Q1 2019 Earnings Call

Company Participants

- Albert Bourla, Chief Executive Officer
- Angela Hwang, Group President
- Charles E. Triano, SVP of IR
- Doug Lankler, SVP
- Frank A. D'Amelio, CFO
- John Young, Group President, Chief Business Officer
- Mikael Dolsten, CFO

Other Participants

- Alex Arfaei, Analyst
- Andrew Simon Baum, Analyst
- Chris Schott, Analyst
- David Risinger, Analyst
- Geoffrey Christopher Meacham, Analyst
- Jason Gerberry, Analyst
- Louise Chen, Analyst
- Navin Jacob, Analyst
- Seamus Fernandez, Analyst
- Steve Scala, Analyst
- Timothy Minton Anderson, Analyst
- Umer Raffat, Analyst
- Vamil Kishore Divan, Analyst

Presentation

Operator

Good day, everyone, and welcome to Pfizer's First Quarter 2019 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 2019 performance and 2019 financial guidance. I am joined today by our CEO, Albert Bourla; Frank D'Amelio, our CFO; Mikael Dolsten President of Worldwide Research and Development; Angela Hwang; Group President, Pfizer Biopharmaceuticals Group; John Young, our Chief Commercial Officer;and Doug Lankler General Counsel.

The slides that will be presented on this call were posted to our website earlier this morning and are available at pfizer.com/investors. You will see here that Slide 3 covers our legal disclosures. Albert and Frank will now make prepared remarks and then we'll move to a question-and-answer session.

With that, I'll now turn the call over to Albert Bourla. Albert?

Albert Bourla {BIO 18495385 <GO>}

Thank you, Chuck, and good morning everyone. It's been a busy and productive first few months as CEO. I've had the pleasure of meeting with many of you to discuss Pfizer's long-term growth prospects. I have also met with thousands of colleagues from around the world, all of whom are committed to driving sustainable growth through scientific and commercial innovation, value-creating capital allocation and a renewed focus on our purpose, breakthroughs that change patients' lives.

I'm pleased to report that we began the year with a strong first quarter. Revenues were up 5% operationally company-wide. This was driven by 8% volume growth, offset by net pricing decline of 3%. If we look at our Biopharmaceuticals Group, which represented 70% of our revenue base this quarter, we generated a strong 11% volume growth, and realized a net pricing decline of 3%. We saw volume growth in several key brands, emerging markets and biosimilars, and we got our Upjohn business up and running.

Let's begin with our result from the Biopharmaceuticals Group. This business grew its top line 7% operationally, due primarily to the continued strength of several key brands, including Eliquis, Ibrance, Prevnar 13, and Xeljanz. Eliquis had a strong start to the year, growing its revenues by 36% operationally in the quarter. Eliquis continues to extend its leadership in many major geographies around the world, and in the U.S. we achieved an all-time high prescription share for the brand this quarter. We remain pleased with the performance of Ibrance. Global revenues in the first quarter increased 25% operationally to $1.1 billion. As you know, the Ibrance growth story is now predominantly in international markets, where we saw 107% operational growth in the quarter. This was driven by continued strong uptake in developed Europe, Japan, and certain emerging markets. In the U.S., we saw 2% growth which reflected continued moderating volumes in approved metastatic breast cancer indications.

Prevnar 13 revenues increased 10% operationally. We saw 31% operational growth in emerging markets, due primarily to favorable overall impact and increased volume associated with government purchases. These gains were partially offset by the non-recurrence of volumes associated with an adult national immunization program in the first quarter of 2018. We saw 6% growth in the U.S., driven by increased government

purchases for the pediatric indication, partially offset by lower sales of the adult indication. Regarding the upcoming ACIP Meeting in the U.S., we continue to believe that maintaining the current age-based recommendation for adults would prevent numerous cases of pneumococcal pneumonia as well as the related hospitalizations and outpatients' treatments.

