Q1 2018 Earnings Call

Company Participants

- Albert Bourla, Chief Operating Officer
- Charles E. Triano, Senior Vice President, Investor Relations
- Frank A. D'Amelio, Executive Vice President, Business Operations and Chief Financial Officer
- Ian C. Read, Chairman & Chief Executive Officer
- Mikael Dolsten, President-Worldwide Research and Development & Executive Vice President

Other Participants

- Alex Arfaei, Analyst
- Andrew S. Baum, Analyst
- Christopher Schott, Analyst
- David R. Risinger, Analyst
- Geoffrey Meacham, Analyst
- Gregg Gilbert, Analyst
- Jami Rubin, Analyst
- Jason M. Gerberry, Analyst
- John T. Boris, Analyst
- Marc Goodman, Analyst
- Steve Scala, Analyst
- Timothy Minton Anderson, Analyst
- Tony Butler, Analyst
- Umer Raffat, Analyst
- Vamil K. Divan, Analyst

MANAGEMENT DISCUSSION SECTION

Operator

Good day, everyone, and welcome to Pfizer's First Quarter 2018 Earnings Conference Call. Today's call is being recorded.

At this time, I would like to turn the call over to Mr. Chuck Triano, Senior Vice President of Investor Relations. Please go ahead, sir.

Charles E. Triano {BIO 3844941 <GO>}

Good morning, and thank you for joining us today to review Pfizer's first quarter 2018 performance. I'm joined today by our Chairman and CEO, Ian Read; Albert Bourla, our Chief Operating Officer; Frank D'Amelio, our CFO; Mikael Dolsten, President of Worldwide Research and Development; and Doug Lankler, General Counsel. The slides that will be presented on this call can be viewed on our website, pfizer.com/investors.

Before we start, I would like to remind you that our discussion during this conference call will include forward-looking statements that are subject to risks and uncertainties that could cause actual results to differ materially from those projected in the forward-looking statements. Additional information regarding these factors is discussed under the disclosure notice section in the earnings release we issued this morning, as well as in Pfizer's 2017 Annual Report on form 10-K. Forward-looking statements during this conference call speak only as of the original date of this call, and we undertake no obligation to update or revise any of these statements.

Discussions during the call will also include certain financial measures that were not prepared in accordance with U.S. generally accepted accounting principles. Reconciliation of those non-GAAP financial measures to the most directly comparable GAAP financial measures can be found in Pfizer's form 8-K, dated today, May 1, 2018.

Any non-GAAP measures presented are not and should not be viewed as substitutes for financial measures required by U.S. GAAP, have no standardized meaning prescribed by U.S. GAAP, and may not be comparable to the calculations of similar measures at other companies.

We will now make prepared remarks, and then we will move to a question-and-answer session. With that, I'll now turn the call over to Ian Read. Ian?

Ian C. Read {BIO 3358997 <GO>}

Thank you, Chuck, and good morning, everyone. During my remarks I will discuss the progress and opportunities we are seeing across the business, as well as the continued strengthening of our R&D pipeline, which we increasingly believe has the potential to drive significant future growth for Pfizer.

In the first quarter, total company revenues declined 2% operationally. This was due primarily to the loss of exclusivity of Viagra in the U.S. in December 2017, biosimilar competition for Enbrel in Europe, and product supply shortages related to our legacy Hospira products in the U.S. and our production facilities in Puerto Rico. These declines were partially offset by continued strong growth in emerging markets biosimilars globally and many of our anchor brands.

I'll begin with a few words about each of our businesses, starting with Pfizer Innovative Health. This business had another solid quarter, growing its top line 3% operationally, thanks to the continued strength of several of our biggest selling medicines. The year-over-year growth rate of the Innovative business was negatively impacted by

approximately 1 percentage point due to the reclassification of U.S. Viagra sales to the Essential Health business, following its loss of exclusivity at the end of 2017.

In addition, both Ibrance and Xeljanz revenues in the U.S. were impacted by customer buying patterns this quarter. But we expect to remain on track for our full-year outlook for both products.

In the first quarter, global Ibrance revenues were up 35% operationally to $933 million, with non-U.S. revenues almost tripling. Ibrance continues to hold a leadership position in first-line hormone receptive positive HER2 negative metastatic breast cancer. Since its launch, approximately 12,000 physicians have been prescribed Ibrance in the U.S. and more than 120,000 patients have been prescribed the medicine worldwide.

The overall CDK class continues to increase penetration within the eligible patient population. And we now see approximately 70% of eligible patients receiving CDK therapy. Within the CDK category, Ibrance again increased its share from 52% last quarter to 56% this quarter.

Xtandi's U.S. alliance revenues were up 21% in the quarter to $159 million. In mid-March, the U.S. FDA granted priority review for the sNDA for Xtandi in non-metastatic castration-resistant prostate cancer with a PDUFA date in July 2018.

In the EU, the EMA has validated the Type II variation submission for the same indication and began the new review process on March 5.

Xeljanz revenues increased 29% operationally in the quarter to $326 million. We recently received two important regulatory milestones for Xeljanz. The FDA Advisory Committee recently gave us a favorable outcome for moderately to severely active ulcerative colitis. And this indication has a PDUFA date in June 2018.

And just last week the Committee for Medicinal Products for Human Use for the European Medicines Agency adopted a positive opinion for Xeljanz 5 milligrams twice daily in combination with methotrexate for the treatment of active psoriatic arthritis. We believe the potential for Xeljanz in psoriatic arthritis, for which we've already received an FDA approval in December, and ulcerative colitis, if approved, could be significant.

Global Eliquis revenues were up 30% operationally in the quarter to $765 million. Eliquis is the number one new-to-brand novel oral anti-coagulant prescribed by cardiologists in 21 markets. In the U.S., it has a 52.1% of the total prescription share for novel oral anti-coagulants, 10 percentage points ahead of our primary competitor, Xarelto.

Finally, we continue to review strategic options for our Consumer Healthcare business, which has delivered another solid quarter. We remain disciplined regarding our capital allocation. And at this time, we have not received an acceptable offer for the sale of this business.

We will continue to manage this very strong business as we explore other alternatives, which could include everything from a full or partial separation of the business to ultimately deciding to retain the business. We continue to expect to make a decision during 2018.

I would like to take a moment to thank all of the Consumer Health colleagues who have worked so hard in the last quarter to produce a strong 4% growth rate.

Turning now to Pfizer Essential Health. While revenues for the quarter declined, due in large part to expected product LOEs and ongoing product supply shortages in the sterile injectable business, we once again saw strong operational growth both in emerging markets and in our biosimilars portfolio.

Emerging markets revenue within the Essential Health business grew 12% operationally for the quarter to nearly $2 billion. China led the way, growing 26% operationally.

Revenues from our biosimilars business grew 53% operationally in the quarter to $173 million. We expect to broaden our biosimilars portfolio in the U.S. by potentially bringing five biosimilars to the market in the next two years.

