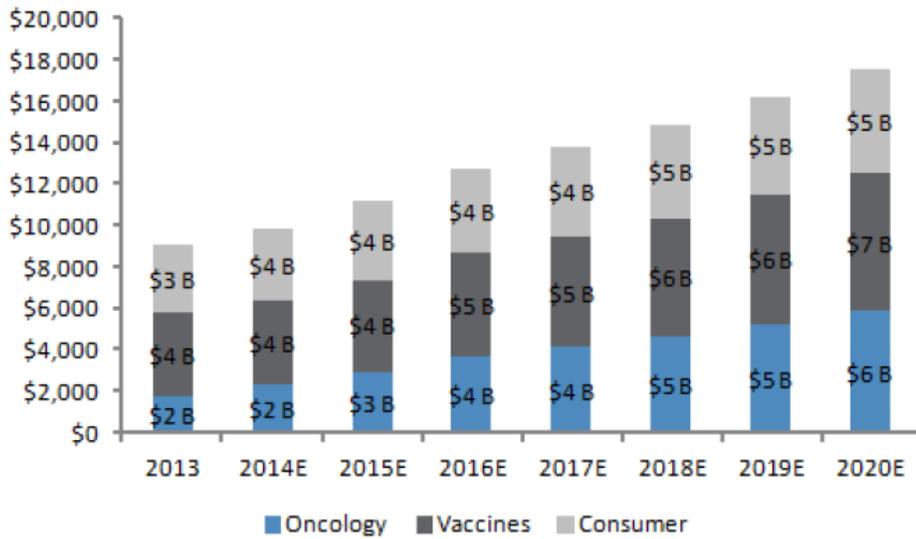
Source: Company reports and J.P. Morgan estimates.

Looking specifically at Pfizer's Vaccines, Oncology, and Consumer Healthcare (VOC) business unit, we see a portfolio that has the potential to grow earnings at a mid-20% CAGR assuming favorable palbociclib data. We believe this growth could support a top-tier biopharma multiple of 20x+ 2016 EPS for the division, which we further explore below. In such a scenario, we estimate the VOC business unit represents the most significant portion of Pfizer's valuation at roughly 40% of the overall value.

We estimate that the Vaccines, Oncology, and Consumer Health business unit accounts for roughly \$10 billion of Pfizer's 2014 top-line and we see 2016 sales in launches ramp. Longer term (and using risk-adjusted palbociclib forecasts), we see this segment growing top-line nearly 10% annually through 2020 and bottom line in the high-teens as the oncology launches drive margin leverage.

From a margin standpoint, we would not be surprised to see the VOC unit report operating margins slightly below the company average (we estimate 32%), but see these margins expanding to close to 45-50% looking out toward the latter part of the decade as the segment's higher sales bases absorbs a fairly fixed infrastructure.

Figure 2: Estimated Vaccines, Oncology, and Consumer Health Sales by Business 2013-2020E
 \$ in millions



Source: Company reports and J.P. Morgan estimates.

Source: JPMorgan/Schott, February 14, 2014

Oncology Indication: Breast

Keyword: Management/Strategy/Financials

[Back to Front Page](#)

AVEO: Astellas Ends Partnership, Signaling Effective End of Tivozanib (RCC) Clinical Development; New Strategy Needed, Most Viable Option is to Acquire New Clinical Assets

Following the complete response letter for Tivozanib in renal cell cancer as well as the recent termination of the Phase 2 BATON program, Astellas is concluding its collaboration with AVEO for the development and commercialization of Tivozanib, effective in 6 months. While we view the end of this clinical program as unfortunate for patients, given the suggestion of activity, at least in renal cell cancer, we view the dissolution of this partnership and the end of Tivozanib development as an opportunity for the AVEO to move forward.

We believe the company's most viable option is to acquire new clinical assets to reinvigorate investor interest in the company. We note that with approximately \$130M in cash as of 3Q13, AVEO is well-capitalized, affording them an opportunity and the time to refocus the company's strategy and trajectory. In addition, a new management team would help reinvigorate investor confidence in the company.

