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EDITED TRANSCRIPT

MRK - Q3 2014 Merck & Co Inc Earnings Call

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OVERVIEW:

Co. reported 3Q14 revenues of $10.6b and non-GAAP EPS of $0.90. Expects 2014 revenue to be $42.4-42.8b and GAAP EPS to be $4.06-4.29.

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PRESENTATION

Operator

Good day everyone and welcome to Merck's third-quarter 2014 earnings conference call. Today's call is being recorded. At this time I would like to turn the call over to Joseph Romanelli, Vice President of Investor Relations. Please go ahead.

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

Thank you, Jackie, and good morning, everyone. I would also like to say good afternoon and good evening to everyone listening outside the United States. Welcome to Merck's third-quarter 2014 conference call.

Before I turn the call over to Ken I want to remind you of a couple of items. First, there are a number of items in the GAAP results such as acquisition-related charges, restructuring costs and certain other items. We have excluded these items in our non-GAAP reconciliation tables and you can see them in our press release in Table 2. This will give you a better sense of our underlying business performance.

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There are three tables in the press release. The first table provides the GAAP results. Table number 2 reconciles our GAAP P&L to the non-GAAP results and Table 3 provides sales performance for the Company's business units and our products, both on a reported basis and excluding foreign exchange.

During the call we will be referring to Table 2 when we discuss the P&L and Table 3 when we talk about revenue performance.

Finally, 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 based upon Merck's current belief and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or uncertainties materialize actual results may differ materially from those set forth in the forward-looking statements.

The Company's SEC filings including Item 1A in the 2013 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 forward-looking statements made this morning. Merck undertakes no obligation to publicly update any forward-looking statement. Our SEC filings can be found on the website at Merck.com and you can also find our earnings release and all the tables there as well.

Now with that, I would like to say good morning to Ken Frazier, our Chairman and CEO; Rob Davis, our CFO; Adam Schechter, Head of Global Human Health; and Dr. Roger Perlmutter, Head of Merck Research Labs. With that I will turn the call over to Ken. Ken?

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

Thanks, Joe. Good morning everyone. Thank you all for joining the call today. We again reported solid earnings this morning but before I discuss our performance, please allow me to remind you of the strategy that consistently guides us. Merck remains focused on bringing forward medicines and vaccines that make a difference to patients, payers and healthcare systems around the world. In a healthcare marketplace where resources are increasingly scarce, our strategy continues to be all about meaningful innovation.

To accomplish this, last October we announced our global initiative to sharpen our commercial and R&D focus, redesign our operating model and reduce our cost base. We launched this multiyear initiative to transform Merck into a more competitive, more innovative Company and to build a platform for sustained future growth.

Now one year later I am pleased to report that this quarter's results reflect the steady progress we have made in each of these areas. We identified four areas of focus where we will compete to win and our investments are paying off.

In our diabetes business, we reallocated resources and invested significantly in Januvia and have now reported our second consecutive quarter of growth in the US and in international markets. This marks an important turnaround from where we were last year.

Our acute care business grew by double digits this quarter as we are now seeing the impact of our investments. These brands will continue to be key drivers of growth in emerging markets.

Our vaccines business remains a fundamental contributor to Merck despite a decline this quarter due to the timing of US public sector purchases. We are also looking forward to regulatory action for V503, our next-generation 9-valent vaccine for HPV. And in oncology, our integrated business unit has made strides to file and launch KEYTRUDA.

This quarter we received approval from the FDA for KEYTRUDA, the first anti-PD-1 therapy approved in the US for advanced melanoma. And I'm happy to report that we also recently received breakthrough designation from the FDA for KEYTRUDA as a potential therapy for advanced non-small cell lung cancer. We continue to study KEYTRUDA in more than 30 different tumor types and are encouraged by recent data presented at the European Society for Medical Oncology in five different cancers. Roger will talk more in a few minutes about the progress we continue to make with the KEYTRUDA program and Adam will discuss the recent US launch in advanced melanoma.

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Also doing the third quarter, we received US approval from the FDA for BELSOMRA, our novel treatment for insomnia which we anticipate launching early next year.

In addition to increasing our focus on the key therapeutic areas that represent our best opportunities, we continued to rigorously prioritize our portfolio to ensure that all of our businesses have the potential to be market leaders and create value for shareholders. This approach led us to divest human health products and business areas that amounted to nearly $1 billion in annual revenue.

That focus also led to the recently completed sale of our $2 billion revenue Consumer Care business to Bayer. We then employed the proceeds of that sale to complete the acquisition of Idenix and to increase our return of cash to shareholders this year.

The same approach led us to a different conclusion with regard to our Animal Health business which we believe will continue to generate long-term value for Merck. Animal Health saw strong growth this quarter across all species. We look forward to additional innovation coming out of our Animal Health pipeline and remain committed to growing this business which is already a market leader in key segments of the global Animal Health market.

Let me now turn to the progress we have made in sharpening the focus of our R&D organization. Along with the strong progress we have made on our KEYTRUDA program, we continue to advance our work to develop a highly effective once-daily oral pan-genotypic regimen for the treatment of hepatitis C. As I mentioned earlier, we also completed the acquisition of Idenix Pharmaceuticals and its promising portfolio of hepatitis C candidates which complement our internal development efforts.

We will continue to focus on our highest potential growth opportunities while rigorously prioritizing our pipeline bolstering it with external assets while divesting our out-licensing programs and candidates that are better suited to create value elsewhere.

For example this quarter, we entered into an agreement to out-license MK-3222, our investigational treatment for chronic plaque psoriasis to Sun Pharma. All of these actions are in keeping with our intention to be the premier research intensive biopharmaceutical company.

Lastly, we have made significant progress in redesigning our operating model and reducing our cost base. You will recall that last October we targeted a net reduction in annual operating expenses of approximately $2.5 billion off our full-year 2012 expense levels by the end of 2015.

As a result of disciplined cost management, I'm pleased that we remain on track to achieve our target for 2015 and our overall savings goal by the end of 2015. These savings have enabled us to better target resources to keep priorities across the enterprise and to accomplish the goals I mentioned today.