Our sterile injectable shortages are primarily for products from the legacy Hospira portfolio. We expect our sterile injectable sales will be roughly flat year on year, and this is incorporated into our financial guidance. We continue with our comprehensive remediation plan to upgrade and modernize these facilities. And we expect additional capacity to be available in 2019.

We continue to strengthen and advance our pipeline, which today is as strong as it's ever been. Let me touch on some of the more promising recent developments.

In Oncology, we have a broad range of targeted compounds that represent potential near-term opportunities. The Phase 3 EMBRACA trial showed that our PARP inhibitor, talazoparib, significantly extended progression-free survival versus standard-of-care chemotherapy in patients with BRCA positive metastatic breast cancer. We are discussing the results with worldwide health authorities and anticipate filing this quarter.

Lorlatinib was recently granted priority review by the U.S. FDA as a potential treatment for patients with ALK-positive metastatic non-small-cell lung cancer with a PDUFA date in August of this year.

Dacomitinib received the same designation in April for EGFR-positive non-small-cell lung cancer with a PDUFA date in September of this year with the potential to broaden our reach to areas of lung cancer where there is great unmet need.

In I-O, we continue to progress our development program for Bavencio with our partner Merck KGaA. Both in monotherapy in combinations with chemo and targeted Pfizer

agents, including Inlyta, in first-line advanced renal cell carcinoma and talazoparib in multiple tumor types.

In Inflammation and Immunology, we have built what we believe is a true leadership position with our JAK franchise. We recently started Phase 3 trials of our once-daily JAK-1 in atopic dermatitis. We currently have 10 ongoing selective immunokinase programs.

In Vaccines, the Phase 3 study for our potential C.diff vaccine, where we have the potential to be first in class, has been enrolling well. Leveraging the success of Prevnar, we are in Phase 2 with our next generation pneumococcal vaccine candidate with the potential to cover 20 serotypes. We expect to see the proof of concept data later in the year and expect to begin Phase 3 in 2019.

We also are currently in Phase 2 with our staphylococcus aureus vaccine. And we are in discussions with the FDA regarding expanding the study to become a Phase 3 pivotal study.

In Rare Diseases, we recently announced a positive Phase 3 study readout for tafamidis for the treatment of TTR cardiomyopathy. And we expect a Phase 3 study readout for rivipansel in sickle cell later in the year.

In Gene Therapy, we recently dosed our first patient using our investigational mini dose dystrophin gene therapy candidate for the treatment of Duchenne muscular dystrophy. And early data for this trial are expected in the first half of 2019.

And in Internal Medicine, we expect a Phase 3 readout for tanezumab in osteoarthritis later in the year. If positive, this could be the first in a new class of non-opioid treatments for this disease.

Through 2022 we see the potential for approximately 25 to 30 approvals, of which up to 15 have the potential to be blockbusters, subject to some expected attrition. This presents an unprecedented opportunity to have a life-changing impact on a growing number of patients, while creating enhanced value for all our stakeholders.

In summary, we continue to deliver on our strategy and believe we remain well-positioned to deliver new medicines to patients and increase value for our investors going forward. Most of our anchor brands are primed for continuous growth. Our pipeline is as deep and focused as it's ever been. Our ownership culture remains a key differentiator for us. And our strong balance sheet and disciplined approach to capital allocation will ensure we have the resources to invest in future growth opportunities.

Looking ahead, we expect that a dramatic reduction of LOE impacts following the upcoming Lyrica LOE in the U.S. will unencumber the potential revenue growth of our key drivers, including the expected realization of our pipeline, and allow us to achieve an inflection point in our topline growth profile. Coupled with continued strong expense

management, we expect this will enable us to continue to drive EPS growth at a rate that exceeds revenue growth.

Now I will turn it over to Frank to provide details on the quarter and our outlook for 2018.

Frank A. D'Amelio

Thanks, Ian. Good day, everyone. As always, the charts I am reviewing today are included in our webcast. Now moving on to the financials.

First quarter 2018 revenues were approximately $12.9 billion, which include the favorable impact of foreign exchange of $430 million, partially offset by an operational decline of $302 million.

Our Innovative Health businesses recorded 3% operational revenue growth in the first quarter of 2018, driven primarily by Ibrance, Eliquis, and Xeljanz, which was partially offset by the loss of exclusivity of Viagra in the U.S. in December of 2017 and Enbrel in most developed Europe markets due to continued biosimilar competition. It's important to note that Viagra revenues generated in the U.S. and Canada, which were previously recorded in the Innovative Health business, are now reported in our Essential Health business at the beginning of 2018.

Revenues for our Essential Health business in the first quarter decreased 9% operationally, primarily due to a 15% operational decline in the sterile injectables portfolio, primarily due to continued legacy Hospira product shortages in the U.S.; a 15% operational decrease from Peri-LOE products, primarily due to the expected declines in Lyrica in developed Europe and Pristiq in the U.S., all of which were partially offset by the inclusion of Viagra revenues in the U.S.; 12% operational growth in emerging markets; and 53% operational growth in biosimilars, mainly driven by Inflectra in developed Europe as well as certain channels in the U.S.

I want to point out that in emerging markets, Pfizer's overall Essential Health revenues grew 12% operationally.

First quarter reported diluted EPS was $0.59, compared with $0.51 in the year-ago quarter, primarily due to a lower effective tax rate, due to the enactment of the Tax Cuts and Jobs Act, or the TCGA (sic) [TCJA] (16:23), in late 2017; and higher other income, due to increased income from collaborations, out licensing arrangements, and sale of product rights; and unrealized net gains on equity securities, reflecting the adoption of a new accounting standard the first quarter of 2018, which were partially offset by lower revenues, primarily in our Essential Health business.

First quarter reported diluted EPS was also favorably impacted by fewer shares outstanding. Adjusted diluted EPS for the first quarter was $0.77, versus $0.69 in the year-ago quarter. The increase was primarily due to the previously mentioned factors.

I want to point out that diluted weighted average shares outstanding declined by 35 million shares versus the year-ago quarter, due primarily to our share repurchase program, reflecting the impact of our $5 billion accelerated share repurchase agreement executed in February of 2017 and completed in May of 2017, to a lesser extent by shares that were repurchased during first quarter 2018, partially offset by dilution related to share based employee compensation programs.

As I previously mentioned, foreign exchange positively impacted first quarter 2018 revenues by approximately $430 million and negatively impacted adjusted cost of sales, adjusted SI&A expenses, and adjusted R&D expenses in the aggregate by $349 million. As a result, foreign exchange favorably impacted first quarter 2018 adjusted diluted EPS by approximately $0.01 versus the year-ago quarter.

As you can see, we reaffirmed all components of our full-year 2018 financial guidance.

Moving on to key takeaways. We delivered solid financial results in the first quarter of 2018, with a 12% increase in adjusted diluted EPS versus the prior-year quarter. We reaffirmed all components of our 2018 financial guidance. We accomplished several key product and pipeline milestones. And we returned $8.1 billion to shareholders in the first quarter of 2018 through dividends and share repurchases. Finally, we remain committed to delivering attractive shareholder returns in 2018 and beyond.

