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AbbVie Inc. (ABBV) CEO Rick Gonzalez on Q3 2019 Results - Earnings Call Transcript

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Q3: 11-01-19 Earnings Summary

Press Release SEC *10-Q*

EPS of $2.33 beats by $0.03 | Revenue of $8.48B (2.95% Y/Y) beats by $111.8M

Earning Call Audio

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AbbVie Inc. (NYSE:ABBV) Q3 2019 Earnings Conference Call November 1, 2019 9:00 AM ET

Company Participants

Liz Shea - Vice President of Investor Relations

Rick Gonzalez - Chairman & Chief Executive Officer

Michael Severino - Vice Chairman & President

Rob Michael - Executive Vice President & Chief Financial Officer

Laura Schumacher - Vice Chairman, External Affairs, Chief Legal Officer & Corporate Secretary

Conference Call Participants

Navin Jacob - UBS

Terence Flynn - Goldman Sachs

Steve Scala - Cowen

Andrew Baum - Citi

Geoff Porges - SVB Leerink

Tim Anderson - Wolfe Research

David Risinger - Morgan Stanley

Operator

Good morning and thank you for standing by. Welcome to the AbbVie Third Quarter 2019 Earnings Conference Call. All participants will be able to listen-only until the question-and-answer portion. [Operator Instructions]

I would now like to introduce, Ms. Liz Shea, Vice President of Investor Relations.

Liz Shea

Good morning and thanks for joining us. Also on the call with me today are Rick Gonzalez, Chairman of the Board and Chief Executive Officer; Michael Severino, Vice Chairman and President; and Rob Michael, Executive Vice President and Chief Financial Officer. Joining us for the Q&A portion of the call is Laura Schumacher, Vice Chairman, External Affairs, Chief Legal Officer and Corporate Secretary.

Before we get started, I remind you that some statements we make today may be considered forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Additional information about these risks and uncertainties is included in our 2018 Annual Report on Form 10-K and in our other SEC filings.

AbbVie undertakes no obligation to update these forward-looking statements except as required by law. On today's conference call, as in the past, non-GAAP financial measures will be used to help investors understand AbbVie's ongoing business performance. These non-GAAP financial measures are reconciled with comparable GAAP financial measures in our earnings release and regulatory filings from today, which can be found on our website. Following our prepared remarks, we'll take your questions.

So, with that, I'll now turn the call over to Rick.

Rick Gonzalez

Thank you, Liz. Good morning everyone and thank you for joining us today. I'll discuss our third quarter performance and highlights, as well as our full year guidance which we are raising again this quarter. Mike will then provide an update on recent advancements across the R&D programs and Rob will discuss the quarter in more detail. Following our remarks, we'll take your questions.

AbbVie delivered another outstanding quarter with adjusted earnings per share of $2.33, representing growth of nearly 9% versus last year and exceeding the midpoint of our guidance by $0.04. Total revenue of $8.4 billion was also ahead of our expectations for the quarter driven by continued strong performance in hematological oncology and immunology.

I'll start with our hem/onc business, which delivered operational sales growth of 38.5% in the quarter. IMBRUVICA continues to perform exceptionally well with global revenue of more than $1.2 billion in the quarter an increase of nearly 30% versus last year. IMBRUVICA has a strong position across multiple indications and remains the clear market share leader across all lines of therapy in CLL.

We are especially pleased with the recent inflection in the frontline setting driven by IMBRUVICA's growing body of clinical evidence, label augmentation and update to treatment guidelines. We are also seeing a substantial contribution from VENCLEXTA with total revenue of more than $200 million in the quarter. VENCLEXTA continues to expand new patient share in the broad Relapsed Refractory CLL segment and we are making very good progress with our recent approvals for frontline CLL and AML.

Now turning to immunology where we strengthened our leadership position with the introduction of two new best-in-class therapies, SKYRIZI and RINVOQ, creating a broad portfolio of therapies well positioned to further improve patient care.

We continue to see excellent performance from SKYRIZI, with total revenue of approximately $90 million in the quarter. The launch is going extremely well with prescription trends that continue to remain well above recent launch analogs in the psoriasis category.

Through the first six months on the market, we already have approximately 3,500 prescribing physicians and more than 9,000 patients treated with SKYRIZI including those in our bridge access program. And in this short timeframe, SKYRIZI has already established its position as the leader for in-play psoriasis patient share. This includes both new patients, and switching patients.

In addition, commercial access for SKYRIZI is now more than 80%, a testament to its best-in-class product profile. We continue to expect SKYRIZI to drive significant growth over our long-range plan.

In the quarter, we also announced the approval of the upadacitinib, known as RINVOQ in the U.S. for the treatment of adult patients who had moderate to severe rheumatoid arthritis. This approval marks yet another major milestone for AbbVie, the 14th new product for a major indication approval in the last five years and continues to demonstrate our commitment and our leadership in immunology,

With a strong benefit risk profile demonstrated across the registrational trials, RINVOQ offers meaningful advantages over products on the market today or in development for rheumatoid arthritis. Feedback from prescribing physicians has been very positive and we have a highly experienced immunology commercial organization to support a strong launch trajectory.

The early trends for RINVOQ are highly encouraging and performance has been tracking ahead of comparable analogs within the RA segment. I'll highlight a few recent datapoints for you. In the month of October, the second full month was on the market, we estimate

more than 1400 prescriptions were filled including both paid prescriptions and those who received RINVOQ in our bridge access program.