At the same time this discipline allows us to return a high level of cash to shareholders through both a dividend and our stock repurchase program. Over the past 12 months, we have returned nearly $11.5 billion to our shareholders.

We are rebuilding Merck for sustainable future growth. We have sharpened our commercial focus and are launching products with the potential to make a significant difference to patients while providing value to payers, providers and healthcare systems.

We've focused and prioritized our R&D efforts so that we may continue to translate cutting-edge science into medicines and vaccines that have meaningful differentiated attributes and we have continued to aggressively manage our cost to ensure that our resources are focused on our most promising opportunities for growth. Taken together, these actions have created near and longer-term opportunities that will allow Merck to continue to drive value for both shareholders and society.

Now I would like to turn the call over to Adam Schechter.

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

Thank you, Ken, and good morning, everyone. This morning I will provide you with an overview of global human health third-quarter results and also provide some commentary on the early days of the KEYTRUDA launch. My commentary will be on a constant currency basis.

Overall sales reached $9.1 billion reflecting the following, growth in core areas such as diabetes, immunology and acute-care which were offset by more than $150 million in product divestitures, hepatitis C market dynamics and patent expiries. First, I will review our core product areas and then I will provide an update on our regional performance and I will start with primary care.

The Januvia franchise reached more than $1.4 billion in sales and grew 5% in the quarter reflecting growth in the US and international markets. In the US, sales grew 6% on continued volume increases. We are encouraged by the growth trends we saw in the third quarter and the month of October. We are seeing positive results from our efforts to defend our 75% market share and to grow the DPP-4 class.

In our international markets, sales grew 4% driven by Europe and the emerging markets. Sales declined in Japan due to a 10% repricing that occurred in April and the overall competitive environment for DPP-4s. We are confident that we will deliver global sales growth for Januvia franchise in 2014.

Next in hospital and specialty care, sales of Isentress were approximately $410 million in the third quarter, a decline of 3%. Internationally our growth in Europe was balanced by the timing of tenders in the emerging markets. In the US, Isentress sales were impacted by customer buying patterns and the competitive dynamics in the HIV market.

Sales of our immunology products reached more than $770 million in the third quarter growing 9%. We are seeing continued strong uptake of Simponi across multiple indications and Simponi remains the fastest growing anti-TNF in markets where we promote. Remicade grew 3% reflecting growth in core markets and offset by biosimilar competition in some of the smaller EU markets.

In acute care, sales exceeded $600 million and grew by 17% this quarter. Growth was driven by continued uptake of Bridion in Japan, Europe and emerging markets and solid performances across our portfolio of antibiotics and antifungals. While growth rates may vary from quarter to quarter due to timing of tenders, we continue to expect this core area to be an important contributor to future growth.

Now turning to our vaccine business. In the third quarter, vaccine sales were approximately $1.7 billion, a decline of 6% primarily due to roughly $100 million of US public sector purchases of Gardasil and RotaTeq in the third quarter of last year that did not occur in the third quarter of this year.

Sales of Zostavax were approximately $180 million in the quarter declining 2% compared to last year. As we enter the flu season in the United States, we have initiated promotional efforts including a new direct to consumer campaign to educate consumers of the importance of talking to their physician and their pharmacist about shingles. We have broad access for Zostavax and we are working with customers to help them understand the reimbursement process.

Now turning to some geographic highlights in the third quarter. In the United States, sales declined 8% as growth in the Januvia franchise and Dulera was offset by lower vaccine sales, the loss of exclusivity of TEMODAR and declines in our HCV portfolio. In Europe sales fell 1%. We drove continued growth in diabetes, immunology and Isentress but sales were impacted by the divestiture of our ophthalmology products, continued declines in the HCV portfolio and a generic erosion for Nasonex.

Sales in Japan declined 14% primarily due to biannual price decreases and ophthalmology product divestitures.

Sales in the emerging markets grew 8%. China grew 33% in part due to timing of purchases. Demand in China remains strong for our broad portfolio of innovative and also established products. Other important emerging markets such as Turkey and Mexico also delivered solid growth in the quarter.

For the full year we continue to expect that the emerging markets will be good growth drivers.

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Now I will spend a few moments speaking about the early days of the KEYTRUDA launch. First, let me say we are very excited to launch the first and the only anti-PD-1 therapy approved in the United States. We are still in the early days of launch but we have been moving rapidly to ensure the medicine is available to patients and feedback from our customers is very encouraging. Upon approval we said KEYTRUDA would be available within a week and we were taking orders and shipping in just a couple of days. Our colleagues in manufacturing worked tirelessly to ensure that patients would have access to this important medication as soon as possible.

On the commercial side, we reached the top ipilimumab prescribers in a matter of days from approval. We have now expanded our reach into community practitioners. We have reached more than 75% of the key physicians and we have made multiple calls into many of the high-volume prescribers.

Regarding access, most payers are covering the cost of KEYTRUDA for its current indication without restrictions. Additionally, we offer patient assistance for patients requiring reimbursement assistance. As we said at approval, we believe there are about 1200 patients in the US who are eligible for KEYTRUDA based upon our current label. Additionally, we expect a few hundred new patients to become eligible for treatment with KEYTRUDA each month.

Since approval in early September, we believe that approximately 900 patients are being treated with KEYTRUDA. Many of these patients were previously part of the expanded access program and are now in a process of moving from the EAP to commercial product.

Our global oncology business unit is passionately engaged on maximizing the potential for KEYTRUDA for appropriate patients. We are looking forward to sharing more launch details with you in the fourth quarter earnings call.

In summary, global human health is transitioning through a period of patent expiries and divestitures. Since late last year, we have consciously redirected our focus to core product areas to core markets and to new product launches. We drove growth in many of these core areas and we are successfully introducing KEYTRUDA to the US market for patients suffering from advanced melanoma.

We continue to prioritize our investments and we are intent on driving future growth and broadening our impact in global health.

Now I would like to turn the call over to my colleague, Rob Davis.

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

Thanks, Adam. Good morning, everyone. We have had solid results in the first nine months of the year. Our third-quarter results demonstrate that we continue to sharpen our focus as a Company and as Ken mentioned, our cost reduction program is on track. This morning I will provide additional color on our P&L and comment on our outlook for the rest of the year. My remarks will focus on our non-GAAP financials.