Now I'll turn it back to Chuck.

Charles E. Triano {BIO 3844941 <GO>}

Thank you, Frank. Operator, can we please poll for questions? Thank you.

Q&A

Operator

Your first question comes from Jami Rubin from Goldman Sachs.

Q - Jami Rubin {BIO 1527982 <GO>}

Thank you. Ian, this is for you as well as Frank. You've talked about an inflection point in growth post the Lyrica LOE, I think starting after 2019. While I'm not asking you for specific guidance, can you give us a sense for the magnitude of that change? Are you talking about sales going from sort of flattish where they have been for quite some time to sort of mid-single digit growth? And earnings, which have been sort of mid-single digit growth too, where can that go?

And, Frank, assuming you don't do a large transaction, can you still drive bottom line leverage? Ian mentioned that you can. But your margins are already 40%. Can they get to 45% without a large deal?

And then just lastly to you, Ian. Every CEO before you has done a major transaction to accelerate revenue and earnings growth. Just curious, because your messaging has shifted a lot on a quarter-by-quarter basis. What will your legacy be before you retire? I mean at one time you had said you aspired to get back to the innovative core. At other times you've talked about wanting to do a large transaction. So just was wondering if you could kind of share with us what you expect your legacy to be? Thanks very much.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you for that. Let me first of all address the starting growth question. And then I'll come back to the more mundane facts of legacy.

We continue to believe that the combination of our late-stage pipeline, as you mentioned, the significant tapering of LOEs post the impact of Lyrica, plus the growth drivers of our pipeline, will give us a substantial inflection point, I believe moving our growth rates in revenue to mid-to-high single digits, and obviously our revenue being at least equal to that.

If you look at our Innovative Health growth drivers today, we have Ibrance, Xtandi, Xeljanz, Eliquis. And we're participating so those products can continue to conform well, They have significant patent lives, and they have a significant extension of data readouts coming on those products.

Our Essential Health business will expect to be growing at that period, having passed through the major impacts of the LOEs. We have our emerging market business, we have our biosimilars business, and plus we have our sterile injectables business, which we think will put past us any of the issues of manufacturing from the Hospira plants.

So all in all, I am really looking forward to the growth rates that we will produce. And if you look over the four years, we have projected the potential for approximately 20 to 30 approvals, of which 15 have the potential to be blockbusters. I think we put out a list of those products. I mean I don't want to extend the answer too far, but it is an exciting list.

We have in Vaccines, Clostridium difficile; we have Staph aureus; we have pneumococcal next gen in Rare Diseases; we have products in Duchenne's; we have rivipansel; we have tafamidis and tanezumab in pain. I probably think tafamidis was the most risky of those alternatives. And we are extremely pleased with the data from tafamidis.

Inflammation, we have JAK-1, atopic dermatitis, JAK-3, TYK2/JAK-1, Xeljanz in psoriatic arthritis and ulcerative colitis. I think we have about 10 potential therapies in our JAK kinase franchise. So I mean really exciting stuff.

And Oncology, we continue to look at targeted cancer agents, Ibrance, intermediate high-risk breast cancer; Xtandi in non-metastatic; we've got PROSPER, EMBARK, and ARCHER. So I think that is what will drive a really robust top line growth.

Now turning to this issue of legacy. I don't really think a lot about that. I think deals are done based on value to shareholders.

As you say, we've looked at different strategies over the years. Our decision making changes when the facts change. Right now, I think – I would like to think that the legacy that when I do retire that I will leave to patients and to Pfizer is that of a extremely robust pipeline that's beginning to deliver and a really strong culture of ownership and doing the right thing for patients.

With that, I'll hand it over to Frank.

A - Frank A. D'Amelio

Yeah, and then, Jami, on operating leverage, let me just run some numbers for this year, and then I'll answer the question.

So if you look at the midpoint of our revenue guidance for this year, if you look at the midpoint of our EPS guidance, compare that to last year, revenue is up 4%, adjusted EPS is up 11%. So clearly, the ability to continue to demonstrate operating leverage in terms of revenue, the top line to the bottom line.

Going forward, I would leave our margins relatively where they are. If you look at our gross margin, look at operating margin, they're very strong, top quartile of the industry. I think for modeling purposes, we'd leave them where they are.

A - Charles E. Triano {BIO 3844941 <GO>}

Thank you, Frank. Can we move to the next question, please, operator?

Operator

Your next question comes from Tim Anderson from Bernstein.

Q - Timothy Minton Anderson {BIO 3271630 <GO>}

Thank you. If I could just go back to the pipeline and your level of excitement, you guys have a long list of products. And it's almost a laundry list. Some of those invariably will be smaller commercial opportunities, like PARP, maybe JAK imatinib, maybe a new ALK inhibitor.

I'm hoping you can narrow the discussion down to maybe two or three of those products that you think will be the most commercially significant drivers of future growth, as you look forward over the next, call it, five years.

And second question, kind of bringing up this old topic of splitting up the company. You've talked about robustness in the business and how both divisions, both Innovative and Essential, are in increasingly better shape. I know some companies have further digested the tax reform rules that came out before, and they've had a different view of

what that means for them going forward. So my question to you on this is, is there any possibility of reconsidering splitting up the company over the next few years? Thank you.

A - Ian C. Read {BIO 3358997 <GO>}

Tim, thank you for the question. I don't think it's a laundry list. I think all of those products we mentioned, either individually or grouped like the targeted Oncology therapies, have potentials to be blockbusters.

It's difficult to pick out one specific product. But I would say when you look at the totality, I would focus on our vaccine franchise, especially C.difficile. I would look at the huge potential of tafamidis, I would look at tanezumab in pain.

And then frankly, I think the Inflammation/Immunology franchise, taken as a whole, is probably the best in the industry. And we could get into all of the different indications and products there. But if you look at the depth and strength of our science in that area, I'm really excited about our ability to drive meaningful growth from that franchise.

Vis-a-vis the tax law and the split potential, I'll ask Frank to make a few comments on that.

A - Frank A. D'Amelio

Yeah, so on the tax law, obviously we've had more time to digest and analyze the new tax laws, tax reform. We're even more comfortable with the guidance we provided for the year, which is approximately 17% on the tax rate.

On the split, what we've said previously on optionality is that we were taking it off the table for the foreseeable future. So from our perspective, no change. We never say never to anything. But right now, for the foreseeable future, we're all about executing on the business.

A - Charles E. Triano {BIO 3844941 <GO>}

Thanks, Frank and Ian for that. Next question, please, operator.

Operator

Your next question comes from Geoff Meacham from Barclays.

Q - Geoffrey Meacham {BIO 21252662 <GO>}

Hey, guys. Thanks for the question. I just have a few. Ian, with the recent win for tafamidis and the technology deals in the space, just wanted to see if Rare Disease is elevated at all in your strategic priority list. It's a good category. But Pfizer would have to add scale to have it really move the needle.