Based on this level of prescription volume, RINVOQ is currently capturing approximately 6% of in-play RA patients. After less than 90 days on the market, RINVOQ's in-play patient share has surpassed REMICADE and several other established products and is rapidly approaching in the in-play share for Enbrel.

We are also seeing very low cannibalization of HUMIRA market share thus far. Commercial access is ramping strongly and in line with our expectations. By early January, we expect RINVOQ to have commercial access above 75% and we expect paid prescription volume to increase significantly as this expands over the next several months.

So while we are still early in the launch, we are certainly pleased by the feedback we received from field from physicians, and the robust demand trends that we are seeing.

Now turning to HUMIRA. HUMIRA grew 9.5% in the U.S. this quarter driven by continued strong volume growth across all three segments, rheum, derm, and gastro.

International HUMIRA sales were down approximately 32% on an operational basis, reflecting the impact of direct biosimilar competition in Europe and other international markets. The international biosimilar trends and dynamics remain consistent with our expectations.

Based on the continued strong momentum of our business in the quarter and the progress year-to-date, we are once again raising our full year 2019 EPS guidance. We now expect adjusted earnings per share of $8.90 to $8.92 reflecting growth of 12.6% at the midpoint, which remains at the top tier of our peer group.

I am extremely pleased with the underlying performance of our business. Additionally, with the planned acquisition of Allergan, we will be adding highly valuable on-market assets with leadership positions across additional attractive growth segments including significant new growth platforms in medical aesthetics and CNS.

The proposed acquisition is proceeding as expected with the recent successful completion of the Allergan shareholder vote who approved the transaction and advancing regulatory reviews around the globe. Integration planning is also well underway and we have made substantial progress. We remain on track for closing in the first quarter of 2020.

The Allergan transaction has significant strategic merit and the new AbbVie is poised to deliver top tier financial performance. Combined, we will generate significant earnings and cash flow to enhance our innovative R&D platform, support a strong and growing dividend and rapidly pay down debt.

As noted in our press release today, we are announcing a 10.3% increase in our quarterly cash dividend from $1.07 per share to $1.82 per share beginning with the dividend payable in February 2020. Since our inception, we have grown our quarterly dividend by 195%.

So in summary, we continue to demonstrate strong momentum and I am extremely pleased with our execution across the portfolio including the progress that we are making with the recent new product launches and our pipeline advancement. We have assembled an impressive set of growth assets and the outlook for our business remains strong.

The Allergan transaction will make us even stronger and more diversified. We remain focused on achieving our long-term strategic vision for the company delivering industry-leading performance and outstanding shareholder value while improving patients' lives.

With that, I'll turn the call over to Mike for additional comments on our R&D programs. Mike?

Michael Severino

Thank you, Rick. We continue to make great progress across all stages of our pipeline with several significant pipeline milestones since our last earnings call, as well as notable data presentations at a number of medical meetings.

In the immunology, we achieved another major milestone and continued to expand our portfolio with the U.S. approval of RINVOQ and its initial indication of rheumatoid arthritis. We are very pleased with the label, which reflects the strong benefit risk profile

demonstrated across our large and comprehensive registrational program.

RINVOQ, which was internally discovered and developed at AbbVie represents an important advancement in the treatment of RA providing physicians with a new, highly differentiated therapeutic option for their patients. The launch is underway in the U.S. and feedback from the medical community has been very positive.

We also recently received a CHMP positive opinion for RINVOQ with an approval decision in Europe expected in the next few months. In addition, we expect approval in Japan in the first quarter. We are making good progress with the development programs for RINVOQ in other immune mediated conditions as well.

We recently announced results from the first of our registrational trials in psoriatic arthritis, the SELECT PSA 2 study. In this study, which evaluated RINVOQ compared to placebo in psoriatic arthritis patients, who had an inadequate response to one or more biologic DMARDs, both doses of RINVOQ met all primary and key secondary endpoints.

We are very encouraged by the strong levels of response on both joint and skin endpoints, including ACR responses and PASI measurements, as well as minimal disease activity scores in the heavily pretreated biologic refractory population. We look forward to presenting detailed results at a medical meeting next year.

We expect to see data from our second registrational trial, SELECT PSA 1 in the first half of next year with our regulatory submissions expected in mid-2020 and commercialization anticipated in 2021. At the ACR Meeting later this month, we will be presenting 26 abstracts for RINVOQ in rheumatic diseases including results from stage two study in ankylosing spondylitis.

In this study, RINVOQ met a primary and key secondary endpoints demonstrating significantly greater improvements in signs and symptoms, as well as physical function and imaging endpoints compared to placebo.

We plan to begin a Phase 3 study in Axial Spondyloarthritis in the coming months, an indication expansion that will further strengthen RINVOQ's position within rheumatology. Both psoriatic arthritis and Axial Spondyloarthritis, our large and important markets in the

rheumatology segment and our key areas of focus for AbbVie's immunology portfolio.

In the Dermatology segment, we expect to see results from the first of RINVOQ's registrational trials in atopic dermatitis in the first half of 2020. We continue to make great progress with SKYRIZI, as well. SKYRIZI was approved in its first indication psoriasis in the second quarter and the launch is going extremely well with its differentiated profile and quarterly administration resonating with both physicians and patients.