Xeljanz continues to perform well. Revenues in the quarter increased 34% operationally to $423 million. Volume growth in the U.S. was strong, aided by the recent addition of new indications. While we are in the early days for both launches, 6% of the 38% volume growth in the U.S. came from psoriatic arthritis, and 7% came from ulcerative colitis. So, 30% of the total volume growth came from new indications. We look forward to these new indications potentially becoming even more meaningful contributors in the future. For Xtandi, alliance revenues in the U.S. grew 6% operationally to $168 million. We believe our broad label indication as well as the potential for new indications represent a major opportunity to make a significant impact on patients' lives and change the standard of care in prostate cancer.

Revenues from our biosimilars portfolio grew 7% operationally in the quarter. We received regulatory approvals during the quarter for two oncology biosimilars, and we see the potential for additional approvals in key markets later this year. In sterile injectables, manufacturing supply constraints continue to impact our top line in the U.S. We have made some progress towards fixing these issues, particularly since Frank D'Amelio assumed responsibility for our global supply organization on November 1, 2018. We expect these issues to be significantly improved by the end of 2019, and continue to expect this business to be a solid growth contributor in the future.

Our Upjohn business revenues grew 1% operationally in the quarter. Emerging markets were the primary driver, including strong volume-driven operational growth in China for such brands as Lipitor, Norvasc, and Celebrex. These gains were partially offset by lower revenues for Viagra, and Pfizer's authorized generic for Viagra in the U.S, and for Greenstone, Upjohn's authorized generic subsidiary, primarily due to continued industry-wide pricing challenges in the U.S. generic space. With its streamlined operating structure, relative autonomy and its leadership located in China, we believe Upjohn will help us seize the tremendous opportunity we see in the emerging markets. As the global middle-class continues to rapidly expand, and as awareness and diagnosis and treatment options continue to improve, we believe the Pharmaceutical segment will continue to enjoy significant expansion in Greater China and other emerging markets. Pfizer's consumer healthcare revenues were down 2% operationally in the quarter. This reflected an 8% decline in the U.S., due in part to a milder-than-expected cold and cough season. This decline was partially offset by 4% operational growth in international markets.

Turning now to R&D, today we released our latest pipeline update, which you can see on this slide. We are very encouraged by our pipeline, both in terms of the breadth of opportunities and the science, and while we have said that we expect our 2019 adjusted EPS to be essentially flat operationally, compared with last year, due to the Lyrica LOE, we believe a look at our pipeline will help bring our expected post-Lyrica growth drivers into clearer focus. Since the beginning of 2019, we have already received five approvals; EU approvals for ZIRABEV, a biosimilar to Avastin for treatment of multiple forms of advanced

or metastatic cancer, and for VIZIMPRO for locally advanced or metastatic non-small cell lung cancer in adults. In the U.S., we received FDA approval for Trazimera, a biosimilar to Herceptin for the treatment of certain forms of breast and gastric cancer, and for Ibrance for the previously underserved male breast cancer population. The Ibrance line extension marks the first time that Pfizer medicine has received an expanded indication based on the real-world evidence. And in Japan, we received approval for Tafamidis for the treatment of ATTR cardiomyopathy.

As you can see in this next slide, we have a diverse range of assets spanning from Phase 2 through registration and they cut across each of our areas of focus. Overall, we are thrilled with the depth and breadth of our pipeline as we are not overly reliant on a single pipeline opportunity. As you know, we announced our up to 15 in 5 cohorts almost two years ago. I'm pleased to say that we are making good progress, despite experiencing some attrition, which is to be expected. Let me touch on just a few of the recent and upcoming milestones. I'll start with oncology. Data from our JAVELIN Renal 101 trial saw that the combination of Bavencio and Inlyta significantly extended median PFS by more than five months compared with SUTENT as a first line treatment for patients with advanced renal cell carcinoma. We have filed this data with the FDA with a PDUFA date in June.

With Keytruda plus Inlyta having been approved earlier this month, Bavencio will become the second Inlyta combination available to patients with advanced RCC. We are preparing to submit our Xtandi ARCHES data in hormone-sensitive prostate cancer in the coming months and in 2020, we expect to have data from a Phase 3 EMBARK trial studying Xtandi for high risk hormone sensitive prostate cancer as well as from two Phase 3 trials evaluating Ibrance in early stage breast cancer. We recently presented data from Phase 2 study of our 20-valent pneumococcal conjugate vaccine candidate for adults aged 18 years and older. We're now in Phase 3 and if the data is supportive, we expect to file by the end of 2020. We also expect Phase 2 data from the infant studies later this year. Additionally, our Phase 3 C-difficile vaccine study is now fully enrolled with pivotal data expected next year.

