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MRK - Q2 2015 Merck & Co Inc Earnings Call

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OVERVIEW:

MRK reported 2Q15 total Co. revenue of $9.8b and non-GAAP EPS of $0.86. Expects 2015 revenue to be $38.6-39.8b, GAAP EPS to be $1.52-1.71 and non-GAAP EPS to be $3.45-3.55.

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PRESENTATION

Operator

Good day, everyone and welcome to Merck's second-quarter 2015 earnings conference call. Today's call is being recorded. At this time, I would like to turn your call over to Joseph Romanelli, VP of Investor Relations. Please go ahead.

Joseph Romanelli - *Merck & Co., Inc. - VP, IR*

Thank you, Darla and good morning, everyone. We would also like to say good afternoon and good evening to everyone listening outside the United States. Welcome to Merck's second-quarter 2015 conference call.

Before I turn the call over to Ken, I just want to point out a couple of items. First, you will see that we have items in our GAAP results such as acquisition-related charges, restructuring costs and certain other items. You should note that we've excluded those items from our non-GAAP results. There are reconciliation tables available in our press release so that you can get a better understanding of their underlying performance.

We've also provided tables to help you understand the sales results in the quarter for the business units, as well for the products. This can be found in Table 3 of our press release and the reconciliation tables I mentioned earlier are on Table 2 of the press release. During the call, we will be referring to Table 2 for the P&L and Table 3 as it relates to revenue.

Second, I would like to remind you that some of the statements we make during today's call may be considered forward-looking statements within the meaning of the Safe Harbor provision of the US Private Securities Litigation Reform Act of 1995. Such statements are made based on the current belief of Merck's management and are subject to significant risk and uncertainties. If our underlying assumptions prove inaccurate or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Our SEC filings, including Item 1A in the 2014 10-K identify certain risk factors and cautionary statements that could cause the Company's actual results to differ materially from those projected in any of our forward-looking statements made this morning. Merck undertakes no obligation to publicly update any forward-looking statements and you can see our SEC filings, as well as today's earning release on Merck.com.

So with that, this morning, I'm joined by Ken Frazier, our Chairman and Chief Executive Officer; Adam Schechter, President of Global Human Health; Rob Davis, our Chief Financial Officer; and Dr. Roger Perlmutter, President of Merck Research Labs. Now I'd like to turn the call over to Ken. Ken.

Ken Frazier - *Merck & Co., Inc. - Chairman & CEO*

Thanks, Joe. Good morning, everyone. Thank you all for joining the call today. Before I discuss our quarterly performance, I want to take a moment to thank Joe Romanelli for ably leading our investor relations efforts for the past two years. Joe is moving on from explaining our numbers to a role in which he will be generating revenue as Managing Director for our business in Taiwan and Hong Kong. We have benefited from Joe's expertise and leadership and he has done an outstanding job. We wish him and his family all the best as they relocate to Asia. Thank you, Joe.

I'm also pleased that joining the call today is Joe's successor, Teri Loxam. Teri comes to Merck with a wealth of experience in finance and investor relations and has worked in the pharmaceutical, entertainment and investment banking industries. Welcome to Merck, Teri. We are pleased to have you on our team.

This is an exciting time for Merck as we advance our promising pipeline and launch new products in the marketplace. It is also a propitious time for biomedical research generally as we are witnessing the introduction of breakthrough therapies and in some cases cures for some of the most difficult-to-treat diseases.

Merck's late-stage pipeline and ongoing launches reflect scientific and therapeutic progress that will provide significant value to patients in society. Over the past few months, I've seen and heard first-hand from stakeholders across the healthcare ecosystem, including patients, payers and government, about the critical impact that our current and future medicines and vaccines can have on improving the health and productivity of both individuals and populations.

These experiences continue to reinforce my conviction that in the evolving healthcare environment success will accrue to those who develop products that not only enable patients to live longer, more productive lives, but that also can help reduce overall healthcare expenditures. By bringing forward these kinds of medical innovations, Merck will create sustainable value for society and shareholders.

Turning to our second-quarter performance, we built on the strong momentum achieved earlier in the year by executing well on our focused and discipline strategy. Global Human Health delivered top-line growth in our four core areas of oncology, hospital acute care, diabetes and vaccines.

Our Animal Health business also grew 10% due in part to the strong growth of BRAVECTO. We are investing resources to grow our strongest brands and to support the most promising assets in our pipeline while at the same time lowering our overall cost base and delivering a leveraged P&L.

Merck is active in many of the most promising areas of science and medicine, including oncology, antibiotic resistance, cardiometabolic disease, hepatitis C and Alzheimer's disease. The progress we continue to make with our pipeline reflects this.

We are advancing both our KEYTRUDA and hep C programs, two of our most important assets. As we move into the second half of 2015, our organization is preparing for these exciting opportunities. Last month, the FDA accepted our supplemental BLA for KEYTRUDA in advanced non-small cell lung cancer and granted KEYTRUDA priority review. And just this past week, the European Commission approved KEYTRUDA for the treatment of advanced melanoma in adults both as a first-line therapy and in previously treated patients.

Earlier today, we announced that the FDA has accepted under priority review the new drug application for our doublet regimen for the treatment of adult patients infected with hepatitis C. Last week, the European Medicines Agency also accepted our application, which they will review on an accelerated basis. Roger will discuss our KEYTRUDA and hep C programs in greater detail later in the call.

I am pleased with the progress we've made with our key pipeline assets. I'm also encouraged by our underlying commercial performance, which Adam will discuss in more detail shortly. We achieved solid growth in both our human and animal health businesses and in particular in our diabetes franchise where we saw 9% growth. We also continue to make progress with the recent introductions of KEYTRUDA, BELSOMRA, ZERBAXA and Gardasil 9, each of which provides an important treatment option for unmet medical need.

The growth of an established brand like Januvia and the successful launch of KEYTRUDA in the competitive melanoma field are examples of how we are bringing greater discipline, focus and execution across our business and especially in those areas where we have the greatest opportunities to grow and to lead.

In closing, Merck is positioned to build on the strong momentum we've achieved during the first half of the year. Going forward, we will focus on the best scientific and medical innovations, sourced both internally and externally, because we believe that is the best path to long-term value creation.

By capitalizing on the significant and exciting scientific and clinical opportunities that lie ahead, Merck intends to play a major role in transforming healthcare for the benefit of patients, payers and shareholders alike. And now I'd like to turn the call over to Adam Schechter.

Adam Schechter - *Merck & Co., Inc. - EVP & President, Global Human Health*

Thank you, Ken and good morning, everyone. This morning, I'll discuss the second-quarter results for Global Human Health and my comments will be on a constant currency basis. Our performance in the quarter reflects continued efforts to drive growth within our core business, coupled with increasing contributions from new product launches. Sales increased 3% with growth in all of our core focus areas of diabetes, hospital acute care, vaccines and oncology. Collectively, these core focus areas grew 9%, excluding the acquisition of Cubist.