One important feature of SKYRIZI's profile is its strong durability of response. We recently presented long-term data at the EADV Congress showing that after 2.5 years on treatment, SKYRIZI continues to provide high levels of efficacy as demonstrated by 61% of patients achieving PASI 100 or complete skin clearance.

Similar to RINVOQ, SKYRIZI is being developed in several additional indications. The Gastro segment in particular, represents a significant opportunity for SKYRIZI and the registrational programs in both crohn's disease and ulcerative colitis are progressing very well.

We expect to see data from a Phase 2b study in ulcerative colitis next year and data from the Phase 3 studies in crohn's disease are expected in 2021.

Moving now to hematologic oncology, where we continue to make good progress advancing our programs and expanding the breadth of data for IMBRUVICA and VENCLEXTA. We've made significant progress this year with IMBRUVICA in the frontline CLL setting. We received a label update to include data from ILLUMINATE study, which evaluated IMBRUVICA in combination with Gazyva in frontline CLL.

In addition, the NCCN guidelines were updated to include data from three important studies in our frontline CLL program. We also reported positive Phase 3 data in the watch and wait population and later this year, we plan to submit data for regulatory approval from the Phase 3 ECOG study in young and fit first-line patients.

An important element of our hem/onc strategy is our ongoing clinical program evaluating combination use of IMBRUVICA and VENCLEXTA.

In the area of non-Hodgkin's lymphoma, we expect to see results from the Phase 3 SYMPATICO study next year, a trial evaluating IMBRUVICA in combination with VENCLEXTA in relapsed refractory mantle cell lymphoma. We are also making good progress with the combination program in CLL. We expect to present data from a Phase 2 study in frontline CLL at the upcoming ASH Meeting and additional data from the Phase 3 program are expected in the next 12 to 18 months.

We continue to advance other programs in our hem/onc portfolio. We will see data next year from two confirmatory Phase 3 studies evaluating VENCLEXTA in frontline AML. And at the upcoming ASH Meeting, we will be presenting data from several early-stage programs including results from a Phase 2 study evaluating Navitoclax in myelofibrosis where we are seeing very encouraging data in patients who have failed Jakafi.

High risk myelofibrosis is a serious hematologic disease in which bone marrow is replaced by fibrotic tissue interfering with bone marrow function. Current therapies attenuate signaling through the Jak-Stat pathway to address symptoms but are not disease modifying.

With Navitoclax, we are targeting the mutated clonal cells causing myelofibrosis for apoptosis through the BCL-xL and BcL-2 pathways, a unique approach offering the potential to modify the course of disease reverse fibrosis and restore hematopoiesis.

Navitoclax may also act to resensitize cells that have developed resistance through Jakafi, thus representing a potentially important treatment option for myelofibrosis patients. Also in the quarter, we submitted our regulator application for Elagolix in uterine fibroids with an approval decision expected in the second quarter of next year.

And in neuroscience, we recently presented data for ABBV-951 demonstrating its potential as a new treatment option for patients with advanced Parkinson’s disease. ABBV-951 is a subcutaneous delivery system for our Levodopa/Carbidopa pro drugs, an innovative approach to treating motor fluctuations in Parkinson’s disease with the potential to provide DUOPA-like efficacy with a less invasive non-surgical delivery method.

If successful, ABBV-951 would represent a transformational improvement to current treatments with the potential to significantly broaden the addressable patient population beyond those treated with DUOPA today.

The Phase 3 program for ABBV-951 is underway and we look forward to updating you as the program progresses. So, in summary, we have continued to make very good progress advancing and accelerating our programs this year and we look forward to many more important pipeline milestones in the coming months until 2020.

With that, I will turn the call over to Rob for additional comments on our third quarter performance. Rob?

Rob Michael

Thank you, Mike. We had another quarter of strong performance. We reported adjusted earnings per share of $2.33, reflecting growth of 8.9% compared to prior year and $0.04 above our guidance midpoint. Net revenues were up 3.5% on an operational basis, excluding a 0.5% unfavorable impact from foreign exchange. Strong growth from several key products and newly launched assets offset the impact of international biosimilar competition.

U.S. HUMIRA sales were $3.9 billion, up 9.6% compared to prior year with volume growth of 8.6% and a favorable price impact of 1%. Wholesaler inventory levels remained below 0.5 a month in the quarter. International HUMIRA sales were approximately $1 billion, down 32% operationally, reflecting biosimilar competition across Europe and other international markets and in line with our expectations.

SKYRIZI continues to demonstrate strong uptake with sales of $91 million in the first full quarter following the launch in April. As Rick mentioned, we are pleased with the launch and – RINVOQ. Sales in the partial quarter were $14 million.

Hematologic oncology global sales were nearly $1.5 billion, up 38.5% on an operational basis, driven by the continued strong growth of both IMBRUVICA and VENCLEXTA. IMBRUVICA global net revenues were more than $1.2 billion, driven by strong share in all lines of therapy in CLL.

VENCLEXTA revenues were $221 million driven by continued share gains across all approved indications.

Global HCV revenues were approximately $700 million, down roughly 19% on an operational basis, driven by lower treated patient volumes in select international markets and increased competition within the U.S. managed Medicaid segment.

Despite the dynamics impacting performance this year, Mavyret remains the global leader in HCV therapy and we expect it to generate durable cash flow for AbbVie well into the next decade. We also saw continued strong operational sales growth for Creon and Duodopa.