In inflammation and immunology, we expect our first Phase 3 data read-outs in May for our JAK1 inhibitor in atopic dermatitis as well as additional read-outs in the second half of the year. Our JAK3 inhibitor for moderate-to-severe alopecia areata which started a Phase 2b/3 trial in December have also received breakthrough therapy designation and the pivotal readout is expected in the second half of 2021. In internal medicine on April 18, we announced the results of the long-term osteoarthritis study for Tanezumab. As we stated in the press release, we are analyzing these findings in the context of the recent Phase 3 results as we assess potential next steps for this medicine. We plan to review the totality of data from our clinical development program for Tanezumab with regulatory authorities.

While we are very focused on continuing to advance our up to 15 in 5 cohorts, I also want to provide an update on some of the exciting areas in earlier stages of development that we are pursuing. These areas combine novel science and significant unmet medical needs. You can see several areas on the chart but today I will highlight three from the rare disease space. Earlier this month along with our partner Sangamo Therapeutics, Pfizer announced interim data from the Phase 1/2 study indicating that SB-525 was generally

well tolerated and demonstrated at dose dependent increase in Factor VIII levels across the four dosage cohorts in hemophilia A patients.

Based on these results, the Safety Monitoring Committee recommended cohort expansion at the high dose. In March, Pfizer acquired a 15% equity interest in Vivet Therapeutics, a privately held company dedicated to developing gene therapy treatments for inherited liver disorders. Pfizer and Vivet will collaborate on the development of VTX-801, Vivet's proprietary candidate for the treatment of Wilson's disease.

At the upcoming PPMD Annual Conference in June, we expect to report data on our investigational mini-dystrophin gene therapy candidate for Duchenne muscular dystrophy. We will continue to explore both internal and external opportunities for the next generation of breakthroughs. At Pfizer, we are keenly aware that the breakthroughs coming out of our pipeline won't mean anything if people can't afford them, that's why we continue to work with policymakers, payers, providers, and other participants in the healthcare system to find solutions to patients affordability. If you haven't already seen it, I would encourage you to read my testimony from the February 26 Senate Finance Committee hearing on Affordable Access to Medicines. It outlines four proposals that we believe will drive meaningful reductions in costs for patients.

In summary, Pfizer is off to a very good start in 2019. We delivered strong financial performance, while reaching millions of people around the world with our medicines and vaccines. Our new commercial structure is designed to maximize today's revenue growth opportunities, while transitioning the company to a period post 2020, where we expect higher and more sustained revenue growth profile. We remain focused on executing on our commercial strategies, managing expenses, advancing our pipeline, and prudently allocating our capital to position Pfizer for sustainable success.

And now, I will turn it over to Frank to provide details on the quarter, and our outlook for 2019.

Frank A. D'Amelio

Thanks, Albert. Good day everyone. As always, the charts I'm reviewing today are included in our webcast. Now moving on to the financials, first quarter 2019 revenues were approximately $13.1 billion, which reflects operational growth of $664 million or 5%. And the unfavorable impact the foreign exchange of $453 million or 4%. Our biopharmaceuticals Group business recorded 7% operational revenue growth in the first quarter, driven primarily by Eliquis and Xeljanz globally, Ibrance primarily in international markets, and Prevnar 13 in emerging markets and the U.S., all of which were partially offset by declines in our hospital and rare disease businesses.