I'll start by reviewing the performance of several key products followed by a brief update by region and then on several launched products. Starting with the Januvia franchise, we delivered our seventh straight quarter of growth. We have steadily increased resources for Januvia to drive growth and our results reflect the positive impact of our strategic resource allocation and the strength of the products.

In the second quarter, the Januvia franchise sales reached approximately $1.6 billion and grew 9%. In the United States, sales grew 14%. While we continue to drive underlying volume growth of about 4%, we had some benefits this quarter from adjustments to rebate accruals.

In the international markets, sales grew 4%. Volume growth in Europe was a key contributor to performance and emerging markets delivered steady double-digit growth. Also, we are pleased that the data presented from the TECOS study at the American Diabetes Association meeting last month confirmed that Januvia did not increase the risk of major adverse cardiovascular events or hospitalization for heart failure. We are now educating customers on these important results.

Sales of ZETIA and VYTORIN declined 8%. In the United States, ZETIA was flat offset by declines in VYTORIN. Outside the US, sales fell as a result of ZETIA's loss of exclusivity in Canada and prescription initiation restrictions in France.

Next, in Hospital and Specialty Care, sales of ISENTRESS decreased 10% to approximately $375 million. We are starting to see the impact of slowing growth of the integrase class and continued competitive dynamics in the US and Europe. We are also having a difficult year-over-year comparison versus second quarter of 2014 in the emerging markets due to tenders.

In immunology, sales of Remicade and Simponi were approximately $625 million, a decline of 1%. Continued growth in Simponi of about 20% was offset by a 7% decline in Remicade. As expected, we are seeing additional competition from biosimilars in the first full quarter since loss of exclusivity. We expect declines in Remicade to accelerate in the back half of this year as tenders are implemented in core markets.

In Hospital Acute Care, sales grew to approximately $930 million. We drove double-digit growth across our portfolio. As a leader in Hospital Acute Care, we are enthusiastic about diversity and the breadth of our underlying business and the promising launch opportunities that we are executing on today and planning for in the future.

Turning to the vaccine business, vaccine sales were about $1.2 billion, up 1% versus the prior year. Growth in the Gardasil franchise was offset by a decline in sales of RotaTeq due to the timing of public sector purchases in the United States. Combined sales of Gardasil and Gardasil 9 grew 6% to approximately $425 million on contributions from the United States and emerging markets. We continue to transition customers to Gardasil 9 and managed care coverage is now similar to that of Gardasil.

Sales of Zostavax were approximately $150 million, a decline of 3%. In the US, sales declined 8%. We continued to work with customers to help them understand the broad managed care coverage and the process for obtaining reimbursement. Also, we will be launching a new DTC campaign for Zostavax in the United States during the start of flu season. This new campaign will focus on increasing brand awareness and patient activation. Outside of the US, Canada drove sales growth. We are continuing to launch Zostavax in more than 25 markets.

Now I'll provide some geographic commentary for the quarter. In the United States, excluding Cubist, sales increased 5% primarily from growth in the Januvia franchise, oncology and hospital acute care. In Europe and Canada, sales decreased 8%. Growth from the Januvia franchise and Simponi was offset by ophthalmology product divestitures, declines in Remicade and declines in ZETIA and VYTORIN.

Japan sales declined 13% primarily from ophthalmology product divestitures and declines in older diversified products. Pneumovax grew on a continued rollout of a national immunization program. Emerging markets sales grew 4%. If you exclude divestitures, sales would have grown 6%. China grew 8% this quarter driven by sales increases in Hospital Acute Care.

Now I'll provide some updates on a few of our key launches and I'll start with BELSOMRA. We are encouraged by results in the early months of the BELSOMRA launch in the United States. Demand for this new medicine is steadily increasing. From an access perspective, BELSOMRA is now covered by commercial payers representing over 100 million lives. Next week, we will begin a branded DTC campaign to enhance consumer awareness.

With ZERBAXA, customer feedback in the early launch is positive. Over 300 hospitals have placed ZERBAXA on formulary. Looking ahead, we are intensifying our focus on increasing access while at the same time driving greater utilization in hospitals where ZERBAXA is on formulary.

In addition, we saw another strong performance for KEYTRUDA with sales reaching $110 million. In the United States, we achieved more than 60% patient share in ipi-refractory melanoma, a testament to our team's strong launch execution. KEYTRUDA is now the number one therapy used to treat melanoma in the US.

Importantly, as we speak, we are launching KEYTRUDA in the EU where the product is approved for use in advanced first and second-line melanoma. The deep clinical experience physicians are gaining through the KEYTRUDA launch in melanoma is building a solid foundation, particularly in the community setting, for potential launches in lung cancer and also other cancers. With an October 2 PDUFA date, our teams are ready for a potential launch in patients with advanced squamous and non-squamous non-small cell lung cancer.

Finally, now that our HCV doublet has priority review with the FDA and accelerated assessment in the EU, we are very much looking forward to launching this important product next year.

In summary, Global Human Health delivered another solid performance in the quarter. We grew through execution in all of our core focus areas of diabetes, hospital acute care, vaccines and oncology. We are gaining traction with key launches that will help to drive future growth. Now I'll turn the call over to my colleague, Rob Davis.

Rob Davis - *Merck & Co., Inc. - EVP & CFO*

Thanks, Adam. Good morning, everyone. As Ken and Adam stated, our results this quarter and for the first half of the year show that we are executing the focused strategy we first outlined nearly two years ago. We're driving top-line growth in core therapeutic areas and delivering a leveraged P&L.

This morning, I will provide some additional detail on the quarter and comment on our outlook for the second half of the year. My remarks will focus on our non-GAAP financials.

Total Company revenues were $9.8 billion for the quarter, a decrease of 11% year-over-year while the underlying base business grew 3%. This excludes a negative 7 percentage point impact from foreign exchange and a net negative 7 percentage point impact from acquisitions, divestitures and the now ended AstraZeneca JV.

I should note that the impact from foreign exchange includes the benefit of approximately $190 million of revenue from our hedging program. Growth overall was properly driven by four core focus areas of diabetes, hospital acute care, oncology and vaccines in our pharmaceutical business and by the 10% growth in our animal health business.

Moving now to expenses, gross margin was 75.4% in the quarter, an increase of 280 basis points year-over-year. Lower inventory write-offs and foreign exchange provided the primary benefit in the quarter. Total operating expenses were $463 million lower this quarter, primarily driven by marketing and administrative expenses, which declined 15% versus prior year due to the favorable impact of foreign exchange, net favorability from acquisitions and divestitures and lower direct selling costs.

Research and development expenses declined 2% as increased spending in the quarter was more than offset by foreign exchange. With our ongoing cost reductions, we are on track to meet or exceed the $2.5 billion in savings versus 2012 by the end of this year.