Total Company revenues were $10.6 billion for the quarter, a decrease of 4% year-over-year with a 1% benefit from foreign exchange. This decrease reflects in part the loss of more than $400 million of sales in the prior year from divestitures and the now ended joint venture with AstraZeneca.

As Adam stated, our sales in the pharmaceutical business were driven by solid performance in our key brands which have benefited from continued resource allocation to our priority therapeutic areas like diabetes and acute care.

Animal Health revenues increased $83 million or 10% year-over-year excluding exchange. These results were driven by strong performance across the portfolio including significant growth in our companion animal and poultry businesses.

Consumer Care revenues decreased 9% excluding exchange. As a reminder, this is the last quarter in which we will record results from the consumer care business since the transaction with Bayer closed on October 1.

Moving now to expenses, gross margin was 74.3% in the quarter which represents a 30 basis point increase year-over-year. We continue to expect the 2014 full-year gross margin to be slightly lower than 2013's full-year ratio of 74.3%.

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Marketing and administrative expenses were $148 million lower than the prior year driven by reductions in direct selling and promotion costs. We continue to focus our resources on key markets and core products while ensuring we appropriately invest in our product portfolio launches and in support of these efforts we would expect M&A expenses to be sequentially higher in the fourth quarter.

Research and development expenses were $1.5 billion in the quarter, $109 million lower than prior year. We expect R&D expense in the fourth quarter to be higher year-over-year as we invest in our portfolio.

Finally, regarding the tax rate, our non-GAAP effective tax rate was 26.5% in the quarter which was in line with our expectations. We continue to anticipate the tax rate for the full year to be between 24% and 26%.

In terms of our bottom-line performance, we earned $0.90 per share in the third quarter as compared to $0.92 per share in the prior-year.

Now our outlook for the rest of the year. On the topline, we are narrowing our revenue guidance to $42.4 billion to $42.8 billion at current exchange rates. This takes into account recent currency movements as well as a public sector vaccine purchase in the third quarter of last year that did not occur this year which Adam described earlier.

We are also narrowing our non-GAAP EPS range raising the bottom end of the range to $3.46 and lowering the upper end to $3.50 while maintaining the same midpoint. Our EPS range reflects our strong performance in the first nine months of the year and includes the absorption of roughly $0.06 to $0.09 of dilution from the consumer care divestiture and the Idenix acquisition.

On a GAAP basis, we expect to earn between $4.06 and $4.29 in 2014. Both M&A and R&D expense in 2014 are expected to be lower than 2013 and as I said earlier, we remain on track to achieve our target of a $2.5 billion reduction in expenses off of the 2012 base by the end of 2015.

Now touching briefly on capital allocation. By the end of the year, we will have deployed the balance of the after-tax proceeds from the Bayer transaction net of cash used for the Idenix acquisition for share repurchase. We continue to project our average diluted shares outstanding will be slightly lower than 2.95 billion shares for 2014.

We remain focused on our commitment to return cash to shareholders and as Ken said, we have returned over $11 billion to shareholders over the past 12 months in the form of dividends and share repurchases.

As we look at capital markets more broadly, we recently took advantage of favorable market conditions and restructured some of our debt through a tender offer and a EUR2.5 billion debt offering. We are pleased with the results of the transactions which created economic value for the Company and will benefit annual interest expense in 2015 and beyond.

In summary, the third quarter was another solid quarter for Merck. Since our announcement at this time last year, we have refocused our business and divested non-core assets with 2013 full-year sales of approximately $3 billion. In addition, we continue to trim our expense base putting us solidly on track to achieve our expense reductions by the end of 2015 while also investing in our promising new product launches and pipeline.

Now I will turn the call over to Roger.

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

Thanks, Rob. The third quarter was an especially busy one for our regulatory affairs group with multiple product approvals in several important areas. In August, our novel first-in-class orexin receptor antagonist, BELSOMRA, was approved by the US FDA. BELSOMRA acts to improve sleep initiation and sleep maintenance in patients suffering from insomnia. As Ken mentioned, the BELSOMRA launch will begin early next year.

In September we gained approval of BELSOMRA in Japan where we also gained approval of Vaniprevir, a potent highly selective protease inhibitor for the treatment of genotype 1 hepatitis C virus infection. Also in September, we received approval for KEYTRUDA, our monoclonal antibody directed against PD-1 for the treatment of patients with advanced malignant melanoma refractory to currently available therapies. As I previously

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mentioned, our development program for KEYTRUDA has expanded to include more than two dozen studies around the world involving more than 6000 patients and addressing more than 30 different tumor types.

At the European Society for Medical Oncology meetings earlier this month, we presented data documenting the activity of KEYTRUDA in patients with gastric, bladder and head and neck cancers and also presented more comprehensive data describing the activity of KEYTRUDA in patients suffering from malignant melanoma or non-small cell lung cancer.

Today we announced that the US FDA has granted breakthrough designation to KEYTRUDA for the treatment of non-small cell lung cancer in patients who have failed platinum based therapies and whose tumors do not bear EGF-receptor or [ALK] gene mutations. We are working closely with the FDA to define an optimal dataset that would permit registration of KEYTRUDA for this important indication.

Later in the year we expect to have a chance to describe our studies of KEYTRUDA in patients with so-called triple negative breast cancer at the San Antonio Breast Cancer conference and then some hematologic malignancies at the American Society of (inaudible) meeting.

Combination studies employing KEYTRUDA for the treatment of a variety of devastating malignancies are also underway. These studies employing conventional therapeutic modalities as well as novel targeted agents will benefit enormously from the broad understanding of KEYTRUDA monotherapy that we are developing.

Turning now to infectious diseases, we are looking forward to the upcoming American Association for the Study of Liver Diseases meeting next month. During the meeting we plan to present complete data from Phase 2 studies of our MK-5172 8742 doublet. I remind you that the FDA has granted breakthrough designation to these agents for the treatment of hepatitis C virus infection. Indeed the Phase 3 registration program for MK-5172 8742 is now completely enrolled and we expect to see data from these studies in the first half of 2015.