Turning now to the P&L profile for the third quarter, adjusted gross margin was 82% of sales, up 30 basis points compared to the prior year, including a 140 basis point benefit related to the expiration of HUMIRA royalties, partially offset by the impact of partnership accounting. Adjusted R&D investment was 14.5% of sales supporting our pipeline programs on oncology, immunology and other areas.

Adjusted SG&A expense was 19.1% of sales, reflecting continued investment in our on-market products and newly launched assets. The adjusted operating margin ratio was 48.4% of sales, an improvement of 120 basis points versus the prior year. Adjusted net interest expense was $288 million and the adjusted tax rate was 8.8%.

In the quarter, we recorded a net charge of $0.56 per share related to the impairment of intangible assets acquired as part of the Stemcentrx acquisition. The net after-tax impact of this impairment and the related adjustment to contingent consideration liabilities was $823 million. This net charge has been excluded from our adjusted EPS results.

Based on our continued strong performance year-to-date, we are raising our full year adjusted earnings per share guidance to between $8.90 to $8.92, reflecting growth of 12.6% at the midpoint. Excluded from this guidance is $3.82 of known intangible amortization and specified items.

We are also increasing our revenue guidance for the full year and now expect growth of approximately 2.5% on an operational basis. At current rates, we continue to expect foreign exchange to have approximately 1% unfavorable impact on full year reported sales growth.

This forecast comprehends the following updated full year assumptions. We now expect U.S. HUMIRA sales growth of approximately 8.5%. We continue to see a robust volume growth and maintain a strong leadership position across all segments. For international HUMIRA, at current exchange rates, we now expect sales to approach $4.3 billion representing an operational decline of approximately 28%.

We now expect SKYRIZI global revenues of approximately $275 million reflecting continued launch momentum. For our hem/onc franchise, we now expect IMBRUVICA global revenues approaching $4.7 billion with U.S. sales growth of approximately 28% and for VENCLEXTA, we now expect sales of approximately $775 million. We are now forecasting global HCV sales approaching $3 billion.

And on the P&L, we now forecast adjusted gross margin of approximately 82.5% of sales and adjusted operating margin to remain just above 47% of sales.

Finally, we now expect a non-GAAP tax rate just below our full year rate in 2018. All other full year 2019 guidance assumptions remain unchanged. For the fourth quarter, we expect adjusted earnings per share between $2.17 and $2.19, excluding approximately $0.49 of non-cash amortization and other specified items.

We anticipate fourth quarter operational sales growth approaching 5%. At current rates, we expect a modest unfavorable foreign exchange impact.

As Rick mentioned earlier, today we announced a 10.3% increase in our quarterly cash dividend beginning with the dividend payable in February 2020. The significant earnings in cash flows with the combination of AbbVie and Allergan will generate allow us to support a strong and growing dividend and rapidly reduce debt.

We continue to expect the combined company to achieve a net debt-to-EBITDA ratio of 2.5 times by the end of 2021. We are further deleveraging through 2023.

In closing, AbbVie has once again delivered outstanding performance and with our strong track record, combined with the momentum of our business, we remain well positioned to deliver top-tier financial performance in 2019 and beyond.

With that, I will turn the call back over to Liz.

Liz Shea

Thanks, Rob. We'll now open the call for questions. Operator, first question please.

Question-and-Answer Session

Operator

Thank you. [Operator Instructions] And our first question today is from Navin Jacob from UBS.

Navin Jacob

Good morning. Thanks for taking the question. A couple please. Number one, just want to understand how we should think about the psoriatic arthritis market for RINVOQ relative to RA. Same I guess for SKYRIZI. And on a relative basis, how big those opportunities could be?

And then four, with regards to IMBRUVICA, there has been some questions around AstraZeneca's Calquence. They're going to be reporting some updated data at ASH. Wondering how you are thinking about the competitive landscape?

And then finally, just on the Allergan transaction, do you have an update on or when should we hear an update about the divestment of some of your assets. There is some questions around SKYRIZI versus brazikumab. So any clarity would be helpful. Thank you.

Rick Gonzalez

Okay. Hi, this is Rick. I think I'll have Mike walk you through PSA and then, I'll cover the Calquence question and I am going to have Laura talk a little bit about the status of the regulatory reviews for Allergan's products. Michael?

Michael Severino

Okay. This is Mike. I'll take the PSA question. The PSA segment is an important part of the overall other segments. I equate as large as RA but it makes a meaningful contribution, that and spondyloarthritis, axial spa it's often referred to.

Those two components provide meaningful revenue in that area and as we announced earlier this week in the psoriatic arthritis study we had at this – we delivered very strong results which were completely in line with our expectations.

We had a very strong impact on both joint measures, on the ACR measures, on the skin measures, and on composite measures of minimal disease activity, which look across both joint and skin and show that we are getting a substantial proportion of patients with very high level of control.

So we think it's a very, very substantial opportunity for RINVOQ in the long-term. We haven't put a dollar on that market yet. But we do think it's going to be a very important contributor to the overall RINVOQ profile.

SKYRIZI is doing very well and its initial indication of psoriasis. We have a psoriatic arthritis program underway. We think it's important to show the benefit of SKYRIZI in a psoriatic arthritis setting. That's not as advanced.