Finally, our non-GAAP effective tax rate for the quarter was 26%. The 180 basis point increase versus the prior year primarily reflects a discrete item recorded this quarter related to an adjustment for deferred taxes associated with restructuring activities.

Overall, we earned $0.86 per share in the second quarter delivering 1% growth despite meaningful headwinds from foreign exchange and the net negative impact of acquisitions, divestitures and the now ended AstraZeneca JV. Our commitment to expense management coupled with focused investments in key brands continues to produce results.

Now turning to the outlook for the remainder of 2015. Accounting for our performance in the first half of the year, we are updating our top-line revenue guidance to a range of $38.6 billion to $39.8 billion. While we feel comfortable moving to a midpoint of $39.2 billion for the full year 2015, we feel the range is appropriate due to the potential impact of foreign exchange volatility.

Moving to PGM, we expect full-year gross margin to be approximately 125 basis points higher versus 2014. We continue to expect an overall decrease in operating expenses as lower marketing and administrative expenses are partially offset by a modest increase in research and development expense. Altogether we anticipate total operating expenses in the second half of 2015 to be approximately $200 million lower than in the prior year.

Regarding our non-GAAP effective tax rate, we now expect the full-year effective tax rate will be between 23% and 24% as we account for the higher rate in the second quarter. Taking these changes into account and given our strong operational performance in the first half of 2015, we are now increasing our non-GAAP EPS range to $3.45 to $3.55. We are also updating the range for our GAAP EPS guidance.

As we've discussed over the past year, we've been monitoring the situation in Venezuela. Based on evolving economic conditions and volatility in the country, our evaluations have led us to take a $715 million charge in the second quarter to revalue our net monetary assets in the country.

While we have taken this action, we will work with the government to continue to get essential medicines into the country and to ensure continued positive US dollar cash flows from our operations. We now expect GAAP EPS to be $1.52 to $1.71 for full year 2015 with the charge related to Venezuela partially offset by the anticipated gain on the previously announced sale of CGRP program, which will be accounted for in the third quarter.

Finally, touching briefly on capital allocation, we remain focused on our commitment to returning cash to shareholders and have over the last 12 months returned $11 billion via the dividend and share repurchase. Altogether, we are encouraged by the growth in our business and the leverage

we are delivering through our focused strategy. As we move forward, we remain committed to transforming our operating model, achieving our cost reduction targets and ensuring we deliver a leveraged P&L. Now I will turn the call over to Roger.

Roger Perlmutter - *Merck & Co., Inc. - EVP & President, Merck Research Laboratories*

Thanks, Rob. I will briefly review some of the accomplishments in research and development during the second quarter. First, with respect to KEYTRUDA, our PD-1 directed monoclonal antibody designed to promote activation of pre-existing tumor-directed immune responses, we announced that the European Commission granted marketing authorization for KEYTRUDA in the first and second-line setting for patients with advanced melanoma. This approval includes data from our KEYNOTE-006 study, which compared KEYTRUDA to ipilimumab in the first and second-line treatment of patients with advanced melanoma.

Details of this study, including the favorable outcomes observed for response rates, progression-free survival and overall survival, were published in the New England Journal of Medicine and were also incorporated into regulatory approval of KEYTRUDA in Australia. We have filed the KEYNOTE-006 data as a supplemental BLA with the FDA and have also filed an sBLA for our KEYNOTE-002 study where therapy with KEYTRUDA proved superior to traditional chemotherapy with respect to both response rate and progression-free survival.

During the quarter, the FDA granted priority review to our supplemental license application for the use of KEYTRUDA in patients with advanced treatment refractory non-small cell lung cancer where EGF receptor or ALK-directed therapy is not indicated. Data supporting this application also published in the New England Journal of Medicine demonstrated that expression of PD-L1, one of two ligands for PD-1, the target of KEYTRUDA in greater than 50% of tumor cells, was associated with substantially higher response rates than were seen in patients whose tumors did not express PD-L1.

These responses occurred irrespective of the underlying histologic classification of the presenting non-small cell lung cancer. These data were included in our recent submission to the FDA, which has an action date of October 2. We continue to see responses in patients suffering from a broad range of tumor types following treatment with KEYTRUDA. Registration-enabling studies are already underway in many of these settings. Data on additional KEYTRUDA responsive tumors were presented at the American Society for Clinical Oncology meetings last month.

Among the most interesting presentations selected from more than 30 abstracts describing the activity of KEYTRUDA was a study from Johns Hopkins University demonstrating that responsiveness to KEYTRUDA in patients suffering from metastatic colorectal cancer was associated with tumor-specific deficits in DNA repair mechanisms. These data, which also appeared in the New England Journal of Medicine, provides support for the view that control of tumor growth following KEYTRUDA administration is in part determined by the frequency of mutations in tumor DNA that could give rise to novel immune targets in the tumor cells. Studies of this type suggest ways in which the efficacy of KEYTRUDA might be further enhanced. Additional studies examining the importance of tumor-specific DNA repair deficits in dictating KEYTRUDA responsiveness in cancer patients will begin in the very near future.

In infectious diseases, the Committee on Human Medicinal Products, or the EMA, recommended approval of ZERBAXA, our next-generation antibiotic targeting resistant gram-negative bacteria, for the treatment of complicated intra-abdominal or urinary tract infections, including pyelonephritis. Once the CHMP decision is ratified by the European Commission, which could occur by the end of September, ZERBAXA will become available in all member states of the European Union.

I'm also pleased to report that both the EMA and the FDA have accepted our filing for the use of our grazoprevir/elbasvir tablet in patients suffering from chronic hepatitis C virus infection. In Europe, our file was granted accelerated assessment for the treatment of infection with hepatitis C virus genotypes 1, 3, 4 and 6. The accelerated assessment was based on the significant unmet medical need that exists in hepatitis C virus-infected patients with chronic renal insufficiency.

The grazoprevir/elbasvir combination was previously granted breakthrough designation by the FDA and have now been informed that our file, which supports the use of the combination for hepatitis C genotypes 1, 4 and 6, will receive priority review with a PDUFA date of January 28, 2016. Site inspections in support of the US filing have already begun.

During this quarter, we submitted our complete response file for sugammadex marketed in over 60 countries around the world as Bridion for the reversal of neuromuscular blockade induced by rocuronium or vecuronium, drugs that are employed during certain surgical procedures. We've been informed that there will be an FDA advisory committee meeting to review the sugammadex filing on November 6 supporting a PDUFA date of December 19.

I should also note that we continue to have good discussions with the PMDA in Japan regarding our filing for omarigliptin, our once weekly DPP-4 inhibitor for the control of hyperglycemia in patients with type 2 diabetes. We anticipate filing for approval of omarigliptin in the United States before the end of the year.

During our first-quarter earnings call, I provided top-line information on the TECOS study, which assessed cardiovascular outcomes in patients receiving Januvia for glycemic control as compared to those treated with other regimens. Details of this study were presented in June at the American Diabetes Association annual meeting and were published simultaneously in the New England Journal of Medicine.