Revenues for our Upjohn business in the first quarter increased 1% operationally, primarily due to 25% operational growth in emerging markets, driven by strong volume driven operational growth in China, primarily from Lipitor, Norvasc, and Celebrex partially offset by a 9% operational decline in developed markets primarily driven by lower revenues for Viagra and Upjohn's authorized generic for Viagra in the U.S. due to increased generic

competition; Lyrica, primarily due to lower volumes in the U.S. from wholesaler de-stocking in advance of anticipated generic competition, beginning June 30 in the developed Europe for continued generic competition, and Greenstone Upjohn's authorized generic subsidiary, primarily due to industry wide pricing challenges in the U.S. Revenues of our consumer healthcare business declined 2% operationally reflecting an 8% decline in the U.S. partially offset by 4% operational growth in international markets.

In the first quarter, we recorded GAAP earnings per share of $0.68. A $0.09 increase compared to the year ago quarter, which was primarily due to the favorable impact of higher revenues in the first quarter of 2019 compared to last year, lower purchase accounting adjustments, fewer shares outstanding, which were partially offset by foreign exchange, higher asset impairment charges and higher net losses on the early retirement of certain outstanding debt securities. Adjusted diluted EPS for the first quarter was $0.85 versus $0.75 in a year ago quarter. The increase is primarily due to higher revenues, fewer shares outstanding which were partially offset by the impact of foreign exchange compared to the year ago quarter. Finally, diluted weighted average shares outstanding declined by 307 million shares versus the year ago quarter,primarily due to our share re-purchase activity in 2018 as well as our first quarter 2019 share repurchases, which totaled $8.9 billion and included our $6.8 billion accelerated share repurchase agreement executed in February. This was partially offset by dilution related to share-based employee compensation programs.

As I mentioned earlier, foreign exchange negatively impacted first quarter 2019 revenues by approximately $453 million and positively impacted adjusted cost of sales, adjusted SI&A expenses, and adjusted R&D expenses in the aggregate by $315 million. As a result, foreign exchange had a $0.02 per share negative impact on adjusted diluted EPS compared to the year ago quarter. Moving on to 2019 financial guidance, we reaffirmed our 2019 financial guidance for revenues. Two items to note. Our financial guidance continues to assume that the age-based recommendation for Prevnar 13 in adults is maintained by the ACIP when they vote both in late June of 2019. And our guidance continues to reflect expected headwinds in China due to pricing reform which is now being implemented. We increased guidance for adjusted other income by $100 million primarily due to milstone income recorded in the first quarter of 2019. As a result, we increased the midpoint of our adjusted diluted EPS guidance range by $0.01 to an updated range of $2.83 to $2.93. This is the net impact of a $0.03 per share operational increase primarily due to the aforementioned adjusted other income and some smaller favorable adjustments within our other guidance ranges partially offset a $0.02 per share impact due to unfavorable changes in foreign exchange rates since mid January 2019.

Moving on to key takeaways, we delivered strong first quarter financial results with 5% operational revenue growth and 13% adjusted diluted EPS growth compared to the year ago quarter. We raised our 2019 financial guidance range for adjusted diluted EPS by 0.01, reflecting a $0.03 operational increase partially offset by a $0.02 unfavorable change in foreign exchange rates since mid January of 2019. We accomplished multiple product and pipeline milestones since our previous quarterly update. And we returned $10.9 billion to shareholders in the first quarter through a combination of share repurchases and

dividends. Finally, we remain committed to delivering attractive shareholder returns in 2019 and beyond.

Now I'll turn it back to Chuck.

Charles E. Triano {BIO 3844941 <GO>}

Thank you, Frank and Albert for your prepared remarks. At this point, we would like to move to our Q&A session please. Operator?

Questions And Answers

Operator

(Operator Instructions) Your first question comes from Tim Anderson from Wolfe Research.