Source: Stifel/Klein, February 14, 2014

Oncology Indication: Kidney

Keyword: Partnerships/Business Developments

[Back to Front Page](#)

Genmab: Partner Janssen Likely to Move Daratumumab (MM) into Combo Trials Over Next 12-18 Months; Cost of Multi-Drug Combos a Potential Limiting Barrier, But Velcade Generics Likely to Ease Access

Daratumumab is the most advanced in the anti-CD38 class of antibody drugs, which we believe have potential to transform treatment multiple myeloma. Based on impressive single-agent activity and benign safety to date, we see an approval in the refractory myeloma setting as a high probability. Given high physician enthusiasm for participation in clinical trials, we believe data from the first registration trial could report as early as the end of 2014. As importantly, we expect partner Janssen to rapidly move into combination trials in relapsed and first-line settings over the next 12-18 months. Ultimately, if initial safety and synergistic efficacy is confirmed biologic therapy could form the backbone of treatment for a majority of myeloma patients, driving sales of biologics of >\$6bn, of which we assume daratumumab can generate >\$2.4bn (with upside to >\$4bn).

We see multi-blockbuster potential for the anti-CD38 class. Our discussions with multiple myeloma experts reveal optimism that combination biologic treatment could ultimately form a core component of treatment for the majority of multiple myeloma patients. Importantly, although new treatments have improved survival significantly, the vast majority of patients ultimately relapse and develop resistance to treatment. Even with aggressive front-line therapy with Velcade plus melphalan and prednisone (known as MPV) (which can achieve CR rates of 30%), more than half of patients still experience relapse and progression of their disease by two years post initiation of therapy. As a result, physicians see significant room to improve on current treatment.

Our forecasts are based on the following basic assumptions:

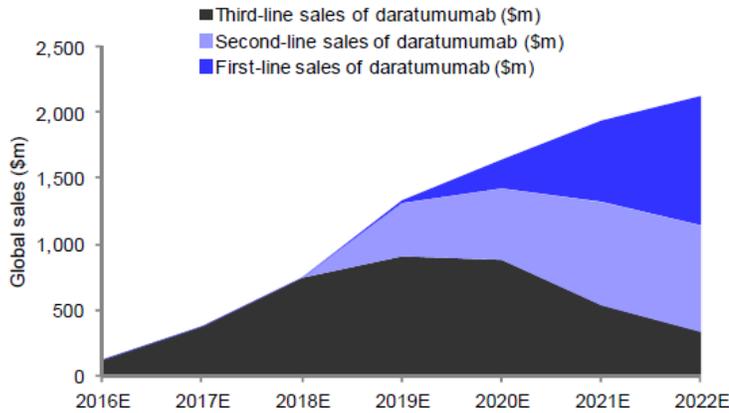
- Daratumumab is launched in 2016 with a label enabling use in patients refractory to Revlimid and Velcade. Approvals are obtained in relapsed and front-line myeloma in 2018-2019.
- Ultimately biologics are prescribed to 70% of first-line patients, of which anti-CD38 antibodies take a 75% share (i.e. anti-CD38 therapy achieves a c.53% penetration in first-line).
- We assume daratumumab takes a 50% share of the anti-CD38 class given its first-to-market status, with upside possible if Genmab's claims over the antibody's *in vitro* potency result in clinically differentiated activity vs other anti-CD38 antibodies in development.
- We assume that ultimately 35% of relapsed patients receive a CD38 antibody, again with daratumumab taking a 50% share of the class.
- We assume a course of daratumumab induction therapy is priced at a WACC of \$63,000 per patient net of discounts (for a 6 month course), with front-line and relapsed patients receiving an average of 12-14 months therapy (based on a proportion of patients receiving consolidation therapy in the front-line setting and maintenance treatment in the relapsed setting). This puts the cost of 12 months therapy at \$89k, which is broadly in-line with the estimated current net price for an annual treatment with Revlimid. We assume realised ex- US prices are c.20% lower.
- These assumptions drive our forecasts for daratumumab to achieve sales of \$2.4bn by 2024E. We apply a probability of 60% to this scenario. We assume Genmab receives royalties of 13-16% on sales dependent on achievement of sales targets. Our sensitivities suggest downside to c.\$1bn in sales if daratumumab is only approved in the relapsed/refractory setting and up to >\$4bn if daratumumab takes a larger share of the CD38 class than we have assumed.