At AASLD, we will also present early data from the C-SWIFT study which pairs the MK 5172 8742 doublet with the nucleoside polymerase inhibitor, Sofosbuvir. The goal of these studies which we announced five months ago at our business reveals is to advance the case for an all oral Ribavirin free genotype independent regimen that can be used in patients irrespective of comorbidities for example in patients with established cirrhosis, simultaneous infection with human immunodeficiency virus and/or renal insufficiency and that will achieve sustained virologic responses over a shorter course of therapy.

Because of the difficulties in ensuring patient adherence in the real world, shorter course of therapy is clearly desirable. Our triple therapy regimens have been enabled by our recently completed acquisition of Idenix Pharmaceuticals through which we gained access to a potent nucleoside polymerase inhibitor that we now call MK-3682. Data describing the effectiveness of MK-3682 monotherapy will also be presented at the AASLD meeting.

Beyond HCV, we continue to make very good progress enrolling other Phase 3 infectious disease therapeutics programs including once-daily Isentress and letermovir, a treatment for patients at risk from disseminated cytomegalovirus infection6.

During November we also expect to present the results of IMPROVE-IT, our study testing whether a cholesterol-lowering regimen of ezetimibe plus simvastatin versus simvastatin alone improves outcomes in patients at high risk for major cardiovascular events. The first patient was enrolled in this trial exactly nine years ago. With design and protocol review, it has been a decade since the question that the trial addresses was first posed.

In all, IMPROVE-IT enrolled 18,145 patients presenting with stabilized acute coronary syndromes. There have been more than 5000 composite events that will soon be reviewed. The MRO clinical team and I, along with the rest of Merck management remain blinded to the data and our statisticians have only a very short period to conduct analyses before the presentation in mid-November. My number one consideration regarding this study has been to ensure that we work closely with our academic colleagues to obtain a complete and robust dataset generated during the decade that it has taken to conduct IMPROVE-IT.

Given the size and complexity of this study, I expect that the IMPROVE-IT data will provide important insights into the appropriate care of patients at high risk for major coronary adverse events.

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Returning briefly to regulatory affairs, we have now submitted our complete response to FDA questions regarding sugammadex, our parenteral agent for the reversal of neuromuscular blockade during anesthesia. Included in this response are new studies designed to examine hypersensitivity reactions that can occur with sugammadex administration as well as an updated review of our pharmaco vigilance experience with sugammadex which is marketed in more than 50 countries as Bridion.

Separately we have had a pre-NDA meeting with the FDA to discuss our odanacatib results. We have agreed together upon a plan to characterize more completely the adjudicated adverse event reporting in this study which will mean that our filing will be delayed until 2015. The data that we presented at the ASBMR meeting in September demonstrate that odanacatib could provide a meaningful therapeutic option to reduce the frequency of osteoporotic fractures in women at high risk for these events.

Finally as Ken mentioned, we continue to work closely with the FDA on the review of V503, our 9-valent human papilloma virus vaccine for the reduction of cervical malignancy. We expect that the FDA will complete its review before the end of the year. Joe?

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

Great. Thank you, Roger. Jackie, I think we are getting ready to start the Q&A segment of the call. Just as a reminder if you can limit yourself to one or two questions that way we can get to as many callers as possible.

So, Jackie, I think we will turn it over to the first caller.

QUESTIONS AND ANSWERS

Operator

Chris Schott, JPMorgan.

Chris Schott - *JPMorgan - Analyst*

Just two questions here. First, with the breakthrough status in lung for KEYTRUDA, can you just update us on anything about your filing strategy or at least key data points we should be watching for that could support a filing in lung?

And then second, just your thoughts on TECOS and risk of heart failure with Januvia. There is obviously been a lot of discussion around this point as of late and we would love just to get Merck's perspective on the risks associated with that study. Thanks very much.

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

Yes, Chris, just with respect to the filing strategy, I think we certainly are pleased to have gained breakthrough designation for non-small cell lung cancer. As you know, we have a number of studies underway, large studies and we have the opportunity to look at those studies and we are working closely with the agency to develop an idea of registration strategy as I indicated. So we won't have any more to say about that than what I have said to this point.

With respect to TECOS, you know I think that we do expect that the final patient will be available, patient data will be available, last patient, last visit by the end of the year. This is of course a study that is being conducted led by academic institutions so we will be made aware of those data.

I think it is important to recognize that a Data Safety Monitoring Board has been following this study extremely carefully. The observations that have been made in other studies employing regimens to treat diabetes are well known to the Data Safety Monitoring Board. The last Data Safety Monitoring Board review was in December of last year. Given that the fact that the DSMB came back and said the study should be continued without

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change I think provides some reassurance with respect to the overall conduct of the study. It is a large study, will provide important answers to questions about the meaningfulness of intervention with sitagliptin in patients with type 2 diabetes.

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

Great. Thank you, Roger. Jackie, next caller.

Operator

Seamus Fernandez, Leerink.

Seamus Fernandez - *Leerink Partners - Analyst*

Thanks for the question. So a couple of quick questions for Roger. Roger, can you talk to us a little bit about -- I don't see PD-L1 status highlighted for the breakthrough designation for KEYTRUDA but my understanding is that much of the data that was generated in non-small cell lung cancer was in the PD-L1 positive patient population. Can you just clarify for us if this indication is specific to the PD-L1 patient population or if it is not and it is actually for the broader patient population?

And then as we think about the next data points in the KEYNOTE-010 study, can you just update us on whether or not you have officially taken the look at the response rates which is sort of specified on clinicaltrials.gov relative to the 2 mg and 10 mg dose and if that look included a comparison to Taxotere? The reason I ask is if that could be utilized as supportive evidence for a potential filing? Thanks.

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

First of all, the breakthrough designation is not specific to PD-L1 positive patients and as you know, we have done quite a lot of work on trying to understand the meaningfulness of PD-L1 positivity what we have shown in a whole variety of settings is that patients whose tumors are judged PD-L1 negative or more precisely that fall into the PD-L1 staining less than 1% category nevertheless do demonstrate some responses and we and other groups that are studying this are still in the midst of trying to understand exactly how to correlate PD-L1 expression status with outcomes.

We know there is a relationship but exactly what the meaningfulness of that is I think remains to be elucidated.