And then just on the product side, just wondering if you guys have an update on the progress of Xtandi moving upstream to the M0 population. I know that was a big part of

the original value proposition with the Medivation deal and just wanted to check on the progress thus far. Thank you.

A - Ian C. Read {BIO 3358997 <GO>}

Well, thank you. I think we have critical mass in Rare Diseases. We've committed capital to that. We've committed capital to production.

We have not only two possibilities in Duchenne's, we have sickle cell, we have tafamidis, we have tanezumab, we have gene therapy. I'm confident that we have the critical mass. And if assets become available that could be added to that as a bolt on that had significant value, we would act on that. But once again we've always been I think very disciplined in our allocation. And we haven't seen those opportunities as yet.

I would ask Albert to talk about Xtandi and its movement into the early population.

A - Albert Bourla {BIO 18495385 <GO>}

Absolutely. And also just to add in the Rare Disease, that it is a multibillion dollar business right now. We have four assets that they are in Phase 3. We are expecting readouts as we speak.

Cardiomyopathy, it is the one that Ian spoke, but we have also rivipansel. And we have the gene therapy platform that we have already in clinic. Three different modality, hemophilia A, hemophilia B, and Duchenne muscular dystrophy, all in Rare Disease.

Now let me speak about Xtandi and your question about earlier treatments. And I do believe, we do believe that moving Xtandi into earlier treatment settings represents a potential significant opportunity.

In the short term, we are focused on the non-metastatic castrate resistant prostate cancer indication, which is based on the positive results and filing acceptance that we got of the PROSPER study. As you know, we had priority review for that. We have a PDUFA date in July. And hopefully we will see this medicine grow to patients in the near term.

Now in the medium term, we believe growth will potentially come from expanding the Xtandi indication into hormone sensitive prostate cancer. We have the EMBARK trial, but it is in non-metastatic hormone sensitive, and we have the ARCHES trial, which is in metastatic hormone sensitive.

So both studies are progressing very nicely. They are definitely on their timeline. And we are very optimistic about their success.

A - Charles E. Triano {BIO 3844941 <GO>}

Thank you, Albert. Can we move to the next question, please?

Operator

Your next question comes from Gregg Gilbert from Deutsche Bank.

Q - Gregg Gilbert {BIO 3565226 <GO>}

Good morning. First, Ian, on Consumer, if timing is not right and, for whatever set of circumstances, you can't get a fair price for Consumer in the near term, how interested are you in doing something external to Pfizer, like a spinner JV, as opposed to retaining and likely needing to invest in it?

And then perhaps, Albert, you can talk about the competitive threat to the Prevnar franchise that you see from Merck. When could you get your next gen Prevnar to market versus Merck's? And what's next on the legal front? Thanks.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you, Gregg. On the Consumer business it's a good asset. We said we were looking at strategic alternatives to see if there was a better owner. As I commented, we don't at this moment see value in the sale.

We'll focus on running the business. We had a very good quarter. I'm very pleased with the way our Consumer colleagues have reacted and are working hard. We'll look during the year at potential spins or joint ventures.

But you know, frankly, the business is a good business. And if we can't get value, we'll retain it, we'll invest in it. And it continues to be important to us in that sense. Albert?

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Gregg. From what we know, Merck has a pediatric program for a 15-valent pneumococcal vaccine in Phase 2. And the adult program is awaiting start of Phase 3. This is what they have said so far, Merck officials.

But let me talk to you about our program. We have entered the clinic with the next generation, 20-valent pneumococcal vaccine. And this is expected to include seven additional serotypes in addition to those covered by Prevnar 13. All seven significantly improve the coverage in the current dosage space.

Our result from Phase I trial demonstrated that the vaccine was safe and it was well tolerable. But more importantly demonstrated that the induced functional immune responses that could kill all 20 serotypes. So these results supported advancement into Phase 2 that was initiated last year. And right now it is fully enrolled. So if everything goes as planned, we could start our Phase 3 trials in 2019.

All in all, assuming regulatory success for both vaccines and not accounting for patent protection issues that we mentioned, we would anticipate launching in a competitive timeframe to Merck, a much broader spectrum of coverage quality.

A - Charles E. Triano {BIO 3844941 <GO>}

All right. Thank you, Albert. Next question, please?

Operator

Your next question comes from Umer Raffat from Evercore.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi. Thanks so much for taking my questions. I had two on R&D and one for Ian.

Maybe starting out on R&D. On Bavencio, so it's my understanding that the half life is materially less than the competitor PD-1. So it's about three days for Bavencio; it's about 14 to 21 days for competitors. However, the dosing frequency of Bavencio is comparable to Opdivo. So my question is, just want to understand the thought process behind that dosing frequency, given the half-life difference? As well as whether you think that's played any role on efficacy in some of the trials we've seen lately?

Secondly, on tafamidis, congrats on the data. And my question is, how do you see the competitive landscape versus Alnylam's patisiran, especially in light of the recent post-hoc analysis that Alnylam showed on cardiac outcomes? And about a 45% reduction is what they were seeing in the post-hoc basis.

And then finally, Ian, there's been some investor commentary lately on whether your recent comments on not looking for transformative M&A is mainly aimed at controlling the price of the potential target, so that it meets the valuation thresholds when you do actually potentially revisit it in three to six months. How do you react to that? Thank you.

A - Ian C. Read {BIO 3358997 <GO>}

Let me deal with that last question first. We continually look at all deals, as I said. We look for value for shareholders. I don't think we're that smart enough to be gaining anything to that extent.

Frankly, we don't – I don't see that we need a transformative deal, nor do I see one at appropriate values right now in the marketplace. We'll continue to use our capital wisely. I believe at this moment in time, although things can always change, marketplaces can change, I believe the best investment we have now is in our own pipeline.

So with that, I'll turn it over to Mikael to answer the half-life question, and then probably take the tafamidis question as well, as it's still in research phase.

A - Mikael Dolsten {BIO 16368411 <GO>}

Thank you for that. Yeah, we did together with our partner Merck KGgA, substantial pharmacokinetic and pharmacodynamic studies. At the current dose, 10 mg/kg intravenously every two weeks, well should cover the PD-L1 target for blocking that receptor.

You may have noted that we also have an aspect that the antibody has ADCC [antibody-dependent cell-mediated cytotoxicity], which could be a unique property. And we have one study that tried to address whether it can be a positive differentiated property with an even more intense dosing regimen.

Concerning tafamidis, we are, as Ian alluded to, extremely enthusiastic to share the positive results that was in a cardiomyopathy population. And as you know, the endpoint was all-cause mortality and cardiovascular hospitalization.

That study includes wild-type TTR and mutant TTR. For cardiomyopathy, it is to a major extent the wild-type and to minor extent patients having the mutant. So this is quite different from the other biotech companies using injectable that primarily were focused on polyneuropathy.

Some of those polyneuropathy patients that have the mutant form may also have later in life cardiac symptoms. To the best of my knowledge, those were measured with more functional data, and there were no hard endpoints related to cardiovascular hospitalization or even more, of course, mortality data related to cardiac patients.