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

Thank you. A couple of questions, please. On your 20-valent Prevnar follow-on, I am hoping you can talk about when you expect that to move in the pediatrics? It's your largest product Prevnar 13. It's a race between you and Merck to come up with a new and improved version of Prevnar 13. You guys are the incumbent, yet you are not yet in phase 3 in peds, and Merck is. I am wondering if that potentially foretells if there is some sort of formulation problems with your product in peds. So asking for assurances that there aren't. Second question is on Ibrance and just the longer term international opportunity. If you look at major cancer drug precedents in the past by other companies, lots of times those products sell more outside the U.S. eventually than they do in the U.S. Wondering if that could happen here with Ibrance in the CDK 4/6 class because it's not how it's being modeled, or have there been too many price concessions made such that that's not really achievable? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Tim, thank you very much. Both excellent questions; I will ask Mikael to address the question on our 20-valent compared to 15-valent from Merck? And then Angela will answer the question about Ibrance. Mike?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yes, thank you. We are very pleased with our 20-valent pneumo next generation vaccine that covers the 13 serotypes of Prevnar 13 plus seven new ones. These seven new ones were carefully selected to make sure we have a broad coverage of emerging invasive pneumococcal disease strains associated with high case fatality rates and antibiotic-resistance in some cases combined with meningitis. We communicated our adult data at the ECCMID Conference recently which showed a compelling profile which also of course was linked to the breakthrough designation by FDA.

We are moving with good and robust pace forward in the pediatric settings. As you know, in the pediatric settings, we have multiple immunization as well as a boost as is the current regimen for use of conjugate vaccines which is different from the adult trials that the fastest, it's only one immunization. We look forward to read out from the infant trial mid of this year in a Phase 2 proof-of-concept study, and pending review those data set, we look forward to interaction with regulatory agency and swift moving forward into a potential pivotal start. We are very pleased with the formulation. It was very well-tolerated this far and think that we have included all experiences from decades of pneumococcal work into our plan.

A - Albert Bourla {BIO 18495385 <GO>}

And I would like also to remind that we have a very strong patent portfolios on Prevnar, Angela, would you like to address the question with Ibrance please?

A - Angela Hwang {BIO 20415694 <GO>}

Thank you. Ibrance revenue growth continues to be very strong ex-U.S. And you heard Albert mention in his opening remarks that currently we are growing at 107% in Q1 of 2019. We believe this growth to be sustainable as we see that there is still significant room to grow in the CDK class as well as our own market share. Just as an example in the EU5m the CDK class is currently 35% of all first-line new patient starts while we have 86% Ibrance class share. In Japan, as an example, this CDK class is only 21% first-line new patient starts and a 100% of the Ibrance class share. So while we are continuing to build our Japan and EU business, we are also intensely focused on our launches in the emerging markets. So far, we have seen 122% operational growth year-on-year in the emerging markets, and led by double digit growth that we are seeing in Argentina, India, Saudi Arabia as an example. We have launches coming up both in Brazil and China which we are very excited about, and we expect these to be very strong contributors to our 2019 growth trajectory. So, in view of the three phases of growth for Ibrance, the first being the U.S., which is where we began with our first indication. Now in our international launches which are moving beyond the developed markets to the emerging markets. And then the anticipation of our adjuvant indications to come with Ibrance, we continue to be extremely optimistic, and I feel very positive about the growth trajectory of Ibrance.

A - Albert Bourla {BIO 18495385 <GO>}

Great. Thanks, Angela. Next question please, Operator?

Operator

Your next question comes from Vamil Divan from Credit Suisse.

Q - Vamil Kishore Divan {BIO 15748296 <GO>}

Great. Thanks for taking my questions. The first on Xtandi. The sales there were a little lighter than we thought and I'm just wondering if there is any onetime item. The prescription trends also seemed a little lower last quarter than what we were seeing in the past. So, comments there. And then just maybe you outlook for that product longer term, I know you have expanded label in new indications coming, so just if you could frame

how you see that longer term? And then second on the DMD data you mentioned coming in June. It's interesting a lot of focus on that even though it's pretty early data, maybe if you could just sort of help sort of frame expectations around that in terms of what we will actually see and what we should be expecting going into just so people sort of have appropriate expectations given that it is such early data. Thanks.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you very much, Vamil. Angela, I think you can cover the Xtandi question, and then, John, if you can please discuss the DMD data on

A - Angela Hwang {BIO 20415694 <GO>}

Thank you. Well, we have seen very strong prescriber adoption of Xtandi across all of our indications. I think that this demonstrates the confidence that prescribers have with Xtandi. Year-on-year neurologists have prescribed -- prescribing has grown 45%. And oncology prescribing has grown 20%. We are also pleased with the uptake of Xtandi in non-metastatic CRPC. This is our PROSPER trial. Even though this was launched just eight months ago, its market share is already equivalent to our metastatic indication which was launched seven years ago. And this market share is more than double that of ERLEADA in non-metastatic CRPC.