We don't have those data readouts yet. But we would expect it to perform well in that setting as well based on Phase 2. So we think between the two we'll really have a very strong portfolio in that important segment of the market.

Rick Gonzalez

So, let me talk a little bit about the – and we got to talk about it maybe a little more broadly, the competitive environment around IMBRUVICA and VENCLEXTA are in the CLL setting. I think, certainly, as we look at Calquence being a BTK, we would certainly expect that it will have positive data and that we will be frankly surprised if it didn't have positive data in first-line.

I mean, obviously, IMBRUVICA have very impressive data and a large and comprehensive data and that will certainly play into the competitive dynamics. I think if you think about the competitive dynamics in this field, you need to think about it sort from two perspectives. What does the competition looks like today? And what's the experience been against that competition?

And then, what way it looks like going forward for a competitor to be able to compete in this market in an effective way and I am specifically talking CLL now. So, Calquence has been in the market now for, I think about two years. It really has not been able to get a label that has any real differentiation. It has today and it's a proved indication of MCL second-line plus about 14% share.

It had between 10% and 14% for quite some time. So, it's kind of vacillated in that area for quite some time. Its current use in CLL is about 1% despite being on treatment guidelines I think since about 2018, and almost all of that 1% is in third-line plus, which gives you an idea of how physicians view it behind IMBRUVICA and VENCLEXTA.

If and when they get approval in first-line, I think it is important to remember or anybody to compete in this marketplace is, how the market operates today. If you look at IMBRUVICA's share of treated patients and what I mean by that is, patients who are currently under active treatment today. IMBRUVICA's first-line share of treated patients is 51%.

So, roughly half of the patients that are under treatment today are utilizing IMBRUVICA. Second-line plus is about 75%. So, three quarters of the patients who are under treatment right now are using IMBRUVICA. IMBRUVICA is treated to progression therapy. I don't see physicians taking well-maintained patients off of IMBRUVICA and switching them to Calquence or anything else.

And if we were seeing that, the duration of therapy which is something we track, we'd be going down, but indeed it's not. It's stable to slightly increasing. So anyone that comes into this market will have to compete for share and will be limited to compete for share by only competing in the areas where you got new patients or you have failure patients.

And in the case of new patients or failure patients, they are also going to have to compete against VENCLEXTA in this market. And as you know, VENCLEXTA is recently been approved in first-line. We are about three months post that approval. If you look at VENCLEXTA's new patient capture share in first-line, it's 5% already. In second-line, it's 10% and in third-line, it's 21%.

So, I think the reality is, we fundamentally believe and I think many physicians believe that we have the two best assets for being able to treat CLL patients and provide them with long durations of disease-free intervals between VENCLEXTA and IMBRUVICA. So, if Calquence gets a first-line approval in CLL, that certainly gets some share.

But I would tell you that I feel highly confident in our position in this marketplace based on our performance, and based on the assets that we have. So, Laura?

Laura Schumacher

Okay. With respect to the regulatory process, the regulatory process overall is proceeding well. We have filed for approval in all major jurisdictions. With respect specifically to the FTC, we received a second request for information at the end of September, which was not unexpected and we are working through those requests with the FTC.

We've also notified them of our intent today about two assets. One brazikumab, which is an IL-23 and the other Zenpep. We have a robust divestiture process ongoing right now with several interested parties. And I think as Rick said earlier, we remain optimistic of a first quarter 2020 closing.

Liz Shea

Thanks, Navin. Operator, next question please?

Operator

Thank you. Our next question is from Terence Flynn from Goldman Sachs.

Terence Flynn

Hi, good morning. Thanks for taking the question. Congrats on all the launch progress. Maybe just two from me. I was wondering with respect to ex-U.S. SKYRIZI, looks to be off to a strong start there. Wondering any more color you can give us in terms of where sales are coming from and anything similar or different versus the U.S. launch?

And then, Rick, how should we think about U.S. HUMIRA pricing next year? Amgen had some comments earlier this week, but we'd be curious to hear your thoughts as well. Thank you.

Rick Gonzalez

I think on an international SKYRIZI, you have to remember, we really only have reimbursement in a relatively small number of countries today. But that reimbursement process, that pricing reimbursement process is ongoing.

So you can expect it's doing extremely well in the markets that it is in. But that's going to expand significantly over the course of the next 12 months as we get pricing and reimbursement in additional countries.

I would expect SKYRIZI to perform reasonably consistently with what we are seeing in the U.S. and certainly in the western European markets. So, I think, there is a good opportunity there and we are excited about that opportunity.

Certainly, as it relates to HUMIRA pricing, we are obviously in the process of going through all of our managed care and I'd say, we are far into that pricing or that contracting process for 2020. I don't view any significant change in the dynamics around HUMIRA pricing in 2020. It would be significantly different from what we've seen in 2019.

Liz Shea

Thanks, Terrence. Operator, next question please?

Operator

Thank you. Our next question is from Steve Scala from Cowen

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Steve Scala

Thank you. Congratulations on a very well executed quarter. Despite all the investor apprehension, HUMIRA foreign has beaten three quarters in a row. How is that success between regions? Were there are biosimilars and AbbVie is just delivering despite the pressure and regions where patents are still in force? So, that's the first question.

And then, second, it seems like the Allergan closing might be earlier than generally thought, the company had been saying Q1, but in the release it says early 2020 which kind of implies January. So, what key steps have been achieved earlier than expected to allow for that earlier closing? Thank you.