And finally, to the best of my knowledge, there are no pivotal studies on wild-type patients outside of tafamidis, which is again, the major patients in United States and the Western world suffering from this difficult fatal disease.

So we believe we are, to the best of our knowledge, years ahead of anyone else to have such interesting data set. And we also believe it's a disease that is not well-diagnosed and has substantial potential.

A - Charles E. Triano {BIO 3844941 <GO>}

Thank you, Mikael. We move to our next questioner, operator.

Operator

Your next question comes from Jason Gerberry from Bank of America.

Q - Jason M. Gerberry {BIO 17237298 <GO>}

Oh, good morning, guys. Thanks for taking my question. Just quick question on Ibrance. As the share of growth shifts in the near to medium term to the ex-U.S. markets, just wondering if you can kind of talk us through the progression in those markets of sales uptick, given that you now have reimbursement in EU established and Japan is coming online. So can you talk us through the progression there? And do you think that ex-U.S. markets can ultimately one day be as big as the U.S.?

And then just secondly, just on Eucrisa. Understand there's still maybe a fair amount of free product in the channel, so difficult to really gauge the product at this point. But could

you provide a little bit of direction or commentary just around when we could start to see a bigger uptick in revenue generating scripts? Thanks.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you, Jason. I'll ask Albert to answer both of those good questions.

A - Albert Bourla {BIO 18495385 <GO>}

Yes. Thank you, Jason. And I'm sure you've noticed we are very, very pleased with the progression of Ibrance in the international markets.

We have very strong growth. It was in excess of 170% of growth of sales, so almost tripled. Volume has been higher than that. As of December, Ibrance made up 98% of the total plus packs sold in the EU5.

And also we did progress a lot with reimbursement. Right now, Ibrance is reimbursed in all of EU5, finally, and in Japan, as you mentioned. And in total we have 25 markets that Ibrance is reimbursed right now outside of the U.S. So we expect to have a significant progress and growth acceleration in that part of the world.

And coming back to your question on the U.S. I think first of all, let me make some comments on the U.S., and then I will compare it with the European markets, the ex-U.S. size of the markets.

But in the U.S. we have seen everything that we predicted. CDK class share in the first line new starts continues to steadily grow, as we had predicted. It is now 69% from 58% at the end of last quarter. And Ibrance continues to hold the leadership position in first line, again as we had also predicted. It grew up the market share this quarter to 56% from 52%.

In fact, the scripts grew much faster than the sales in the U.S. We've had 26% growth of scripts, we had 19% growth of sales. And mainly the gap is attributable to fluctuation of buying patterns. I think it's going to be back to normal situation in the months ahead.

And also I want to remember that the growth opportunities in the U.S. have not been exhausted by any means. Right now, in the U.S., while the CDK market of first line new patients is 69% of the CDK, if you see across all lines of treatment, it is only 53%. So we believe that there is significant opportunity to grow the class. And of course Ibrance has now more than 90% of the class share right now.

The size of it too. I think that when it comes to utilization, penetration, and volume of patients, yes, the European markets will do as well if not better than the U.S. market. Of course there is very different price point that needs to be factored when we try to assess the total market.

Now a few comments on Eucrisa. The prescriptions were 90,000 this quarter and – 94,000. And that was a growth compared to previous quarter of 6%.

However, it was slower growth than we had in the fourth quarter, but we had all times peak of the growth. We had 55% growth in the fourth quarter of last year. And this slow down in growth is attributable to the year beginning effort, in which churn in the insurance market suppresses branded prescription demand, as patient adjust to changes in their insurance plans. This has been reported by other companies as well. And to give you a magnitude, we grew 6%, while the total atopic dermatitis was flat.

Right now, we are focusing our efforts in Eucrisa in two areas. One, to make sure that to broaden trial and adoption rates. A lot of dermatologists are entrenched to use steroids right now. And also to improve access. And we have plans in place to do both.

A - Charles E. Triano {BIO 3844941 <GO>}

Thanks, Albert. Next question, please?

Operator

Your next question comes from Andrew Baum from Citi.

Q - Andrew S. Baum {BIO 1540495 <GO>}

Thank you. A couple of questions, please. Firstly, Ian and Frank, on capital allocation, given your collective observations on some of your competitors premium biotech acquisition, together with your comments, Ian, about the pipeline strength and its under appreciation perhaps, should we expect further additional buybacks on top of what you've already committed to this year?

Second, on U.S. biosimilars, and this feeds into your mature products business, do you expect a significant increase in the adoption of biosimilars in the U.S., driven by insurers taking on board biosimilars first, given the pressure from the FDA, HHS, as well as the vertical integration taking place?

And finally, for Mikael, should we expect an interim for the PALLAS adjuvant trial for Ibrance in 2019? Many thanks.

A - Ian C. Read {BIO 3358997 <GO>}

So on the biosimilars, Andrew, we continue to make progress in the U.S. with our own commercial efforts. But I believe that it will take an effort by the administration to move that market, given the substantial advantage the entrenched companies have over the rebating system. So I'm looking forward to activity from the administration on that.

But that being said, we continue to look for a good growth in that area. And it will certainly accelerate post any action from the administration. PALLAS, Mikael?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah, we expect the PALLAS trial for intermediate and high-risk early breast cancer in adjuvant treatment to run until the primary completion date, which is in 2020 to have

sufficient number events.

We remain very encouraged about the translation for metastatic to early breast cancer and have very much confidence in the strengths of IBRANCE based on other new adjuvant studies of the same type of tumor that has been positive.

A - Ian C. Read {BIO 3358997 <GO>}

Okay. So I would agree with you, Andrew. 100% of the pipeline is undervalued. I would ask Frank to make a quick comment on capital allocation.

A - Frank A. D'Amelio

Yeah, so on capital allocation, Andrew, our priorities haven't changed. They remain dividends, share buybacks, investing in the business, and M&A where it makes sense.

Specific to buybacks, to answer your question, in the first quarter we did $6.1 billion in share buybacks at an average price of $36.23. And just in terms of a little history, if you go back to 2010 we've repurchased $61.7 billion worth of our shares, 2.2 billion shares retired at an average price of $27.35. So it's been a very good trade.

In terms of going forward, which is really what you asked me, we announced that $4 billion accelerated share repurchase on March 12 of this year. It'll take several months for that to complete. Once that completes, we'll assess where we are. And then we'll make a decision on whether or not to do anything further on buybacks.

A - Charles E. Triano {BIO 3844941 <GO>}

Thank you, Frank. Next question, please, operator?

Operator

Your next question comes from David Risinger from Morgan Stanley.

Q - David R. Risinger {BIO 1504228 <GO>}

Yeah, thanks very much. I just wanted to dig in a little bit deeper on the opportunity for Ibrance in early stage breast cancer. First, could you please discuss the NSABP's Ibrance PALLET trial? I understand that it's small. It's a neoadjuvant, and it's 14 weeks. But I was hoping that you could frame your expectations for that trial?