With respect to the KEYNOTE-010 study, as I have indicated, we have a variety of different ways that we can look at these data in order to come up with an optimal registration strategy and that is something that through the close interaction that we have with the FDA and will have more particularly because of the breakthrough designation that we are going to be doing in order to come up with the best possible strategy.

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

Thank you, Seamus. Jackie, next caller.

Operator

Mark Schoenebaum, ISI.

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Mark Schoenebaum - *ISI Group - Analyst*

Hey, guys. Thank you for taking the question. Maybe just a follow-up on Seamus. The KEYNOTE-010 trial, Roger, what is the timeline for a data readout on that? Can you update us? I believe last time you spoke about it you had talked about late 2015. Could you just remind me if that is correct or incorrect data?

And then on hepatitis C if I may, Roger, last call you expressed a great -- what I interpreted to be a great period of optimism for the four-week regimen. Obviously the bar is very, very high given the Gilead data that is out there. I was wondering if you could update us on your expectations for the four-week data?

I know this is the third but this is just a yes or no. Just to be clear, the breakthrough designation was for -- if I am reading the press release right, was actually for second line and later lung. Is that correct?

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

Mark, so first of all, the breakthrough designation doesn't specify line of therapy. The breakthrough designation is for patients who have failed platinum-based therapies. And that is understandable of course because you get breakthrough designation for those circumstances under which there is a -- the anticipation of a meaningful intervention beyond what exists as standard care. So that is understandable I think.

With respect to the KEYNOTE-010 study again I think the timing remains as before. We continue to march forward with that study. We, as I said, have opportunities to examine that data at different times and one of the things that we will be doing is discussing that with the agency but we do expect to have data available by the end of next year for sure.

Then with respect to hepatitis C, I think the important thing to remember here is that what we proposed when we described the study back in May was that a triplet regimen would provide the opportunity to test whether it was possible to get sustained virologic responses that is eradication with very short regimens. We don't know what the nature of those regimens would be until we have tried to book-end those four genotype 1 and genotype 3 in the C-SWIFT study.

We have access now of course to 3682, our own nucleoside polymerase inhibitor and the things that we learn from our studies was Sofosbuvir can then be applied to our triplet studies with 3682 recognizing of course that no two polymerase inhibitors will behave in exactly the same way. But it basically provides the kind of guidance that we need in order to design effective Phase 3 studies. So we are looking forward to having the opportunity to review those data in detail.

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

Thank you, Mark. Jackie, next caller.

Operator

Alex Arfaei, BMO Capital Markets.

Alex Arfaei - *BMO Capital Markets - Analyst*

Good morning. Thank you for taking the questions. Roger, just a follow-up on those comments. Could you please remind us what the similarities and differences are from what you can tell from your new (inaudible)?

Adam, could you please give us a little bit more on the Gardasil performance and your outlook. It seemed to have been a little bit lower than expectations. Thank you.

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

So, Alex, you will have the opportunity to see Phase 1b data for MK-3682 at AASLD which will be interesting but of course it is very difficult to compare two different agents when they are not studied in a head-to-head context because of differences in patient population. I can't really speculate about that. We will have the opportunity to look at those kinds of data some time later but right now I think the important thing will be to look at the data, the Phase 1b data which I think you will find intriguing.

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

Alex, regarding Gardasil, let me provide some additional context. The sales in total were $590 million for the quarter. The US declined 7%. The US declines were mostly due to higher public sector purchases in 2013 that did not occur in 2014.

If you look at the cumulative 15- to 18-year-old penetration rates in the US, it is about 65% for females and about 50% for males. So there is still room to grow there. If you look at males, we continue to have good uptake and if you look at the private sector data it suggests that about 50% to 55% of first doses are now being administered to males.

If you look outside the US, the declines were due to Korea and also there is the end of the catch-up cohorts in several of the smaller markets. But overall we continue to be pleased with our market share, greater than 90% on a global basis and 99% in the US and we believe that there is still room for additional growth in the future.

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

Great. Thank you, Alex. Jackie, next caller.

Operator

John Boris, SunTrust.

John Boris - *SunTrust Robinson Humphrey - Analyst*

Thanks for taking the questions. First question, just for Ken. I think you traditionally go through your planning process this time of year. I know you can't give or you are not ready to prepare to give guidance for 2015 but if you can just help us understand what some of the pushes and pulls are especially since 2015 you have indicated as a return to growth year going into that year. So that would be very helpful.

Then for Roger, if you can just characterize why it is so difficult to potentially to get to four weeks of therapy in the HCV population either four or eight weeks going forward that would be real helpful. Thanks.

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

Thanks, John, for the question. So let me start by saying of course we are not giving 2015 guidance today. We will do that on our fourth-quarter call. But you are correct. We still expect to grow off our 2014 base and there are a number of factors that are going on outside right now. For example, there has been a change in currency rates which will have an impact on 2015. But also on an operational standpoint, we are looking forward to several launches. We are looking forward to the continued development of several key programs in our pipeline.

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So from an operational standpoint, we are pleased with the progress that is being made in our pipeline and with the upcoming launches and obviously they will have to be looked at in the context of the overall headwinds that I think everyone is experiencing from things like currency. Roger?

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

Yes, John, the duration of treatment in infectious disease is always a difficult process to assess. I think first of all, there are aspects of molecular cell biology to consider that you have hepatocytes that are infected with HCV. They differ almost certainly one cell from another in terms of replication rate. Those that are replicating more slowly, it can be difficult to inhibit that process and there will be variability in terms of the degradation of the viral nucleic acid. So there is a lot of heterogeneity in the liver itself and then there is also variation in terms of the exposure to drug in individual liver cells. And beyond those sort of molecular cellular considerations, there is also the clinical context.

So we all recognize that despite the fact that we have more or less understood the nature of for example just to pick one, the nature of osteomyelitis, bacterial infection in bone, the length of treatment in the clinical setting is different in different parts of the world in different regions. We really don't have an established length of treatment that we can justify with good clinical data. And one can expect that it will be easier in HCV because we can measure viral burden much more readily. But still the clinical context will change depending upon for example, the degree of liver disease. So you can imagine where there is a lot of fibrosis and it is difficult to get drug penetration that that will make things more challenging.