Rick Gonzalez

Yes, so, if you look at – you are correct, Steve. This is Rick. On OUS HUMIRA, if you go back to our guidance in the fourth quarter of last year, we guided to overall erosion at about 30%. As Rob said in his comments, our forecast now is that that erosion will come in at about 28%. So, slightly lower than what we expect and you've seen that in each of the quarters. As you indicated, we've overachieved.

I would say, the bulk of that is slightly better performance in the areas where biosimilars are impacting the market. There is a portion of it, that's a little better performance in the other market as well. But the majority of it is driven by stabilization of pricing in those markets at a level that came earlier than we would have expected.

As far as the closing is concerned, I don't think we were trying to telegraph an earlier date, if that's how the market interpreted it. We are making good progress on the Allergan closing. Integration activities are going extremely well. We are obviously managing that very tightly. As Laura indicated a few minutes ago, the regulatory processes are advancing.

But we'd like to stay with the current guidance that we've had and that is a first quarter close. Obviously, we'd like to close it as rapidly as we can and we are pursuing that activity to get that done. But at this point, I wouldn't want to change what the original guidance was. So, that's how it was interpreted. That was not our intent.

Steve Scala

Thank you.

Liz Shea

Thanks, Steve. Operator, next question please?

Operator

Thank you. Our next question is from Andrew Baum from Citi.

Andrew Baum

Thank you. Couple of questions please. First, on Washington, obviously, it's very dynamic, but the Senate's Finance Committee proposal probably has more legs than most. Within that, there is a proposal to fund the cap and out-of-pocket spend through funding of the catastrophic coverage periods from both pharma as well as the planned sponsors.

Thinking about IMBRUVICA, how do you balance the impact of that? I am thinking on the positive side of increased volumes due to compliance adherence versus a negative of both the direct hit to net revenues, but also the indirect hit from payers playing you off against competitors, including Calquence in order to claw back economics.

The second question is on rheumatic arthritis. So both Novartis and Lilly have failed to show ACR-20 improvements in front-line setting versus HUMIRA given your waiting date to next year for your trial, are you confident that RINVOQ will enable you to do that?

I know it's dangerous making cross-trial comparisons in the second-line from what you presented today doesn't necessary provide significant reassurance. But I am interested in that.

And then finally, could you comment on the infection rates that you saw with RINVOQ in the 30 milligram of the psoriatic arthritis trial versus placebo? Many thanks.

Rick Gonzalez

Andrew, this is Rick. I'll cover the first one and I will have Mike cover the other two. Certainly, as you indicated, the situation is still pretty dynamic. Although, I'd say, it's a little lighter over the last month or two. They had been across the summer. But I still think there is a lot of interest and a lot of activity that's still going to continue to look at ways to try to open up access and affordability, particularly in the Medicare population.

And I think that's appropriate and I would tell you, we as a company support that. We do believe we need to make medicines more affordable to Part-D patients. The Senate Finance Bill goes in a direction and I think it's helpful. It takes those out-of-pocket costs down from where they are today on a therapy like IMBRUVICA or even a therapy like HUMIRA as an example.

It takes them down fairly significantly to an out-of-pocket cost. It's about $3,000 or $3,100. I would say, we still fundamentally believe that's too high for most Medicare patients. The average Medicare patient has an income of $2,600. We think it needs to be more in the neighborhood of something below $2,000 and our government affairs people are working to try to articulate that position.

The other issue with it is, there is still front-end loaded in the year. So from a cash flow standpoint, the patient has to come up with that $3,100 in the first two months, typically the first three months and most of these individuals don't have that kind of cash flow.

So, coming up with a structure that will allow it to be spread across the full year would be certainly a more reasonable approach to allow those patients' affordability.

As it relates to the funding in the catastrophic area, certainly, if you look and trying to make these drugs more affordable to patients and have broader access, someone has to pay for that. And certainly, I can't speak for the entire industry. But I can speak for AbbVie. We have said and I testified at the Senate Finance Committee, I said we are willing to step-up and cover more of that cost.

Healthcare plans have to pay more of the cost and obviously the government needs to pay a piece of that as well. It moves in that direction, although I will say, the way they structured it so far, it is more punitive or more costly to companies that have more

innovative therapies and it actually gives a benefit to certain companies who have drugs where the total cost would be below $6,000 per year.

I don't think that was the intent, I doubt seriously. They were trying to give a benefit to any specific company. So, really looking at where that threshold is and the overall percentage in the catastrophic base is something that would be an important aspect of modification to this bill. But I'd say, it moves in the right direction.

Specifically, the answer your question about volume, we have looked carefully not just to move it up across our entire portfolio. We do believe there will be some volume increase. Net-net, I can tell you the volume isn't enough to offset the overall cost.

But I think in the grand scheme of where we want to go with this, I think this is a reasonable approach and with some modifications, I think you could have a meaningful impact on the issue and potentially put the debate to rest. So, it's something that with modifications I am supportive of it.

Michael Severino

Thanks. This is Mike. I'll take the question on psoriatic arthritis. One thing that's important to keep in mind is that the study that we just released is in a bio IR population. And in fact, it was in a pretty heavily pre-treated bio IR population where a number of patients had failed two or three prior biologic DMARDs despite that we drove very high levels of response at the ACR-20 level and at higher levels on the joint endpoints.