Sales of biologics in multiple myeloma could reach \$5bn in sales

	US patient population	Penetration of biologics	Cost of treatment course at launch	Cost of US course in 2022E	Sales of class	Daratumumab share	Daratumumab sales (\$m)
First-line	23,663	53%	89,051	112,808	1,401	50%	700
Second-line	16,356	35%	94,543	119,764	686	50%	342
Third-line	12,951	20%	70,907	89,823	233	50%	116
Daratumumab US sales (\$m)							1,159
Daratumumab global sales (\$m)							2,432
Global sales of biologics in multiple myeloma (\$m)							6,488
% of pts ultimately exposed to anti-CD38 antibody (US)							88%

Source: Deutsche Bank

DBe daratumumab global sales forecast



Source: Deutsche Bank

Cost of multi-drug combinations could be limiting but Velcade generics likely to ease access. Our thesis on daratumumab's potential is that multi-drug combination therapy (including an anti-CD38 antibody backbone) will ultimately become standard-of-care for first-line multiple myeloma treatment. While this will require demonstration of improved outcomes in terms of disease progression and survival, initial data supporting synergy with current standard multiple myeloma drugs is highly encouraging. However, one potential barrier to widespread use of such regimens is that of cost. With a course of Revlimid costing c.\$85k and Velcade costing c.\$45k, doublet or triplet therapy with a CD38 antibody could cost as much as \$130k-215k per patient. This level of treatment cost could be a meaningful barrier to uptake. In fact, although doublet therapy with Velcade/Revlimid based regimens are already widely used in the US for first-line treatment, cost is limiting to uptake elsewhere and thalidomide is often used as a cheaper alternative to Revlimid. However, with generic Velcade expected to become available from mid-2017, the cost burden is likely to ease significantly by the time daratumumab is approved in the relapsed and first-line settings in 2018-19.

Source: Deutsche Bank/Parkes, February 14, 2014

Oncology Indication: Hematologic

Keyword: Market Overview

[Back to Front Page](#)

Genmab: Anti-CD20 to Remain a Core Component of CLL Treatment; Expanded Development Plans for Arzerra Will Read Out Throughout 2014

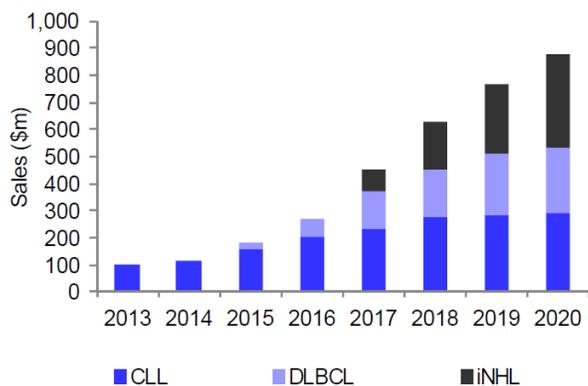
The most bullish analysts expect sales of Arzerra in cancer to reach \$1.0-1.5bn at peak, growing from its current low \$120m base. Unfortunately, forecasting future sales is challenging given uncertainties over: (1) the likelihood of success in ongoing Phase III trials in aggressive and indolent lymphoma; (2) the impact of novel oral agents on use of CD20 antibodies in both CLL and FL; and (3) competitive threats from Roche's own new CD20 therapy, Gazyva, which has arguably shown more potent efficacy in clinical trials to date. Despite this, we expect **CD20 antibodies to remain a core component of CLL treatment**. As a result, an expected approval for Arzerra in front-line CLL (PDUFA April 19, 2014), along with its attractive tolerability profile and price point, should still enable it to remain a growth franchise, despite competitive headwinds. Should an ongoing Phase III trial in relapsed DLBCL (head-to-head with Rituxan) report positively (due in mid-2014) and thus confirm Arzerra's putative benefits in Rituxan resistant settings, then \$1bn in sales would still look like an achievable goal. Unfortunately, while data has been encouraging to date, it remains challenging to predict with confidence the outcome of this key head-to-head Phase III study.

DB Arzerra market share assumptions

	US peak penetration	Global sales (US\$m)	Current probability applied	Risk-adjusted sales
First line CLL sales (\$m)	14%	114	100%	114
Relapsed CLL sales (\$m)	21%	120	100%	120
Maintenance CLL sales (\$m)	43% of treated pts	69	100%	69
Relapsed DLBCL sales (\$m)	40%	255	70%	179
Relapsed indolent sales (\$m)	15%	254	70%	178
Refractory indolent sales (\$m)	35%	190	70%	133
Total sales		1,002		792

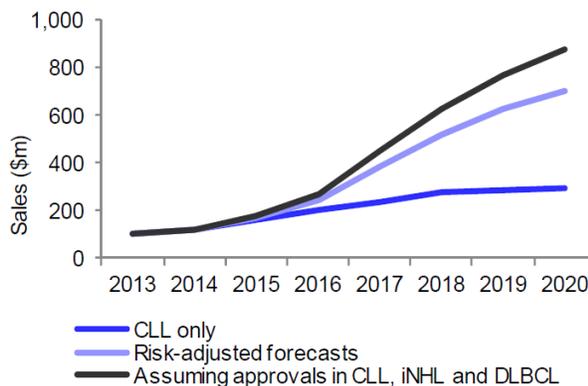
Source: Deutsche Bank; * - as percentage of Arzerra treated patients