And then, Mikael, I know that you commented on Ibrance in the adjuvant setting in response to the prior question. So if you could just comment about both of those trials, both PALLAS and PENELOPE-B, and your level of confidence in success in late 2020? Thank you.

A - Ian C. Read {BIO 3358997 <GO>}

Albert, all yours. No, sorry, we need Mikael to answer it.

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah. Thank you. First of all, on the PALLAS study, which we think – it's run by a collaborative organization, academic, but we think it will readout relatively soon and be reported in the fall.

I have high confidence that we will see a very robust signal based on previous similar studies in the adjuvant, such as the study run by Washington University's of Dr. [Cynthia] Ma and [Dr. Matthew] Ellis that showed a very profound complete cell cycle arrest and also quite impressive responses, complete responses, in a neoadjuvant setting. And it's a very similar patient population to the PALLAS study that you referred to.

And to study the primary endpoint, they used the very same Ki-67 proliferation marker. So I have a strong confidence in a good outcome of pilot based on previous science.

And we think therefore that we should have a very optimistic view on PENELOPE [-B] and PALLAS event-driven, adjuvant trials to hopefully, for the benefit of patients, expand Ibrance into a population of early breast cancer that may be twice as big as the metastatic population. So we look forward to see those studies conclude.

A - Charles E. Triano {BIO 3844941 <GO>}

Thank you, Mikael. Next question, please, operator?

Operator

Your next question comes from Vamil Divan from Credit Suisse.

Q - Vamil K. Divan {BIO 15748296 <GO>}

Great. Thanks so much for taking the questions. Just a couple questions, one on the innovative side with Xeljanz. The product was a little bit less than what we had expected. I'm just wondering if there's been any impact seen on that product, given some of the concerns around thromboembolic disorders with baracitim (49:55), as that went through its review process. And maybe if you can also just frame what you see as the opportunity for UC ahead of that action date next month.

And then on the biosimilar side, just a question on biosimilar Remicade. I just noticed it did have a little bit of a decline sequentially from last quarter in developed Europe, and I assume it was due to competition. But just wondering if you can give a little more clarity on what exactly is driving that. And if it is competition, is it driven by Biogen/Samsung? Or is it driven more by the fact that Celltrion has other distributors selling the product as well? Thanks so much.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you. Albert, if you could take both those questions?

A - Albert Bourla {BIO 18495385 <GO>}

Yes. Xeljanz revenues were up this quarter 30% in the U.S. Particularly like you referred, the growth was 19%. However, the scripts grew 33%. So there is a sizable gap between the scripts and the sales. And most of that is attributable, as with Eucrisa, in buying patterns that, as I said, also other companies reported.

But the fact that this quarter already we see that this is normalized in the months after the quarter. So there is no slowdown on scripts as a regard of any concern. And as we have repeatedly said, that we do not think that there is any correlation in Xeljanz with this type of side effects.

Going to the UC, it is, as you know, under registration. The opportunity, it is large. In the G7, the market, it is approximately $5 billion, affects approximately 1.8 million of people.

We are very encouraged by the efficacy and safety results of Xeljanz in the OPAL Study for psoriatic arthritis and OCTAVE study for UC. We had a very positive advisory committee. We have very positive interactions with regulators. And frankly, we expect that the product will be approved in the near future.

Now, ulcers. I cannot comment on Remicade. But our self, we grew 53% globally and 39% versus last year. And we are very happy with how things are evolving in the international markets, frankly.

A - Charles E. Triano {BIO 3844941 <GO>}

All right. Thank you, Albert.

A - Albert Bourla {BIO 18495385 <GO>}

Our history is in the U.S., where there's disproportionately smaller penetration than whatever is happening in the rest of the world, because of some contracting practices.

A - Charles E. Triano {BIO 3844941 <GO>}

Thanks, Albert. Next question, please, operator?

Operator

Your next question comes from John Boris from SunTrust.

Q - John T. Boris {BIO 2563403 <GO>}

Thanks for taking the questions, and congrats on your results. First one for both Ian and Mikael. If you look at your portfolio of assets and your pipeline, you certainly have the makings of a decent sized orphan disease platform. Certainly your hemophilia franchise through your Factor VIII and IX business, along with your gene therapy programs with Spark [Therapeutics], along with tafamidis and other assets, seems as though that might

be going forward, a very important strategic area. So, Ian, just your thoughts around that and the build-out of that pipeline also, Mikael.

Second question for Frank. On other income, was $250 million in the quarter, but you're guiding to only $400 million. That seems to be a little low. What are some of the pushes and pulls there?

And then lastly, FDA has been pretty vocal on advancing new policies to try and stimulate more biosimilar development, with about a dozen policies that incrementally could move the ball in the direction to try and create more biosimilar competition. What are some of the policies and procedures that you think could move the needle in favor of biosimilars going forward?

And then just any commentary on your Herceptin Complete Response Letter? And when you think you might resolve that? Thanks.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you. Mikael, why don't you talk a little bit about our orphan disease portfolio? I believe we're investing in it. I don't think there's any restrictions in our capital investment. If we see opportunities outside, we'll take them. But internally we have a lot of substrate to work with. Mikael?

A - Mikael Dolsten {BIO 16368411 <GO>}

Thank you. Yeah. Basically, we are focused on hemophilia neuromuscular disease and with some interest also in metabolic rare disease.

Hemophilia, as you know, we have a long history and successful presence in the marketplace treating hemophilia A and B. We are very excited about our hemophilia B program that concluded successfully based on gene therapy, is successfully proved for concept and is progressing in partnership with Spark towards pivotal studies.

We have a hemophilia A, partnered with Sangamo [Therapeutics], where we make progress in dose escalation. And we also have a Pfizer monoclonal antibody against TFPI for weekly subcutaneous convenient delivery for all types of hemophilia, where we've seen some early encouraging sign. Also we think it's a really interesting portfolio.

On the neuromuscular disease side, Ian alluded to that we started gene therapy for Duchenne's. And we also have a pivotal readout with a monoclonal antibody against myostatin in Duchenne's, which we look upon as a high-risk high-reward opportunity.

And of course within cardiomyopathy with tafamidis, we look very much forward to share the data and to swiftly advance the regulatory dialogues.

And finally, end of the year in sickle cell disease, another component of our hematology opportunity in Rare Disease, we have also likely year of the – end-of-the-year readout for

rivipansel. And we are look forward with encouragement based on that mechanism has played out well in the Phase 2.

As Ian alluded to, we think we are well-resourced with all modalities in immunotherapy and end-to-end capability, as well as non-in-therapy modalities. And we will continue to do internal as well as licensing flash bolt-on to accelerate.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you. Other income deductions, Frank?

A - Frank A. D'Amelio

Yeah, so, John, other income for the quarter was actually about a $320 million good guy, income for the quarter. So then that relative to the 400 million for the year, really three major drivers there.