And if you look at the placebo subtracted differences, they are entirely in line with our expectations. So, these data would increase our confidence in the overall program and our ability to hit our marks in the second study which includes not only the head-to-head comparison, but also the structural endpoint.

The second thing that I would add is that that second study is a very large and robust study because it has a structural endpoint. So it's very well powered to show the effects that we would expect to see. So we remain confident in the head-to-head and in our overall psoriatic arthritis program.

And then, on the third part of your question with respect to infection rates, in the data that we just released in psoriatic arthritis, we did see numerically higher rates of infections and serious infections in the 30 milligram dose. That's not uncommon in a therapeutic immunomodulator class.

This is our first study. We are going to have to see how that second study plays out, not only with respect to the safety parameters, but also with respect to the dose response that we see or do not see across doses on the joints and other endpoints and we'll make a determination of the most appropriate dose to carry forward based on that complete dataset as we did in RA.

Liz Shea

Thanks, Andrew. Operator, next question please.

Operator

Thank you. Our next question is from Geoffrey Porges from SVB Leerink.

Geoff Porges

Thank you very much and I appreciate the questions. Congratulations on the strong results. Two questions if I may. First, on VENCLEXTA and IMBRUVICA, could you give us a sense of whether you really think significant volume of CLL patients could really be treated with a non-chemo, non-CD 20 regimen? And how are you thinking about the duration of VENCLEXTA in that setting, because it could be potentially transformational?

And then, Rick, could you just talk a little bit about capital allocation? I am sure there is some relief out there that the dividend went up. Now you are getting close to closing the Allergan transaction. Could you talk about how confident you feel about the outlook for the dividend and your ability to continue the long record of dividend increases? Thanks.

Michael Severino

This is Mike. I'll take the first part of your question on VENCLEXTA and IMBRUVICA combination used in CLL. I mean, we do think there is a very meaningful opportunity there. When you look at the CLL population, it's a heterogeneous group and that ranges

from patients who develop CLL later in life and have a number of co-morbidities.

Those patients today tend to receive rich progression therapy with IMBRUVICA. We are seeing that shift very strongly as we've released those IMBRUVICA data. But there are other patients, patients who developed CLL earlier in life, patients who had less co-morbid illness, who are interested in treatment intensification and getting very, very deep responses.

And for those patients in particular, the VENCLEXTA and IMBRUVICA combination, I think is very compelling based on the data that we've generated to-date. We see very deep responses. We'd expect that to translate into long disease-free intervals and we think it's a therapy that will be an important treatment option.

With respect to the specific duration, that's going to be tailored based on the data to individual settings. But those combination regimens do tend to have fixed duration therapy.

Rick Gonzalez

Okay. Hi, this is Rick. I'll take the capital allocation question. Let me start maybe with more broadly about capital allocation. We have basically three priorities when we look at capital allocation. We want to invest in the business. We want to continue to drive a strong and growing dividend and we want to pay down debt. And those are the priorities for us.

We have a debt pay down plan that we have put in place that’s consistent with the objectives that Rob indicated in his formal comments and that will be something that we will absolutely drive towards. Now we are fortunate that we are in a business that generates a tremendous amount of cash flow in the combination of Allergan and AbbVie together will generate very, very significant cash flow.

And so, we have the luxury that we are able to do both. And we certainly would not have increased our dividend double-digit now if we had any concerns about that going forward. So, I can tell you we are committed to a strong and growing dividend and we are committed to paying down debt and we have the ability to be able to do both.

And I think the dividend increase that we are announcing today is a reflection of our confidence in that cash flow generation.

Geoff Porges

Thank you.

Liz Shea

Thanks Geoffrey. Operator, next question please.

Operator

Thank you. Next question is from Tim Anderson from Wolfe Research.

Tim Anderson

Thank you. Going back to Astra's Calquence, if that product is able to show differentiation either on side-by-side analysis to your product or in the head-to-head that reports out next year, where does that come? And what form does that come? Is that likely to be efficacy or on safety?

And I understand the commercial dynamics still might keep them on the sidelines, but in terms of what the clinical data shows with these next-gen products like Calquence, if it were to be better, where would that be?

And then, a second question on Allergan, obviously the lead asset is Botox. Wondering if you can give us some indication of your view of the product's durability over an extended period of time and your long-range planning assumptions, send it off competition well in the past.

There is obviously certain new threats on market now, what is your long range planning assume? Is it continued positive growth through the next decade at about the same rate for example?

Rick Gonzalez

Okay, Mike?

Michael Severino

So this is Mike. I'll take the first part on Calquence. We really wouldn't expect to see differentiation on efficacy or safety, based on our look at the data. We understand the positioning that that some of the follow-on BTK inhibitors have put forward. But when we look at the data, they look like me-toos as Rick has said.

If you look at like-for-like data in second-line CLL, for example, which is the only indication where they have publicly available Phase 3 data and you line that up against our Phase 3 data. If you look at response measures, they look very, very similar. And that's despite the fact that in the assorted of study they had a median number of prior therapies at one prior therapy and we had a median number of three prior therapies.

So, a much more heavily treated patient population and yet the same efficacy results. So that's not indicative of likely differentiation in our mind and you wouldn't expect that based on mechanism of action. It's a BTK inhibitor.