DBe Arzerra global sales forecast



Source: Deutsche Bank

Arzerra sales scenarios



Source: Deutsche Bank

Expanded development plans will come to fruition through 2014. Despite expected competitive pressure on use of single agent Arzerra in refractory CLL, results of Genmab/GSK's expanded development programme have already begun to mature. These trials could lead to approvals for Arzerra in significantly larger markets that are also likely to be more resilient to competitive pressures from novel oral drugs. This programme follows encouraging levels of activity observed in Phase II trials of Arzerra in combination with various chemotherapy regimens in first-line follicular lymphoma, relapsed/refractory DLBCL and Rituxan-refractory follicular lymphoma.

Positive headline data was reported from the first of these randomized trials, COMPLEMENT-1 in previously untreated elderly CLL patients in May 2013. The data was later presented at the American Society for Hematology meeting in December 2013. Results showed superiority for treatment with Arzerra plus the chemotherapeutic chlormabucil over treatment with chlorambucil alone. Further large scale randomised Phase III trials of Arzerra are expected to report over

the next 6 months, including trials in relapsed CLL induction treatment (ofatumumab plus fludarabine and cyclophosphamide (FC) vs FC alone: mid- 14), relapsed CLL maintenance (ofatumumab vs no treatment; mid-14). In addition, a head-to-head study with Rituxan in relapsed DLBCL (ofatumumab plus chemotherapy vs Rituxan plus chemotherapy) is due to report in mid-14. Further to this, a Gilead sponsored Phase III study of a combination of ofatumumab plus its oral PI3 kinase, idelalisib is expected to report by the end of 2014. This latter trial could determine if there are differentiating characteristics between Arzerra and Rituxan when combined with tyrosine kinase inhibitors. A similar trial of Rituxan plus idelalisib was recently presented at the ASH conference, Dec, 2013.

Source: Deutsche Bank/Parkes, February 14, 2014

Oncology Indication: Hematologic

Keyword: Clinical Trials/Pipeline

[Back to Front Page](#)

Synta: Recent Publication Underscores Ganetespib Potential in RAF Inhibitor Resistant, Mutant BRAF Melanoma

In a recent Molecular Cancer Therapeutics publication (Acquavia et al., January 2014), Synta investigators, using in vitro and in vitro mouse models, show that treatment with ganetespib effectively reduces growth of mutant BRAF tumor cells that are otherwise resistant to RAF inhibitors. Moreover, co-treatment of ganetespib plus MEK inhibitor was shown to be as, if not more, effective at slowing drug-resistant tumor growth compared to MEK plus RAF inhibitor combinations. In our view, these data underscore a meaningful clinical opportunity for ganetespib, specifically for the 40-50% of BRAF melanoma patients underserved by RAF inhibitor therapies Zelboraf and Tafenlar (dabrafenib, GSK).

HSP90 inhibition with ganetespib overcomes intrinsic and acquired resistance in BRAF mutant melanoma. This capacity was demonstrated in two key experiments, the first used a model BRAF melanoma cell line that overexpressed MAPK pathway intermediate COT, previously shown to confer resistance to both RAF and MEK inhibitors. Treating the cells with low nanomolar doses of ganetespib resulted in durable downregulation of MAPK and AKT signaling pathways and high levels of apoptosis induction. Ganetespib also maintained its antitumor activity in xenograft tumors derived from a second mutant BRAF melanoma cell line cultured to resistance in the presence of vemurafenib. Further, combining ganetespib with MEK inhibitor (TAK-733, Takeda) was shown to induce tumor regression in similar vemurafenib-resistant xenografts, with only incrementally greater toxicity in mice.

Data hold meaningful clinical implications, although proof-of-concept trials are not likely to begin in the near- to mid-term. Rather, Synta will continue to be primarily rooted in the GALAXY program in NSCLC in combination with Taxotere, as well as the HER2-negative breast cancer opportunity based on compelling data presented at the San Antonio Breast Cancer Symposium in December. Additional opportunities in ovarian cancer and AML are also being explored following the recent announcement of the GANNET53 European investigator sponsored study in p53 mutant platinum-resistant ovarian cancer in combination with paclitaxel and two front-line AML studies (AML-18 and AML-19) in combination with standard chemotherapy led by Cancer Research UK. We view the latter trials as particularly robust proof-of-concept studies, offering potential upside with negligible impact to the company's balance sheet.