All of which means that it may be hard to get to a single short course recommendation for all patients but instead patients will have to be stratified and maybe the stratification can be determined before treatment begins but most likely it will be in response to therapy.

These are the things that we have to learn now that we have these potent direct acting antivirals and our C-SWIFT studies I think will provide important data on this.

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

Thanks, John. We will take the next caller.

Operator

Jami Rubin, Goldman Sachs.

Jami Rubin - *Goldman Sachs - Analyst*

Thank you very much. Just a few questions. Roger, do you expect to receive priority review for your doublet hepatitis C therapy? I know you mentioned you have completed enrollment. Those trials should be completed by the end of -- sort of, I guess, middle of next year should we anticipate priority or review and timing of approval?

Second question on KEYTRUDA for lung. When is the earliest we can expect to see randomized data showing overall survival for KEYTRUDA?

Then thirdly, a question for you, Ken. We had read I guess rumors in the press about Merck considering selling its diversified product line or its legacy business. Can you give us an update in terms of how you are thinking about that? There have been a couple trades, as you know, of those businesses. I am just wondering how we should think about that for Merck. Thanks very much.

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

The first question, of course we do have breakthrough designation for the doublet, and that doesn't by any means stipulate that the priority review would occur. I think it will be driven in large part by the strength of the data and assessment of meaningfulness. So we will get to that point when we have a chance to evaluate all of the Phase 3 data and get it submitted.

With respect to the randomized overall survival, again, we do have data coming from the KEYNOTE-010 study. There are other possible approaches to this, but certainly one would expect towards the end of next year, so we would have an early look at that. Again, a lot depends of course on the survival statistics for the population, but we will have data around that time, Jami.

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

Thanks, Jami, for the question. Let me start with a broader focus on it, and that is this. We continue to prioritize and focus within our business. And as we communicated last October, that has required us to look across the entire business to determine which assets might have more value outside Merck versus inside the Company. As part of that, you have seen us take action and divest assets with approximately $3 billion in 2013 sales, including MCC and certain GHH products.

We will continue to evaluate opportunities as appropriate but specifically with respect to the diversified brands, we will also be considerate of the fact that all lot of these more mature assets also provide strong cash flow which enables us to continue to invest behind a meaningful innovation that is at the heart of our strategy.

So we will continue to look at opportunities as we move forward but we've got to balance the cash flow concerns as well as what we can do to monetize assets where appropriate.

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

Thanks. Next caller.

Operator

Tim Anderson, Sanford Bernstein.

Tim Anderson - *Sanford C. Bernstein - Analyst*

I would love to get your thoughts on the KEYNOTE-006 trial, pretty important in that it compares your anti-PD-1 head-to-head versus it be in first-line melanoma and I am wondering if you can update us on timing of read out and just more generally, your views of CTLA-4 antagonist and specifically your views of those products from a risk-benefit standpoint as part of combination therapy with PD-1s in two settings, melanoma and lung?

And the just a quick question on TECOS, is it possible you would topline those results by late 2014 and more generally how we handle data disclosure when you do have those results?

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

For KEYNOTE-006 yes, we do expect that the data moving along and we will have comparative data versus sifalimumab and there is nothing particularly to update with respect to KEYNOTE-006. What you see on clinicaltrials.gov is a fair reflection of what we have and we are expecting to have data next year.

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You ask the more general question of how we view PD-1 antagonism versus CTLA-4 ipilimumab in particular and there has been a lot of discussion of this as you know very well. There has not been an opportunity for us to compare KEYTRUDA vis-a-vis ipilimumab directly to this point although ultimately we will have those kinds of data.

I think what we have seen from the registration materials for these drugs is that at the current exposure levels, there is a substantial amount of systemic toxicity that is seen with CTLA-4 antagonists but time will really tell how that plays out particularly as there are dose adjustments and different approaches to combination therapy. So I don't think we can say that that is going to turn out to be an impossibility.

I think that the important thing in order to design combinations correctly, speaking not just for ipilimumab or CTLA-4 but speaking for the totality of combinations, is we have to have a firm understanding of how these molecules behave as monotherapy. And we have a very large monotherapy program for KEYTRUDA which involves more than 6000 patients as I have noted.

In addition, we have 17 combination studies currently underway which explore KEYTRUDA in a variety of other settings used with other drugs. So we will have the opportunity with this firm foundation of monotherapy results to understand the meaningfulness of combination therapies including combinations with CTLA-4 antagonists like ipilimumab.

Oh yes, TECOS, so the TECOS data as I have indicated, we should have last patient last visit, I remind you this is a study that is coordinated by an academic group. They are managing the study but we should have last patient last visit by the end of this year we hope and the data will be presented in 2015. That is all we know about it. I mentioned before the Data Safety and Monitoring committee that is overseeing the study as well but we don't know anything more than that.

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

Thank you, Tim. Jackie, next caller.

Operator

Marc Goodman, UBS.

Marc Goodman - *UBS - Analyst*

Ken, obviously the restructuring program takes your expenses down pretty significantly by the end of next year and I am just curious from there, are we now reset and as we start to see this topline from the new launches kick in, will we get the operating leverage that we would expect to see given that hepatitis C, oncology, these businesses that are not primary care kind of drive the topline? I am curious how much investment you need to make in those areas that would offset and that we wouldn't see that operating leverage?

And then Adam, if you could just talk about the emerging markets just a little bit more. Obviously China was really strong. What type of one-timer was there or was this kind of the catch-up for the year? And maybe you could talk about just some of the key drivers and what is going on in the emerging markets.

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

So if you look at the emerging markets, I have always said that growth can vary from quarter to quarter and timing of tenders becomes very significant in the emerging markets. China as you mentioned, had strong growth of 33%. A lot of that was in the acute care products of which timing played a part in and also the diversified brands continued to show good growth which was not related to timing.

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I also mentioned that in Turkey and Mexico we had a very good quarter as well and that was driven by specialty products but also cardiovascular products.

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

On the overall issues with respect to our cost structure and how we are approaching it, we have been pretty aggressive in the first nine months to reduce costs and change our operating model and we are on track for the overall $2.5 billion in cost savings by 2015. And so we think that actually positions us well as we move into the future. Beyond that I can't say much because we are not providing guidance in today's call.