Beyond TECOS, I will remind you that we are also engaged in a 30,000 patient outcomes study called REVEAL testing whether anacetrapib, our novel CETP inhibitor, can, when added to standard therapy, reduce the frequency of major cardiovascular events in patients at significant risk for such events.

As I mentioned in April, the REVEAL steering committee continues to evaluate a change in the study protocol to include ischemic stroke as a component of the primary composite endpoint. Their proposal must be fully vetted by governance committees and regulatory agencies and I expect that they will publish the proposed modifications. The steering committee estimates that the first interim analysis with this new protocol will take place towards the end of this year. In the meantime, the study is proceeding as planned.

Finally, we've continued to make progress in business development. To cite two recent examples, last week, we announced an important expansion of our agreement with Ablynx, enabling us to select up to 12 additional programs involving nanobodies, the products of B lymphocytes in the South American llama. Nanobodies are small, single chain antibodies that may be concatenated relatively simply using well described molecular engineering techniques to produce multivalent therapeutic candidates, including nanobodies that block multiple immune checkpoint targets simultaneously.

In a second related example, today, we announced the acquisition of cCAM Biotherapeutics, an Israeli company pursuing novel immunotherapies for cancer. Included among their drug candidates is CM24, a humanized monoclonal antibody in Phase 1 trials for the treatment of advanced malignancy. CM24 is specific for the cCAM one cell adhesion molecule, which, based on preclinical analyses, affects the ability of tumor-specific lymphocytes to control the growth of malignant cells. Additional details regarding this acquisition can be found in our press release.

In sum, during the second quarter, our teams made meaningful progress in developing key new therapies for the treatment of malignancy, hepatitis C virus infection and resistant bacterial infections. I will now turn the call over to Joe.

Joseph Romanelli - *Merck & Co., Inc. - VP, IR*

Thanks, Roger and Darla, we will begin the Q&A segment of our call this morning and for the callers, if you can limit yourself to one or two questions, that way we can get through as many people in the queue as possible. So Darla, we will take our first caller, please.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions). David Risinger, Morgan Stanley.

David Risinger - *Morgan Stanley - Analyst*

Thanks very much and I guess I should start by congratulating you, Joe. It's been great to work with you and we will miss you and want to offer my congrats to Teri as well. I look forward to working with you again.

With respect to my questions, I guess one question on Remicade biosimilar that I'm not clear on is are governments trying to leverage the Remicade biosimilar and push down pricing of other branded anti-TNFs? And along those lines, do you expect any implications from the NOR-SWITCH study when that report is out? So that's my first question.

And then I guess my second question is could you just walk through what we should focus on in the fall at upcoming cancer conferences on your I/O franchise? Thank you.

Adam Schechter - *Merck & Co., Inc. - EVP & President, Global Human Health*

With regard to biosimilars, right now, we are not seeing a major impact in products outside of Remicade. So for example, if you look at Simponi, we continue to see good Simponi growth and we haven't seen any significant impact to Simponi based upon Remicade being a biosimilar.

At this point in time, we are not seeing a major impact from substitution. As you mentioned, there is the study that's being done in Scandinavia. We will see the results of that study and over time, I believe that there will be additional impact from studies as such, but I think it will take time, Dave.

Roger Perlmutter - *Merck & Co., Inc. - EVP & President, Merck Research Laboratories*

Yes, the question was the fall conferences. In the fall, we are going to have a lot of data at AASLD and I expect we will have the opportunity to present some data with respect to our triplet therapy, which will be quite interesting going forward. And in immuno-oncology, there are a variety of oncology meetings. I think the ESMO meetings are probably going to be the most interesting in Europe.

Operator

Marc Goodman, UBS.

Marc Goodman - *UBS - Analyst*

Just to continue on the Remicade, just curious -- help us with how pricing is being with the biosimilar. And can you talk about China a little bit? Obviously, sales were pretty good there, but we are hearing a lot of slowdown in China. There's a lot of things going on there. Talk about your new product launches relative to what's happening in China and how we should expect your growth. Can we grow double digits for the next couple of years there? And then just lastly on the gross margin, can you just give us the impact that foreign exchange had on the gross margin? Thanks.

Adam Schechter - *Merck & Co., Inc. - EVP & President, Global Human Health*

Let me start with the biosimilars. I'll give you some additional context and then I will briefly talk about China. If you look at what's occurring in the marketplace, we've definitely seen an increased impact in our first full quarter since loss of exclusivity in the second wave, the core European markets. We are seeing mandatory price reductions based upon reference pricing impacts. And as I reported last quarter, biosimilar discounts we've seen as high as 45%.

However, we still maintain about a 95% marketshare and we are facing mostly the reference pricing as the key issue as we speak right now. Over time, we believe that as more new patients come into the market, we will lose marketshare because we've been able to hold on to the vast majority. We've won most tenders for existing patients. So it really is the new patients coming in that over time we'll begin to lose.

So taking all of that together, we expect that the impacts from loss exclusivity on the Remicade business for this year will exceed the growth that we are seeing for Simponi. But I will mention as I said before we expect Simponi will continue to grow despite the increased utilization of Remicade biosimilars.

If you look at China, we had 8% growth and we saw growth across our hospital acute care business and diversified brands. There is no doubt that we are seeing some macro trends of a slowdown, but I still believe there's significant opportunity there. We have good traction with multiple key products that we have, the products that you would think of, but we are also pursuing innovation and we are looking forward to having NRDL pricing approval for products like Januvia and ZETIA in the future, which I think could be growth drivers for us in that market. So despite the macro trends, I do believe over time that China can remain an important market for us.

Rob Davis - *Merck & Co., Inc. - EVP & CFO*

With regards to your question on the impact of foreign currency and gross margin, it accounted for about half of the increase you saw in the 2015 second quarter versus second quarter of 2014.

Operator

Tim Anderson, Bernstein.

Tim Anderson - *Sanford Bernstein - Analyst*

Thank you. A couple of questions. Obviously, one of the important controversies with investors is how KEYTRUDA's label will read in second-line lung. I'm wondering if you can give us your latest thinking. Will it likely be broad, meaning in allcomers, or will it likely be narrow, meaning only in PD-L1 positive patients? I know in the past you've said you think the label would probably want to reflect the data in both patient populations, but I don't really know what that means in terms of the indication per se.

And on the same line of questioning, what's the most updated data you have on KEYNOTE-001 in PD-L1 negative patients in terms of the number of patients you have? I think originally that data set was around 40 patients. I think at ASCO I saw that it had grown to about 70 patients that were PD-L1 negative. What's going to be the final number that FDA has in the KEYTRUDA application?