Source: JMP Securities/King, February 13, 2014

Oncology Indication: Hematologic

Keyword: Clinical Trials/Pipeline

[Back to Front Page](#)

Ariad: Iclusig Usage Expected to Increase Over Next 12 Months, Including in 2nd-Line CML Patients Without T315i Mutation

Following the return of Iclusig to the U.S. market, we performed a survey of 39 U.S. hematologists to gauge the physician reaction to updated FDA Iclusig cardiovascular risk analysis. We also recently held a meeting with Ariad management to discuss the return of Iclusig to market.

Post-market withdrawal 85% of physicians continue to prescribe Iclusig. We believe this is a testament to the efficacy of Iclusig, which we view as the most potent TKI available for CML. We believe the Street underestimates the long-term growth potential of Iclusig and its ability to penetrate 2nd-line CML. We note the updated Iclusig label is restrictive and only permits usage in 2nd-line CML for patients who test T315i positive; however our survey and Ariad estimates both indicate there is currently usage of Iclusig in 2nd-line CML patients without T315i, which we expect should increase time on therapy.

Our survey indicates that only 22% of CML patients treated by our surveyed physicians are at high risk for cardiovascular events and that the cardiovascular risks are manageable. We also found that 62% of physicians prescribe an average dose of 30mg versus the approved dose of 45mg as part of their risk mitigation strategy.

We see opportunity for Iclusig to gain use in the high percentage of patients switching therapies early, leading to longer treatment duration:

- 26% of 1st-line CML patients switch therapies each year with a 26-month therapy duration thereafter
- 27% of 2nd-line CML patients switch therapies each year with a 17-month treatment duration thereafter
- This is important because earlier line switch patients will likely have a longer duration of therapy, generating sales in some cases well over one year per patient

We currently estimate the T315i prevalence at 2% of the total CML population but expect this to increase to 4% by 2022 due to higher usage of 2nd generation TKIs such as Sprycel and Tassigna which select for the T315i mutation at a higher rate than Gleevec.

Source: Stifel/Sendek, February 13, 2014

Oncology Indication: Hematologic

Keyword: Market Overview

[Back to Front Page](#)

Celgene: Polymorph-Related Event (Cephalon's Nuvigil) in 1H14 Could Have Some Relevance to Revlimid's IP

We wanted to highlight a polymorph-related event in 1H14 which could have some relevance (either good or bad) for Celgene's own Revlimid polymorph patents.

This year the Court of Appeals for the Federal Circuit (CAFC) will set a precedent for polymorph patents in the Nuvigil case (Cephalon v Lupin/Mylan/Sandoz). Oral arguments are scheduled for March 6th at 10AM. The District Court of Delaware affirmed Cephalon's polymorph patents but the generic challengers have filed provocative appeal briefs with the CAFC. Historically, the CAFC has reversed 26% of District Court affirmed drug patents and partially reversed 16% of District Court affirmed drug patents, but polymorph patents have historically not fared well at the CAFC (0/4 by our count).

The Nuvigil polymorph patent decision will have relevance (albeit imprecise) to other polymorph patents, particularly Revlimid. Many view Revlimid as having a stronger polymorph patent position than Nuvigil, but the Nuvigil decision could still have read-throughs given the broad nature of the generics' arguments.

Patent laws pertaining to pharmaceuticals can be difficult to predict. The rules of patent law are not always applied in an expected way by the Court of Appeals for the Federal Circuit (CAFC). The CAFC may consider the 'social agenda' in applying the law to evolving technologies. There are few 'absolutes' in patent law (particularly polymorph patent law) when it comes to the CAFC.

Revlimid's market exclusivity may extend through 2023/2024 based on method of use, or 2027. These additional years are important since Revlimid will potentially be selling >\$5bn/yr in those later years. Even if Revlimid's polymorph patents are upheld, there's still the potential that another company could create an amorphous (no crystal pattern) form. However amorphous forms may not be able to replicate Revlimid's PK profile or establish equivalence. It might be months or years before we figure out the extent of Revlimid's market exclusivity in the U.S.

Source: PiperJaffray/Schimmer, February 13, 2014

Oncology Indication: Hematologic

Keyword: Policy/Legal