One is we had some one-time milestone payments to the tune of about $115 million. We had $110 million in unrealized gains on equity securities. And we don't try to project those. And those could turn one way or the other going forward. And then the third big ticket item is net interest expense. Interest income for the quarter, about $75 million. Interest expense, about $315 million. You net that out, about $240 million per quarter in net interest expense going forward for the remainder of the year.

When we put that together, we think it's prudent to leave the other income at approximately $400 million.

A - Ian C. Read {BIO 3358997 <GO>}

Albert, biosimilars, including Herceptin

A - Albert Bourla {BIO 18495385 <GO>}

Yes. Let me start with the first one was around the policy of biosimilars. Look, we are very encouraged by the words of FDA and other people in Trump's administration. We just wait now to translate these words into tangible actions that can reverse the situation.

Keep in mind that the biosimilars penetration – let's take infliximab. In Europe, it's 56%. In the U.S., our share is 6%, so there is something wrong with that.

A - Ian C. Read {BIO 3358997 <GO>}

But not in closed systems.

A - Albert Bourla {BIO 18495385 <GO>}

Actually, thank you for raising that. You see in closed systems, we have 66% in this quarter. Half of our sales are coming in closed systems. Closed systems meaning when the

provider is the same person with the person – who the payer. And when it comes to value, we always win. And this is what we want to see that prevails.

Now back to your question about trastuzumab. We did receive, unexpectedly actually, a Complete Response Letter from the FDA. Basically FDA was asking additional technical information clarifications. We didn't think that something like that would come to a Complete Response Letter.

I want to clarify that those questions were not related either to safety nor to clinical data submitted. And they had nothing to do with – pertaining to our manufacturing abilities.

But nevertheless, at this times we do not anticipate that the FDA action will have any impact on our plans to launch of trastuzumab. We think that we will be able to respond to this queries and get it approved before our protected launch date.

A - Charles E. Triano {BIO 3844941 <GO>}

All right. Thanks, Albert. Next question, please?

Operator

Your next question comes from Chris Schott from JPMorgan.

Q - Christopher Schott {BIO 6299911 <GO>}

Good. Thanks very much for the questions. Just two here. Maybe first on the Essential Health business. Could we just get a little bit more color on the legacy Hospira shortages? I believe you said you expect the injectable business to be flat year over year, but the Q1 results were still showing some erosion. Could we just talk a little bit about how you see these issues resolving? How quickly you think you can recapture share once you're back at normalized capacity?

And the second question was on tafamidis. Can you just comment on the size of the cardiomyopathy patient population you're going to be pursuing? And do you believe the ATTR-ACT data suggests potential for this product in polyneuropathy? And if so, do you have to run additional studies there? Or can you refile in that setting? Thanks very much.

A - Ian C. Read {BIO 3358997 <GO>}

Albert, why don't you handle those questions, and ask Mikael to comment as you see fit?

A - Albert Bourla {BIO 18495385 <GO>}

Yes. Thank you 9very much, Ian. Look in PEH, a general comment, as you know, we – the business declined 9%. But I think you see the legacy Pfizer, the decline was only 2%, despite the loss of exclusivities. Most of the decline came from the Hospira legacy, 38%, partly because of the divestment of the device businesses, but also because of supplies that we fail with our sterile injectables.

We do believe that the revenues from this portfolio roughly will be flat this year compared to last year. I think we had the decline this quarter, likely we will see a decline next quarter as well. And then we'll see growth in the third and fourth quarter. So overall, we'll be roughly flat.

We anticipate this situation. And we have incorporated into the guidance that Frank provided, the beginning of the year. And we continue our very comprehensive remediation plans to upgrade and modernize these facilities in Hospira. We are in constant contact with the FDA. And we have increased substantially our investments into this manufacturing site. So we believe that as I said we will be flat. And then next year, we will start providing much more capacity available that we do not have now.

As regards to tafamidis, let me make a comment on the market opportunity, and then I will ask Mikael to help into the more scientific question. The TTR cardiomyopathy is a rare progressive disease. And it is a fatal disease. People that are diagnosed with this disease, they have a life expectancy of three to seven years unfortunately. It is almost like unfortunately a death sentence.

The prevalence of the disease is currently unknown, but it is expected that less than 1% of the people are diagnosed in the U.S. And already, this number is several thousand. So we believe that by working towards improving awareness and diagnostic rates of this disease, we will be able to provide meaningful assistance to those people that they have virtually no options. Mikael?

A - Mikael Dolsten {BIO 16368411 <GO>}

Thank you. That was terrific background of the disease. So I can only build on what Albert said.

Its data suggests the disease is vastly underdiagnosed. And we've seen some recent external figures estimating that just in U.S., it may be more than 100,000 patients related to TTR cardiomyopathy. This is likely driven by the wild type, the senile systemic amyloidosis caused by the wild type, as its increase is dramatically – has contributed to cardiomyopathy with growing age in an aging population.

And now with increasing availability of diagnostic tools and of course availability of drugs potentially pending regulatory dialogues, a drug like tafamidis, there would be large incentives to do more early diagnosis that will allow patients to be treated for longer time before they progress and have this dire prognosis that Albert alluded to.

There's also the mutant form that can be diagnosed very easily earlier in life. But we do think there are opportunities to also diagnose wild type in a more efficient manner. So that's why we're excited about this, having this large data set on wild type TTR cardiomyopathy. And we look forward to the dialogues with regulators and potentially how to contribute to early diagnosis, awareness of the disease to help patients.

A - Albert Bourla {BIO 18495385 <GO>}

And the population of our study, Mikael, included both types, right? Wild types and...

A - Mikael Dolsten {BIO 16368411 <GO>}

It does. Of course initially, the patient group accessible will be mainly with academic medical centers, which is a fraction of the number I shared. But as awareness grows, the disease will be likely diagnosed at many cardiology clinics.

A - Charles E. Triano {BIO 3844941 <GO>}

All right. Thank you, both, Albert and Mikael. Next question, please?

Operator

Your next question comes from Steve Scala from Cowen.

Q - Steve Scala {BIO 1505201 <GO>}

Thank you. Ibrance Q1 EU sales were flat with that in Q3 of 2017. Given the negative sales in Q4, I would have expected a nice recovery. So can you speak to that specifically? And is price the explanation for this disparity?

Second, what were Ibrance and Xeljanz stocking numbers in Q1?

And then lastly, on tafamidis, sorry to ask again, but just to clarify prior answers. Based on the data you have and the data you'll present this year, can you get a broad label for patients with predominantly neurological manifestation and a broad label covering a range of disease severities? It sounds like the answer is yes on both, but please just confirm. Thank you very much.

A - Ian C. Read {BIO 3358997 <GO>}

Mikael, could you give a brief comment on the potential avenues for diagnosis and labeling?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah, we certainly believe on the comprehensive data that we have an opportunity to discuss a broad label for cardiomyopathy. Concerning neuropathy, we do have earlier trials, smaller in nature. But it was sufficient for registration in Europe. And we do have registered to date, though, many patients in Europe that they're doing very well on tafamidis.

And we will look at opportunity in dialogues with the various divisions at the FDA for an opportunity that would cover multiple patient population, as you alluded to.