Roger Perlmutter - *Merck & Co., Inc. - EVP & President, Merck Research Laboratories*

First of all, with respect to the explicit language of the label, I can't comment on what FDA will ultimately decide to do. Obviously, the major claims in the study, as I indicated, relate to response rates in PD-L1 positive patients and that fundamentally is what we will be focused on. But, at the same time, as I've said before, I don't think that the data that exists in the PD-L1 negative population can be ignored. The exact number of PD-L1 negative patients in the file -- we would have to get back to you on that, but you are right, it's going to be somewhere close to 100 patients. So as I say, it's a considerable number there and there are meaningful responses in that patient population, which one would guess will be reflected in one way or another.

Operator

Jami Rubin, Goldman Sachs.

Jami Rubin - *Goldman Sachs - Analyst*

Thank you. A couple questions. Ken, first for you. Just am wondering if you guys are giving any second thoughts to how you might consider unlocking the value of the diversified brands business. I know last year there were rumors in the press that you were considering bundling that business and selling it. And I think you decided not to because of the substantial tax leakage, but, as you know, we are seeing companies come up with all sorts of creative ways to either spin out certain assets, sell assets, etc., etc. So I am just wondering maybe if you or Rob can comment on what you might be thinking in terms of options for that business because obviously it is having a significant drag on your top line.

And my second question for you, Roger, is on anacetrapib. If you could comment on the drug's long half-life, how much of a disadvantage do you see this? Obviously, I think the Street has basically written your CETP off because of this issue. If you could put that into context for us. Thanks very much.

Ken Frazier - *Merck & Co., Inc. - Chairman & CEO*

First of all, as we've said before, we are really focused on prioritization and as we look across our entire business, we continue to challenge ourselves to determine whether specific assets, including diversified brands, would have more value outside of Merck or as part of our business. You've seen us take action and divest certain assets -- I would say ophthalmology, MCC -- when we feel that we can do that in a way that's advantageous to the Company long term.

So while we are cognizant of the issue that you just raised relative to the top-line growth, we have to look at the difficulty associated with it and what are the vehicles that we could use to do that. So I could just summarize it by saying that we will look at these mature assets and we will focus on the impact that they have on cash flow, as well as the impact that they have on growth and we will try to make the right decision relative to the specific opportunities that we have. Thanks.

Roger Perlmutter - *Merck & Co., Inc. - EVP & President, Merck Research Laboratories*

Jami, with respect to anacetrapib, I think the really important issue is the benefit/risk ratio. We have a very large, as you know, study, 30,000 patient study, which will go on for quite a long time and we are capturing all the adverse experience data within that patient population.

The benefit of reducing major cardiovascular events is significant; it's very meaningful. It can in fact -- it's certainly a morbidity benefit -- it could in fact be a mortality benefit. That has to be then juxtaposed with the adverse experience profile. Because we have so many patients who have been treated for such a long time, I think we will have a very good sense of that and depending upon the magnitude of the benefit that we see, the consequence we believe of LDL cholesterol-lowering, also HDL raising, LPa-lowering, all of those things together will have to be juxtaposed with what the adverse experience profile looks like. Once we have the data, I think we will have a better sense of that.

Adam Schechter - *Merck & Co., Inc. - EVP & President, Global Human Health*

Jami, this is Adam. The only thing I'd add is I'm sure you remember when we launched the 4S trial, also when we launched the ASCOT trial in the cholesterol area, I wished we had an outcomes trial at the time of launch for either Zocor or Mevacor. I think it would've made such a substantial difference. So I'm very excited about the potential opportunity of launching a product with a 30,000 patient outcomes trial into an area that we know extraordinarily well, which is the cholesterol-lowering market.

Operator

John Boris, SunTrust.

John Boris - *SunTrust Robinson Humphrey - Analyst*

Thanks for taking the questions and congrats, Joe. First question on the oncology franchise for Roger and Adam. Can you maybe just articulate, especially in lung, when you think you might have an OS benefit? And Adam, for you, having or not having that in the label, how does that position you relative to your competition, most notably Opdivo, that has that in the label?

And then second question, it looks as though, Ken, and this is also for Rob, repatriation seems to be a real possibility this year in order to pay for some highway trust fund funding. You have a significant amount of cash on the balance sheet. We estimate at the end of 1Q at about close to $29 billion with 80% to 90% of that offshore. If you do have an opportunity to potentially repatriate that, how are you thinking about deploying that if you are able to bring it back? Thanks.

Roger Perlmutter - *Merck & Co., Inc. - EVP & President, Merck Research Laboratories*

So John, with respect to the 010 study, which is a study that will provide a first look at an overall survival benefit for KEYTRUDA in the non-small cell lung cancer setting, this is a study that compares two doses of KEYTRUDA, 2 milligrams, 10 milligrams versus conventional chemotherapy. It's a good sized study and there is the opportunity for an interim analysis, which, of course, is event-driven. At the time when sufficient events are accrued, then the data monitoring committee will look at that.

In principle, they could see a benefit that would result in a recommendation to modify the study or they could continue the study, which is designed to end sometime around the end of the year. So those are the times when we potentially would see the overall survival benefit.

Adam Schechter - *Merck & Co., Inc. - EVP & President, Global Human Health*

John, let me provide some context and then I'll answer your question directly. First of all, I'm sure you've seen the IMS data, and the May IMS data just came out. And KEYTRUDA has more than an 80% anti-PD-1 share in all of melanoma patients. In addition to that, KEYTRUDA is now the number one treatment in melanoma at a 35% overall patient share. So hopefully, you've seen that we are able to do well in the marketplace.

With regard to lung, we've built an oncology business unit to maximize KEYTRUDA over the long-term. Just as we were ready to launch in melanoma, we will be ready to launch in lung. We are ready for that. We think it's a very significant opportunity. Of course we'd prefer to have overall survival data to promote. And as Roger said, those data are maturing in our broad clinical program.

But we have the capabilities now to be successful, and I think physicians have seen the overall survival data in melanoma. They begin to assume that you'll have overall survival data once you have the studies underway. So although we prefer to have it at the time of launch, the good news is that as Roger said, we have the study to show it over time.

Roger Perlmutter - *Merck & Co., Inc. - EVP & President, Merck Research Laboratories*

Maybe the only other thing to emphasize is if you look at the PD-L1 positive population, so in those individuals with proportion scores above 50%, the response rates are really quite extraordinary. So in treatment naive patients, the response rates were 50%. Those are really quite unprecedented response rates in non-small cell lung cancer. One would expect those to translate into survival data. We will have a chance to see.

Rob Davis - *Merck & Co., Inc. - EVP & CFO*

John, with regard to your question about repatriation, firstly I would say, obviously, we are very supportive of comprehensive tax reform. And I think listening to the dialogue as it's evolving in Washington, clearly it is something that I think is a possibility. As we look at it, it's important that it is comprehensive, that it does look at a territorial system, that it does consider a flat tax and it does look at ways to advantage companies that develop intellectual property in the United States.