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

Jackie, next caller.

Operator

Andrew Baum, Citi.

Andrew Baum - *Citigroup - Analyst*

Good morning. Regarding anacetrapib, a question for Roger, would a positive protocol analysis for IMPROVE-IT at AHA make you any more confident about the anacetrapib trial given the beta about its proposed LDL mediated mechanism of action? And I know you are aware there are two presentations are scheduled.

Second, just following up on a KEYNOTE-010 trial, should I be thinking about an earlier interim analysis for your trial compared to Bristol's equivalent given you are selecting PD-L1 patients and it is obviously much larger and therefore where would that put the interim just on your modeling?

And then just an adjunct to that, do you still remain convinced that looking at PD-L1 expression on tumors rather than on the different cohorts of white blood cells is the right way to go to optimally select patients?

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

Andrew, three questions. First of all for anacetrapib, you know of course we don't, as I have been indicated, we have no idea what the results of the IMPROVE-IT are going to be. IMPROVE-IT tests the question as you know of whether or not one can by aggressively lowering LDL cholesterol levels in patients who already are optimally managed with simvastatin one can achieve a beneficial effect on cardiovascular events and the magnitude of that effect. Our studies with anacetrapib are different and because we have an anacetrapib, both the significant LDL cholesterol-lowering effect but also the HDL elevating effect, I'm not sure that I could read out much of anything from IMPROVE-IT to anacetrapib. I think anacetrapib is testing really quite a different question and we will just have to wait for the results of the REVEAL study.

With respect to the KEYNOTE timing, I can't speculate about how Bristol-Myers is pursuing their analyses versus our own. I have indicated when we expect our data to become available and we are going to examine those and make decisions based on that.

With respect to PD-L1, we have presented really quite a lot of data using our proprietary PD-L1 antibody to look at expression in tumors and what we have shown is that there is substantial association between PD-L1 expression in tumors which is just a different cut points and responses to KEYTRUDA and we have shown that in a number of different tumors and most recently we showed it in our presentations at ESMO.

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The important thing to recognize as I say is that doesn't mean that there are no responses in those who are PD-L1 negative. It is simply an association. It is an association that is biologically plausible but we don't by any means feel that we are able to inventory all of the PD-L1 that is expressed in and around those cells that might be responsible for tumor killing and so no matter what, we only get a partial picture of it.

My feeling is that PD-L1 assessment in the tumor is much more likely to be revealing than PD-L1 assessment on circulating white blood cells as an example and certainly that is our experience.

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

Okay. Jackie, next caller.

Operator

Colin Bristow, Bank of America Merrill Lynch.

Colin Bristow - *BofA Merrill Lynch - Analyst*

Good morning. Thanks for taking the questions. Sorry if I missed this but on hepatitis C, how important do you view hitting four weeks from a commercial standpoint? It feels like physician feedback has not indicated a high level of importance as perhaps we would expect.

And then just a second one on IMPROVE-IT study. If the trial does not meet the primary endpoint, how do you think about the level of investment in the franchise going forward? Thanks.

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

This is Adam, Colin. With regard to hepatitis C, this is a very large market. In the US alone there is about 3.2 million people with chronic HCV of which only about 50% are diagnosed and only about 150,000, 200,000 are cured so the market is very large. I believe that four weeks would be helpful but as long as in the competitive dynamics there is equality in terms of the regimens, I think that you can be successful commercially under either circumstance.

At this point we are not commenting specifically on IMPROVE-IT. We continue to believe in the LDL cholesterol hypothesis and of course we prepare for all scenarios but there is nothing specific at it this moment.

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

Jackie, next caller.

Gregg Gilbert - *Deutsche Bank - Analyst*

Gregg Gilbert, Deutsche Bank.

Gregg Gilbert - *Deutsche Bank - Analyst*

Thanks. I have two. Adam, you mentioned that roughly 900 patients are being treated with KEYTRUDA. I was curious if you are seeing orders in shipments that are pretty consistent with that? Is it a pretty tight relationship between individual patient to manage shipments or is the system kind of gearing up for broader usage even though you can't talk about broader usage from Merck's standpoint?

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Roger, how confident are you and the scientific community if you can speak for the community in the reproducibility of a particular patient's PD-L1 status? It sounds like investors kind of want things in neat boxes. I am not so sure it is actually going to play out that way but curious on your thoughts there on the testing and the status and whether that could flux within patients?

Thanks.

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

So first of all as I said before, we are pleased with the uptake in customer feedback that we have early in the launch but we are still very early in the launch. We are taking orders from KEYTRUDA since the first day of availability. Nearly all of the top 50 accounts have purchased since we launched the product and the majority have made repeat purchases. At this point in time we believe we have about 900 patients that are being treated with the product.

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

You are absolutely right with respect to PD-L1 status and that the PD-L1 gene itself is responsive to a variety of different stimuli including cytokines so the inflammatory (inaudible) could easily influence how much PD-L1 is expressed and that could be different from one for example site of metastasis to another so there could be quite a bit of variability. That variability may underlie the challenges that people have experienced in trying to dissect the relationship between PD-L1 expression and responsiveness to anti-PD-1 therapy.

Nevertheless the fact is there is such an association so summing over everything, there still is a general relationship between PD-L1 expression in tumors and responsiveness that has been seen many times.

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

Jackie, next caller.

Operator

Tony Butler, Guggenheim Partners.

Tony Butler - *Guggenheim Partners - Analyst*

Thanks very much. Two brief questions, Roger, we have talked about 010 in platinum failures. The question is what is the difference between 024 and 042 in the Phase 3 setting at least in first-line advanced non-small cell lung?

The second question, Adam, the top 50 accounts having ordered KEYTRUDA, can you provide any additional color on the percentage of patients who were already on therapy in the access program and have moved onto if you will as a paying customer and those that are actually new to therapy? Thank you.

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

So right now as we said, we believe there is about 900 patients that are being treated with the product. Many of those, many of those we believe are coming from the EAP program.

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If you look at the top 50 accounts, it is not easy to tell where the purchases go, to which patients exactly so you can't comment on that. But I think the bottom line is we are on track for all in 60 days to move from the EAP program into the commercial area. So we are working hard on that and we are on track for that.