A - Ian C. Read {BIO 3358997 <GO>}

On the Ibrance question, when you are in a phase of looking for listings in Europe, it's very difficult to get a read on the total value of the products, as very often you sell under emergency protocols at a price that is not necessarily relevant to the final price you get or to the U.S. price, for that matter.

So we see very robust uptake with physicians of Ibrance. And we see an impact of course on the revenue, as we adjust to the reimbursement levels of Ibrance that will give us sustained and a growing opportunity for a substantial patient number increase in Europe. So I think this is part of what we do when we negotiate for access. And we feel we have a very strong strategy around access and future growth in Europe.

Albert, do you want to add anything to the questions?

A - Albert Bourla {BIO 18495385 <GO>}

For Europe, I'd say you said it very well. And we think that the prices that we got represent good value. And they are in line with what usually products are priced in Europe.

A - Ian C. Read {BIO 3358997 <GO>}

And the inventory levels of the movement in – can we – it's very difficult for us to measure that, because it's very – a lot of it's specialty. And we don't have a very strong control, whereas with the distributors in general, we know very well what inventory levels are.

So by deduction, we know that the scripts were up. We know where the revenue was. We know that we don't believe it's a net pricing effect. So by difference, it has to be inventory movements.

A - Albert Bourla {BIO 18495385 <GO>}

And just to add that our calculations reveal that most of the gap, it is because of inventory movement.

A - Ian C. Read {BIO 3358997 <GO>}

Yes.

A - Charles E. Triano {BIO 3844941 <GO>}

Great. Thank you. Next question, please?

Operator

Your next question comes from Alex Arfaei from BMO.

Q - Alex Arfaei {BIO 15433937 <GO>}

Okay. Good morning, folks. Thank you for taking the questions. First on Xeljanz. Roughly, what proportion of Xeljanz in the U.S. is coming from TNF-naïve patients as opposed to

TNF experienced?

And a follow-up on biosimilars. It appears that the Europeans are becoming more aggressive in their adoption of biosimilars. Wondering if I could get your thoughts there. And could you comment on the implications of that both as a headwind for Xeljanz and a tailwind for your biosimilars pipeline? Specifically, would you be able to provide some expected launch timeframes for some of the key biosimilar products in Europe? Thank you.

A - Ian C. Read {BIO 3358997 <GO>}

Albert, would you like to address this?

A - Albert Bourla {BIO 18495385 <GO>}

Yes. On the Xeljanz question, we estimate that more than 50% of our patients comes from naïve patients. And...

A - Ian C. Read {BIO 3358997 <GO>}

And the other question, I think, the Xeljanz opportunities in Europe are just beginning. It's in the actual usage of the product. It's not that the majority is naïve to TNFs, because the growth of the marketplace itself is slow. So it has to be people who've converted over from TNF to using Xeljanz.

The important thing with Xeljanz is that it's a lot of usage in monotherapy, which we think allows us to distinguish ourselves from the TNFs as they go off patent. So I see a very aggressive growth rate for Xeljanz in Europe and a very aggressive growth rate for our biosimilars as well.

A - Charles E. Triano {BIO 3844941 <GO>}

Thank you. Next question, please?

Operator

Your next question comes from Tony Butler from Guggenheim Partners.

Q - Tony Butler {BIO 1504193 <GO>}

Thanks very much. Two brief questions. Mikael, given the outcome of the JAVELIN lung study, what's the position that you feel Pfizer will be in relative to lung as a histology for Bavencio or any other combination and/or combinations moving forward?

And then second to that, does that actually change or does the outcome actually change your strategy or the focus from one of identifying patients, who may respond to a particular monotherapy, I-O monotherapy, or simply combinations for everybody? Is that strategy, is there a difference that may occur perhaps as a result of JAVELIN lung? Thanks.

A - Ian C. Read {BIO 3358997 <GO>}

Mikael. And then perhaps Albert may want to add anything on the strategy or commercial strategy.

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah, we've always been focusing on combinations as the way to go over the longer term. And over the next 18 months, we have six pivotal readouts across five tumor types, of which five of them are combinations and only one is monotherapy to first line lung, including first and second line ovarian, with chemo, renal, in light as a targeted therapy, gastric with Bavencio as maintenance off the chemo. Bladder with Bavencio as maintenance off the chemo.

And the first line lung was designed very differently from the second line. It contains hierarchical readout for high PD-L1 and intermediate PD-L1. And a combined endpoint for PFS and overall survival.

So I think we will be able to mitigate any impact or crossover from control group to either marketed PD agent that we recorded in the second line earlier. So we feel pretty good about this cohort of readouts in the next 18 months. And of course many earlier clinical studies that are not pivotal but will generate the good combination data.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you, Mikael.

A - Charles E. Triano {BIO 3844941 <GO>}

Great. Thank you, Mikael. And, operator, if we can take one last question, please.

Operator

Your final question comes from Marc Goodman from UBS.

Q - Marc Goodman {BIO 1853567 <GO>}

Yeah, just a continuation on the I-O. I was curious your thoughts, Mikael, about TMB as a biomarker? And how much development work you think should be put into that?

And then just on Prevnar, just in the U.S. I know U.S., you can give us a little color on what's going on and how you think about the growth there. Thanks.

A - Mikael Dolsten {BIO 16368411 <GO>}

Concerning TMB, we think it's interesting to explore additional biomarkers beyond PD-L1. To the best of my knowledge, I think PD-L1 is the biomarker right now that has solid data concerning both PFS and overall survival, while TMB is, at this stage, mainly reported PFS data and far less OS data.

So I think we need more time to understand how TMB will fit into it. But obviously we think it's the way to go to have numerous ways to analyze high responders. But our strategy as I said previously will be to utilize those information pieces with drug combinations.

A - Ian C. Read {BIO 3358997 <GO>}

Albert?

A - Albert Bourla {BIO 18495385 <GO>}

Yes, on the Prevnar. First of all to say that the overall sales were slightly declined 3%. And as you mentioned, U.S. was the main driver of the decline with 12%. But I want also to emphasize the significant growth in emerging markets. We had 45% growth. And this is due to multiple factors. But the most important is we just launched in China, where we expect that we will have very good uptake.

Now the specific information you asked for, the U.S. In the U.S. we've had a 12% decline. And this is a combination of both adult and pediatric. Pediatric actually declined 14%, but that was purely CDC purchasing patterns. This is common. CDC, when you have big governmental purchases, they can happen one month or the other, and that can affect your growth. So we think that the pediatric U.S. will grow eventually for the year.

And the U.S. adult declined 7%. Actually, I think it is rather positive, the fact that now we are slowing down the declines as we are coming more to steady state of the adult penetrations.

A - Charles E. Triano {BIO 3844941 <GO>}

Great. Thank you, Albert, and thank you, everybody, for your attention this morning.

Operator

Ladies and gentlemen, this concludes Pfizer's First Quarter 2018 Earnings Conference Call. Thank you for your participation. You may now disconnect.