So all of that is being discussed and we are very supportive of that. As far as the cash we have offshore and what we would do if we did have a major repatriation, right now I don't want to get into specifics about a strategy. I would just go back to say our overall capital allocation philosophy remains the same. First and foremost, we are going to fund the business. And then beyond that, we will look to deploy capital towards business development opportunities, primarily focused in areas that help to augment our pipeline. I think you heard some examples of that even this morning on the call from Roger.

And then clearly, we remain committed to our dividend and we will consider a share repurchase. If you look at what we've done over the past, we have deployed meaningful capital back to shareholders and all of that would remain the same. So as we would see that, all of that will inform any strategy we think of in using the cash.

Operator

Mark Schoenebaum, Evercore ISI.

Mark Schoenebaum - *Evercore ISI - Analyst*

I really appreciate you taking the question. Start with Adam, if I may. Maybe -- it's early, early days, you don't have a label, understood. But post-ASCO, doctors have seen that you are on the NCCN. Roughly speaking, how many second-line patients have you guys treated with KEYTRUDA and do you anticipate that once fully approved by FDA that second-line patients that want to elect for KEYTRUDA will need a biopsy prior? So in other words, at the time of initiation of second-line therapy, they will need what presumably would be a second biopsy?

It appears not to be the case with nivolumab because obviously they are doing an allcomers trial, but whether Merck gets PD-L1 positives and negatives on the label, I'm just curious to know whether or not you think physicians are going to want to get a biopsy?

And then also, Adam -- well, this is more for Ken and Rob, I suppose -- this builds on Jami's question -- you've considered in the past very thoughtfully I think what to do with animal health and you elected to keep it. But now the PE arbitrage is substantial again, Zoetis at 30 times, Merck at 17 times, which is just a pretty dramatic opportunity if you were to separate those businesses and liberate value. Is your choice to not do it now have to do with these PE multiples in animal health just aren't sustainable, or is there some other reason why you wouldn't come back to this and study it hard again?

And then finally for Roger, I just wanted to ask, there's been some confusion around this question, so I apologize. I've asked you this before, but I just want to just get the truth out there. But the CETP (inaudible) ongoing, is that trial powered to hit on the final analysis assuming only an LDL impact on outcomes, or does there also need to be some sort of contribution from the raising of HDL on outcomes under base case assumptions in order for that trial to hit the endpoint? And then how is enrollment going in the prodromal-based trial? We've heard it slowed. Just wondering if that's true. Thank you.

If you don't want to answer all those questions, you can pick and choose. But I figured it's Joe's last call, so I can tick him off a little bit.

Adam Schechter - *Merck & Co., Inc. - EVP & President, Global Human Health*

So Mark, let me give you some context on KEYTRUDA. So if you look at KEYTRUDA, as you know, we only promote the product on label. And if you look at the data we have, about 85% of the use we believe is in melanoma. Of that 85%, we believe about 70% of it is on label, which is within the improved indication. So that gives you a sense of where that is.

With regard to the diagnostic testing, diagnostic testing for treatment decisions has really become a standard and widespread in the treatment of cancer. So go to HER2, ALK, EGFR. So we believe that physicians will do that as a standard practice and we expect that we will have the availability of the test on the day that we launch lung. So we believe it will be easy for them to do. They typically are doing it already and we will make sure it's widely available.

Mark Schoenebaum - *Evercore ISI - Analyst*

Do you think the FDA's going to require that before getting second-line KEYTRUDA in lung?

Roger Perlmutter - *Merck & Co., Inc. - EVP & President, Merck Research Laboratories*

I really can't speculate, Mark, on what the FDA will say. They will look at the totality (multiple speakers).

Adam Schechter - *Merck & Co., Inc. - EVP & President, Global Human Health*

Irrespective of what the FDA says, Mark, I think it is going to become standard practice that the doctors are going to want to know if they are PD-L1 expressive because it's going to have a very different discussion with the patient if they know that they are expressive or not. If you can say to a patient based upon your expression to clinical trials, you could have a greater than 50% response, that's different than saying you'd have a 10% response rate. So I think physicians are going to want that information and data irrespective of what the FDA puts on the label or not; and I also believe that payers, particularly outside the US, are going to be very interested in having that worked on.

Mark Schoenebaum - *Evercore ISI - Analyst*

And Adam, just to be clear you believe the physicians will want to have the second biopsy done at the time of second-line standard of care.

Adam Schechter - *Merck & Co., Inc. - EVP & President, Global Human Health*

I think they will do it as a first biopsy. I think they are going to just want to know it as part of standard of care from the beginning as we move forward.

Joseph Romanelli - *Merck & Co., Inc. - VP, IR*

(multiple speakers) CETP in (inaudible).

Mark Schoenebaum - *Evercore ISI - Analyst*

And also the animal health PE arbitrage question.

Roger Perlmutter - *Merck & Co., Inc. - EVP & President, Merck Research Laboratories*

But I won't answer that one for you, Mark. Just to be clear, you've asked the question before, but the REVEAL is powered to see the LDL cholesterol lowering effect based on the nomogram that associates LDL cholesterol lowering with reductions in major cardiovascular events. So we would see that, we believe.

And with respect to the base studies, prodromal enrollment is always challenging. There is no question. And part of the issue with respect to prodromal enrollment is that there are a lot of people out there who believe they have cognitive impairment, are concerned about their mental functioning and when you actually image those people, a small fraction of them have evidence of plaque and so the screen failure rate is significant. Nevertheless, we are making good progress in that study.

Ken Frazier - *Merck & Co., Inc. - Chairman & CEO*

Mark, this is Ken Frazier. I'm going to try to take a shot at your arbitrage question. I am pleased that you characterized it as an arbitrage question. The fact of the matter is our animal health business grew very strongly this quarter. It continues to grow well. It continues to have a very good pipeline and so we think about the issue that you put on the table as we think about ways in which we can create value. But we also look at the business from a long-term perspective and I would say that while we don't take anything off the table, we always consider changes in the marketplace.

I want to come back to what I've always said. We plan to augment our animal health business with additional BD. We continue to see this business as a key growth driver with healthy margins and a strong market outlook over the long term. And as for the difference between potential PEs for the animal health business versus the human health business, we are going to continue to focus on running our business. We are going to continue to focus on what's in our control, which is running the business, getting our products approved, augmenting the pipeline, launching these drugs.

Operator

Seamus Fernandez, Leerink.

Seamus Fernandez - *Leerink Partners - Analyst*

I assume we are done with Mark's questions and congrats, Joe. Just quickly, this is more for Roger than anything. Just in terms of -- to follow up on Tim's questions -- prospects for a broad label versus the file patient group. Can you just give us a sense of the importance of KEYNOTE-010 to the initial filing? And then can you maybe give us a little bit of color on when you expect the KEYNOTE-010 study to read out? I know the primary analysis is in the patient group that's over 50% PD-L1 expression, which I think many of us would have thought could have stopped in an interim, but it would seem that the overall patient group would also be very important to fully understand. So is that part of the reason why we continue to wait for KEYNOTE-010?