And when you look at safety, that story has evolved as well. It started off as no bleeding and no afib because now we see both of those in their label and those events are showing up in their larger scale clinical trials, as well. And if you go back to that same study comparison that I talked about, you see rates that they fit that actually looks pretty similar if you look at corresponding time points.

So we don't really see differentiation there either. I mean, it's important to keep in mind that labels evolve over time. If you look at how our label has evolved, as we have unblinded multiple large Phase III trials and also accumulated extensive post-marketing experience, things get added to your label and that's the natural course of a product's lifecycle over time.

If you look at their label today, compared to IMBRUVICA's label at a corresponding time point, they look pretty similar. So, to our eyes, these look like me-toos and we wouldn't expect to see that differentiation.

Rick Gonzalez

Okay. This is Rick. Tim, I'll answer your second question about Botox. And I am getting answer it in the backdrop of the work that we did as it relates to the acquisition, the market research that we did leading up to the acquisition. So we look carefully at Botox and the durability of Botox. It's an important product for Allergan.

And I would tell you the Allergan organization I think has done an outstanding job with Botox. But if you look at competition, it comes in two forms or potentially it can come in two forms. One, other branded toxins, which is what they've experienced thus far and we expect to see more other branded toxins.

And I would tell you that what the market research clearly told us is that the brand equity of Botox in the channels that they operate is so strong that it is extremely difficult for those practices to operate without offering Botox, because many patients when they walk in the door, ask for it by name.

And so because of that, they have a bundling program that has been extremely effective and being able to manage the competitive dynamics around this asset quite well.

And in fact, I would say as we built our model for the Allergan transaction, we've built and we've said this a number of times. We've built a fairly conservative model and we did that across virtually every single product. And so, our model is more conservative than what the Allergan current performance is and it's certainly more conservative than their longer range forecast. But it still does project growth for Botox going forward.

I would say we've watched the quarterly performance last quarter and Botox despite the fact that there was a lot of speculation. The competition was going to have a big impact, Botox performed very, very well. We'll see their performance here soon.

But I would expect that Botox will continue to perform very well. And so, I think that organization deserves a lot of credit for the way they have handled the competition and the way they continued to grow this brand quite well.

The second aspect as you have to look at as it relates to Botox is whether or not you are going to see any biosimilars for Botox and we've talked to investors in quite a bit of detail around here.

But the short answer is, based on the uniqueness of this particular molecule, we have come to the conclusion there would be extremely difficult to create a biosimilar version of Botox and I would tell you, we looked at this very extensively with a lot of outside expertise and we feel very confident that that's the case.

So, that was a long answer to basically say to you, we feel good about Botox. We feel good about our ability to be able to continue to grow Botox both in the aesthetics area, as well as the therapeutic area. And I think all of the data thus far only further supports our confidence.

Tim Anderson

Thank you.

Liz Shea

Thanks, Tim. Operator, next question please.

Operator

Thank you. And our next question is from Dave Risinger from Morgan Stanley.

David Risinger

Thank you very much. So obviously the results were quite impressive. I just had a question on the gross margin. So that was down slightly sequentially to 82.0%. Could you just comment on that? And the outlook for AbbVie's gross margin?

Second, with respect to a comment you made earlier, Rick, you said that RINVOQ is capturing 6% of in-play RA patients. I was wondering if you have the SKYRIZI in-play psoriasis patient percentage as well.

And then finally, with respect to IMBRUVICA, there was a recent Blood article on the product's link with hypertension. Could you just comment on that? And talk a little bit about how you are managing that? Thank you.

Rob Michael

David. So this is Rob. I'll take your first question. So if you look at our year-to-date gross margin profile, we are at 82.7%. I have given guidance of approximately 82.5% for the year. The key thing to keep in mind within a particular quarter, you will have sales mix and it can be more pronounced and more pronounced impact on gross margin profile.

In Q3, we saw stronger sales from partnered products like IMBRUVICA and VENCLEXTA, as well as the seasonal impact of Synagis. But keep in mind that we also share expenses with our partners for IMBRUVICA and VENCLEXTA. So that gross margin impact was offset in our expense profile. So as a result, you can see that we've exceeded our guidance on the operating margin profile this quarter.

We just achieved an all-time high at 48.4%. So it's really important when you think about those partnered products to be really focused on operating margin, as opposed to just gross margin.

Rick Gonzalez

And then David, this is Rick. On SKYRIZI, the in-place psoriasis share for SKYRIZI is over 20%, right now and growing pretty rapidly.

Michael Severino

And this is Mike. I'll take the IMBRUVICA question regarding hypertension. So hypertension has been seen with clinical uses in IMBRUVICA and other BTK inhibitors and obviously, we believe that it's important to pay close attention to patient safety and then it needs to be managed effectively. And we think it is managed very effectively both in clinical practice and in our clinical trial programs.

If you look at the overall benefit risk profile, it’s very strong. We have released data from a number of Phase 3 studies across a wide range of settings and that benefit risk profile comes, I think very clearly in all of our data. So we are very confident in the overall profile of the molecule and we are managing hypertension I think quite effectively.

David Risinger

Great, thank you.

Liz Shea

Thanks, David. Operator, we have time for one final question.

Operator

And I am showing no further questions at this time.

Liz Shea

Okay, thanks a lot. That concludes today's conference call. If you'd like to listen to a replay of the call, please visit our website at investors.abbvie.com. Thanks again for joining us.

Operator

Thank you. And this does conclude today's conference. You may disconnect at this time.