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

If you look at 024 and 042, you will see that we are talking about similar kinds of studies but they differ in size and they differ in primary outcomes and that is kind of understandable and not atypical for registration strategies in these sorts of settings.

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

Next caller.

Operator

David Risinger, Morgan Stanley.

David Risinger - *Morgan Stanley - Analyst*

Yes. Thanks very much. I have a couple of questions. First, with respect to your hepatitis C program, could you talk about your development vision for the Idenix nuke including the timing for Phase 3?

Second, I have a little bit of a lengthy question on KEYTRUDA and this relates to the KEYNOTE-006 trial. So the approved dose of KEYTRUDA is 2 mg per kilogram every three weeks and it costs $150,000 a year but in KEYNOTE-006, the KEYTRUDA dosing is 10 mg per kilogram every two or three weeks which would cost $1.15 million or $750,000 a year respectively.

So since KEYNOTE-006 is supposed to read out early next year and assuming that it shows that KEYTRUDA is superior to Yervoy in first-line melanoma, it should get Compendia listed at 10 mg per kilogram but how should we think about actual use in the real world and how should we think about pricing for that compound? Thank you.

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

Yes, so I guess the question is first of all with respect to MK-3682 and the timing, I should note that for MK-3682 and again the data will be -- Phase 1b data will be at AASLD, we do have an IND now in the United States for that molecule and Phase 2 studies will begin shortly. And thereafter based on the results of that, we will begin to decide how best to conduct registration strategies so that is more or less how we are thinking about it, fairly conventional.

And then with respect to KEYNOTE-006, as you know, we began our studies of pembrolizumab in a variety of different doses, at 2 mg Q3, at 10 mg Q2, at 10 mg Q3 and what we have learned in the course of those studies is that the dose response curve is relatively flat and 2 mg Q3 was selected as the dose to go forward in melanoma. We are also working on a fixed dose at 200 mg Q3 which will give the equivalent exposure of 2 mg Q3 for most patients and doesn't require the weight calculation.

My expectation is that because we will have a large amount of data from all of these different settings we will be able to make the appropriate analysis. I can't speak of course to how Compendia will look at this and any other aspect of the commercialization process.

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

What I would say is we have been very active to ensure the patients that are in need of KEYTRUDA have access to it and claims are being paid for KEYTRUDA consistent with the indication without restrictions and we have got our clinical presentations with all of our top 30 targeted health plans either occurred or are going to occur.

So as we look at the future of course we continue to work to maintain access as appropriate.

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

Jackie, I think we have time for just two more callers.

Operator

Vamil Divan, Credit Suisse.

Vamil Divan - *Credit Suisse - Analyst*

Thanks for taking the question. A couple here. One on Januvia and Janumet. From what we understand I think that product starting in 2015 is not going to be available to people with United Healthcare commercial plans. Can you just confirm if that is indeed the case if there has been a change there? And while I assume that losing one plan is not likely that material to you guys, are there any other changes to the access of that franchise that we should be aware of as we start thinking about 2015?

And then the second question just on the PD-1 side of things, any update you can provide on the status of the lawsuit that you guys filed against Bristol in Europe and also the one that Bristol has filed in the US against you guys once you get the approval for KEYTRUDA. Thanks.

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

Januvia continues to have good access in 2014 and based upon preliminary reviews in 2015, we expect to continue to have good access. Januvia is still on formulary for United Part D plan in 2015 and continues to have preferred access. The contract with United was signed recently but since it had not been signed when United filed their 2015 formulary with CMS, the United Part D website and CMS required notice to insurees that did not list Januvia as on formulary but I just want to repeat that it still is on formulary for Part D in 2015.

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

Thanks for the other question. We are confident with respect to PD-1 and the litigation associate with the patents. We are confident we will be able to market KEYTRUDA to any country in which it is approved. Litigation appeals, they are a multiyear process so you won't hear anything from us for a while. If there are any updates, we will provide those in the Q.

Jackie, I think we have time for the last caller.

Operator

Jeff Holford, Jefferies.

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Jeff Holford - *Jefferies & Co. - Analyst*

Thanks for taking my question. I wondered if you could just give us a bit more color on what the biosimilar situation in Europe looks like, what you are really learning from the early stages of this and what you are going to take forward as access to biosimilars becomes more prevalent in Europe? Thank you.

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

So if you look at Remicade and Simponi as I said, we had about $775 million of sales, about 9% growth. We continue to have growth of Remicade of about 3%. That was driven by the core EU markets driven by Gastro indications but there was some offset due to biosimilar competition in the smaller markets.

If you look at the biosimilars specifically, there has been relatively limited uptake of either biosimilar product or acceptance on tenders in formularies and what we have seen so far is where there has been movement of the biosimilars, it has limited to new patients only. However, we have seen increased pricing pressures that are required in order for us to compete with the biosimilars. So we expect the pressure to continue in the small markets this year and then we expect there to be some pricing pressure and new patients in the core EU markets after February 2015 loss of exclusivity.

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

Thank you, Adam. Ken?

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

So just in closing, we reported another solid quarter of Company performance. As I mentioned earlier, we are making great progress on our strategic initiatives we announced last year. We are now seeing the benefit of investing in our core therapeutic areas like we have seen in diabetes. We have made significant advancements in some of our most important research programs including the launch of KEYTRUDA and receiving breakthrough therapeutic designation in non-small cell lung cancer and as Roger mentioned this morning, we are making steady progress in hepatitis C as our registration study for the doublet is now fully enrolled.

We also continue to focus on improving our operating model. Over the past year we have seen our operating expenses decline significantly. We will remain on track to achieve our $2.5 billion of cost savings.

Our prioritization has also led us to divesting $3 billion in sales through the MCC transaction with Bayer and other divestitures in human health. We have use those proceeds to fund the Idenix acquisition and repurchase shares this year. Over the past 12 months, we have returned more than $11 billion via the dividend and share repurchase program. We remain strongly committed to returning cash to our shareholders.

So again, thank you for joining us, hanging in with us for a little bit of a lengthy call and we look forward to updating you again on our fourth-quarter earnings call.

Operator

Thank you. This concludes today's conference call. You may now disconnect.

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