And then lastly, on REVEAL, with anacetrapib, Roger, can you just update us on when we might expect the paper on baseline characteristics? I think it would be interesting to know the baseline LDL in REVEAL, particularly in the context of a similar design to [HBS25]. And just additionally on anacetrapib, could you comment on some recent genetic findings correlating the risk of developing macular degeneration? I'm interested just more if the FDA has requested any substudies evaluating this risk. Thanks a lot.

Roger Perlmutter - *Merck & Co., Inc. - EVP & President, Merck Research Laboratories*

Okay, a lot of questions. First of all, with respect to the KEYNOTE-010 study, as you've said, there will be the final results, which we expect sometime towards the end of the year. But as I mentioned earlier, we have the potential for an interim analysis, which is event-driven. So I can't tell you when that interim analysis would take place, but that interim analysis could in principle result in a recommendation from the Data Safety Monitoring Board that the study be changed, potentially even stopped, I suppose, depending on the strength of the data. So it could happen sooner than that. The information from that study could in principle then contribute to the initial finding based on the [001F] in particular cohort, but it depends again on those analyses.

With respect to REVEAL, the baseline characteristics of patients -- we will present those baseline characteristics. I don't have the date exactly of when that would happen and of course, the study is being run by the Oxford Group, so they are the ones who are making decisions about publication of the REVEAL data, so we can get back to you on that. And of course, we are well aware of the potential association between CETP mutations and macular degeneration.

One of the things that we've done is looked very carefully in our patient population because we were aware of this. We did additional eye exams in our patient populations. The Data Safety Monitoring Board has been looking at that and thus far, we are not aware of any adverse affects. Nothing has been called to our attention. Of course, irrespective of the strength of the genetic association, we have to keep in mind that what we are doing

is interdicting CETP function quite late in life; individuals who inherent a genetic anomaly of course have it from the time of conception. So that would have a different impact. But thus far, we are not aware of -- we are looking at it closely and we are not aware of any impact.

Seamus Fernandez - *Leerink Partners - Analyst*

Very helpful. Thank you.

Operator

Tony Butler, Guggenheim Partners.

Tony Butler - *Guggenheim Partners - Analyst*

Adam, I've asked this question of you in the past, but just want to get an update. As the SG&A year-over-year declines, Rob made some references to that, but yet at least in the EU you are launching ZERBAXA and KEYTRUDA in melanoma. And it would strike me that the need for additional capital given you're not in oncology in Europe would require a substantial expense. So I would love for you to touch on that.

And then, Roger, lastly, just some update if you could on your compound with Plexxikon -- or the compound, yes, with Plexxikon and its role with PD-1 and/or GITR. Would appreciate that. And then, finally, Joe, all the best on your second tour and welcome back, Teri.

Adam Schechter - *Merck & Co., Inc. - EVP & President, Global Human Health*

So Tony, we are very much focused on maximizing each and every launch opportunity that we have. And when you look at the first dollar we spend, it's with the launch opportunities in Januvia, frankly. And what we've been able to do is make sure that when we see growth, we are able to put the money towards that growth. So even though you see SG&A declining overall, if you were to look at oncology or Januvia, you would see SG&A increasing over the past several years. And if you look at oncology, we are already there in Europe with Emend and we have a salesforce, we've increased that salesforce and we are continuing to grow.

So I just want to assure you that any time there's a growth opportunity, we are making sure that we have the right resources to maximize those opportunities for patients, but also obviously to grow those products.

Roger Perlmutter - *Merck & Co., Inc. - EVP & President, Merck Research Laboratories*

And just with respect, Tony, to the combination studies, of course, we have a very broad set underway. Nothing really to update you on there except to say that, with respect to the GITR studies, those studies began -- GIRT agonist -- began in June of last year. We have to progress fairly slowly because of the fact that it is an agonist antibody and hence an immune stimulator as opposed to something that relieves inhibition, or is a dis-inhibitor like KEYTRUDA.

Nevertheless, we have progressed and are moving forward in our Phase 1 studies and we've just begun combination studies with our GITR antibody and KEYTRUDA, so that's moving right along.

Operator

Colin Bristow, Bank of America Merrill Lynch.

Colin Bristow - *Bank of America Merrill Lynch - Analyst*

Thanks for taking the questions and, Joe, congrats; and Teri, looking forward to working with you. So just as we think about the hep C opportunity, recently, one of your peers highlighted that US hep C volumes have been trending lower than anticipated and the expectation was approximately 180,000 patients treated per year. Is this in line with your observations and expectations? And I'm just curious how you see this evolving over time.

And then secondly on the TECOS trial and Januvia trends, just to what extent do you expect TECOS to have a positive impact on Januvia volumes and share? Thanks.

Adam Schechter - *Merck & Co., Inc. - EVP & President, Global Human Health*

With regard to hepatitis C, I still believe that that represents a very significant opportunity for Merck, as well as a number of patients that will be treated. You've seen anywhere from 100,000 to 120,000 patients at maximum treated in the past. Now you're seeing even 170,000 to 200,000, which is still a significant increase from what was treated in the past even today.

It's not uncommon to see warehousing before a new drug comes to market. You saw that earlier before the Gilead compound came to market and obviously, as you have warehousing, you get a big bolus of patients and then it slows down a little bit over time. But I don't think there is a fundamental issue in the overall hepatitis C market. I still think it remains a very good attractive market and we are very excited about getting into that marketplace as soon as Roger and the team working with the regulatory agencies can get us into the market.

With regard to TECOS, obviously, we are very excited about the result. It's an important area for us, diabetes. We disproportionately invest in that area. I think that in general TECOS validated what physicians already were thinking in terms of the favorable tolerability profile of Januvia.

With that said, in markets around the world, we are able to promote it now. We've begun to promote it and I think that it has a very good perception in the marketplace. In other markets like the United States where we have to wait for it to be on the label before our representatives can actively promote the product, we are looking forward to getting the data in our label so we can promote it in the future. Obviously the results are helpful.

Operator

Gregg Gilbert, Deutsche Bank.

Gregg Gilbert - *Deutsche Bank - Analyst*

A couple quick ones. First, Adam, on diabetes, what would the implications be in your view if we saw positive outcomes for Lilly's SGLT2 inhibitor? Secondly, given Merck's history and expertise, are you interested in the lipid disorder space either from a BD or R&D standpoint? And lastly, perhaps for Ken and Rob, short of an overhaul of the US tax system, which seems unlikely, what is Merck doing to address the tax line longer term, as well as maximize access to your ex-US cash? Obviously, you've returned a lot of cash to shareholders, but you certainly could do more if you made certain corporate decisions. Thanks.

Adam Schechter - *Merck & Co., Inc. - EVP & President, Global Human Health*

First, with regard to SGLT2s, in general, if you look at the utilization of SGLT2s, they are typically after the use of Januvia. So typically it's metformin first, add on Januvia and then it's after the addon of Januvia. So that's the way they are currently being used. I don't see a significant change; although obviously we are not going to speculate on what the trial results could be for the SGLT2 drugs. So I still remain optimistic about our diabetes franchise.

With regard to lipids, I'm very excited about the potential opportunity to launch a CETP inhibitor. Lipids is an area that Merck has been involved in for many, many years starting with Mevacor and Zocor and this is an area we know very well. We continue to be there for other reasons with cardiovascular medicines and we will just see what the results show from the REVEAL trial.

Rob Davis - *Merck & Co., Inc. - EVP & CFO*

And Gregg, with regards to your question about the tax rate, obviously, I don't want to get into specific strategies, but it's safe to say that, as we look forward, we will continue to look for planning opportunities to bring the rate down and I do believe those opportunities continue to exist. So we are focused on understanding what our tax rate can be and trying to optimize that position with or without repatriation.

Operator

Vamil Divan, Credit Suisse.

Vamil Divan - *Credit Suisse - Analyst*

So just one more following up -- you talked about TECOS and the impact on Januvia financially. Just on IMPROVE-IT with VYTORIN and ZETIA, I would've thought even though it's not on the label yet that we may have seen some benefit there, but it didn't seem to have much of an impact yet. So I'm just curious how you think about the benefit from IMPROVE-IT maybe for the later part of this year and then maybe for next year after presumably you will have the data in the label at some point.

And then second, just separate topic on Pneumovax, if you can just kind of talk about the implications there with Prevnar having the adult indication. Have you seen any impact on Pneumovax from the added competition? Thank you.

Adam Schechter - *Merck & Co., Inc. - EVP & President, Global Human Health*

Sure, Vamil. With regard to IMPROVE-IT, obviously, we were very pleased with the results of the IMPROVE-IT trial. As you mentioned, in the United States, we can't promote that trial until we have it into label and we are looking forward to having it in the label as soon as possible.

With regard to what's happening in the marketplace, in the US, you've actually seen a flattening of ZETIA since the announcement of IMPROVE-IT because I think a lot of physicians became aware of the trial through the New England Journal of Medicine and reading about it very quickly. But what you haven't seen is a stem in the decline of VYTORIN in the United States. Once it's in our label, our representatives will actively be able to promote it.

With that said, as you know, in the US, the products will be going generic towards the end of next year. I think the greater impact for IMPROVE-IT is to try to help in the future when you start to think about a CETP inhibitor and the ability to get more patients to goal and lower LDL cholesterol levels.

Outside the US and Europe, we've seen where they are able to promote the product, that it does have a positive impact, but at the same time we've lost exclusivity of ZETIA in Canada, which has had a significant impact and we've seen some changes in France in terms of the ability to have guidelines of when these products are utilized.

Regarding Pneumovax, we have seen increased competition from the ACIP recommendations that now include Prevnar and we've seen it in this quarter. We believe we will see it in this year. However, if you look at the ACIP, Pneumovax is still recommended as a second dose after Prevnar. So we believe that over time we will catch up again because the patients will get the second dose. So the question is how long would this short, interim impact occur and when will patients come back to the second dose. And our teams have been working on how to find ways to encourage the patients to come back to the second dose.

Operator

Chris Schott, JPMorgan.

Chris Schott - *JPMorgan Chase - Analyst*

Couple quick ones. Maybe, Roger, can we get your updated view on the role you see for combination therapy as we think about the first line non-small cell lung cancer opportunities? Particularly just interested in your view of chemo/PD1 combos versus I/O, I/O combinations and just maybe just relative to monotherapy as we think about this playing out in the next few years.

Second question is on the BACE-inhibitor and just updated thoughts on that opportunity in light of the Lilly extension study and the updated Biogen data we just saw at AAIC. And I'm just going to wrap it up there. Thanks very much.

Roger Perlmutter - *Merck & Co., Inc. - EVP & President, Merck Research Laboratories*

First of all, with respect to combination therapy, I believe absolutely that we will find over time that while KEYTRUDA is foundational for therapy for a wide set of malignant diseases that there will be ways to optimize that therapy still further. And I think it will be based on molecular characterization of tumors because we want to preserve the most favorable benefit/risk profile. That's one of the reasons why we have so many of these combination studies going on and we are exploring the full set of combinations.

Without going into detail, the work which we've done and the work reported by our colleagues at John Hopkins really points to the importance of neo-antigens in tumor recognition. So one expects that therapies that increase the representation of mutations within tumor, that could be as simple as radiation therapy, it can be things that are chemotherapeutic agents that damage DNA, it can be ways of immunizing against tumor antigens, all of those things are things that we are pursuing. There are thousands of potential combinations one could pursue and we are trying to be smart about which ones have the highest likelihood of success. So we are also looking at things that affect tumor metabolism.

All of those are quite interesting and data from those will become available in not too long a time, so I am expecting that we will move to that, but I again point out how remarkable it is when you look at the response rates to KEYTRUDA monotherapy, particularly in selected patient populations. They are very impressive.

And second with regard to BACE, the data that have been presented with respect to antibodies directed against a beta, that's really quite a different mechanism from BACE inhibition. And I go back to sort of bedrock data. There is very impressive genetic data that tells us that individuals who have relatively high activity at beta secretase are at higher risk for developing dementia in their lives and they will develop it earlier as opposed to those who have lower levels of beta secretase. And that strongly suggests -- it's the most powerful data that we have and it strongly suggests if we can phenocopy that low level of beta secretase activity, we should reduce the risk of dementia. Whether we can do that in an individual in their seventh decade is in fact exactly what we are testing using our BACE-inhibitor in both mild to moderate and prodromal studies.

I don't think that we can look at the data from an a beta sequestrant, an antibody directed against a beta, and really interpret it in the same way because it's really unclear what those antibodies are doing. We know they cause an inflammatory response and are associated with an adverse affect; exactly what they do in terms of delaying the progression -- if they do that at all -- delaying the progression of either plaque or cognitive impairment, I think more time is needed.

Joseph Romanelli - *Merck & Co., Inc. - VP, IR*

Great. Thank you, Roger and Ken, do you want to give some final thoughts?

Ken Frazier - *Merck & Co., Inc. - Chairman & CEO*

Again, thanks, Joe, for all you've done. This has been another solid quarter for us. Our four therapeutic areas grew 9%; animal health grew 10%; KEYTRUDA launch is progressing ahead of expectations. But the most important thing is, as we move into the future, we are tremendously excited by the opportunities that we have in hep C, with KEYTRUDA, particularly with non-small cell lung cancer coming up and we will continue to augment our pipeline as you saw this quarter, we did with BD deals, like cCAM and Ablynx. The chance to augment our pipeline is there. We are very excited about the transition to the future that is going on inside Merck. So thank you very much for your continuing interest.

Operator

This concludes Merck's second-quarter 2015 earnings conference call. You may now disconnect.