We have yet to realize the full potential of PROSPER, because the impact of patient accumulation and the longer days of therapy are still to come, and just as a reminder, the days of therapy for the PROSPER trial is 18 months. This quarter, as you say, the U.S. net revenue did lag behind total patient demand. But this was due to some gross to net adjustments, some inventory differences, and our free drug program. But we continue to believe in the strong growth potential of all of our indications, and we look forward to our indications from both the ARCHES and the EMBARK trials, which will continue to drive growth through expansion into new patient segments and offer longer days of therapy. So we need to stay the course with our strategies, and we believe the impact from PROSPER as well as our new indications will drive future growth, change the standard of care, and meet high patient unmet needs.

A - John Young {BIO 17639257 <GO>}

Thanks. Hi, Vamil. So thanks for the question about our DMD program. So Albert obviously touched on this in his prepared remarks and just to emphasize again we are going to be presenting data from mini-dystrophin DMD gene therapy candidate at the PPMD meeting in Orlando, which is at the end of June. For our DMD program, the first patient was dosed with an infusion of the mini-dystrophin gene therapy in March of 2018. In total, six patients have been treated in two dose groups, one E14 and three E14 dose regimens. Part of the trial protocol, muscle biopsies were to be taken at baseline two months post treatment and 12 months post treatment. And to the extent that that biopsy data is available and mature, it will be presented at PPMD. We also intend to present an update on the safety profile of this therapy at PPMD and we are excited to present the data and obviously particularly to continue to work with the DMD community for a disease that is so devastating for so many boys with this condition.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, John. It's a devastating disease, and we all hope that the solution that we are working and others, but the solution that we are working would be really transformational. Next question?

Operator

Your next question comes from Chris Schott from J.P. Morgan.

Q - Chris Schott {BIO 6299911 <GO>}

Thanks very much. Just two bigger picture questions, I guess, the first one with the progress you've been seeing on the pipeline, can you just update us in terms of where you see business development fitting into the longer term view and strategy for the company. I guess, specifically, I think you have been clear that larger deals are off the table for now, but when we think about bolt-ons, what type of size of deal could that encompass and what are the latest priorities in terms of commercial stage assets versus clinical assets et cetera? And my second question with the Upjohn division, do you believe that it will be possible to eventually separate and spin this division from the rest of Pfizer and if so what are the factors and kind of data points we need to be watching that would make that type of separation something that would be possible over time? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Yes. With the business development, I will ask John to comment and you have heard our comments that we plan to invest significantly in business development. It's a little bit different, the way that we plan to do it right now. Before we were targeting revenues, now or soon. Right now, the focus, it is how to -- and because this is what we needed at the time. Now our growth trajectory, I think organically is going to be robust post 2020. So what we are looking for, it is to enhance even further our pipeline. So, as regards the direction in how we are selecting clinical opportunities -- clinical -- John, can you please make a comment? John has the responsibility of managing this strategic area for us.

A - John Young {BIO 17639257 <GO>}

All right. Thanks, Albert, and thanks Chris for the question. So I wouldn't repeat what Albert has already said about the reorientation of our focus of BD from revenue, now seeing opportunities to really strengthening our pipeline with clinical stage assets. I think, if you were to look into the future, I think you'll see us continue to be very active in business development, but I think with our focus generally on earlier to mid stage opportunities where clinical risk may be higher as data is less mature, but we believe that the opportunity for value creation is greater. And the risk, importantly, of operational disruption to the pipeline, internal pipeline, which is obviously maturing, we believe, very nicely, is going to be lower. Certainly, in terms of what size we consider to be a bolt-on, generally, we don't comment specifically on size. I think you would say that assets that are in the range of a few billion dollars, we consider to be bolt-on acquisitions, and to really complement our pipeline. So we are very excited about the opportunities that we have

and that's something that particularly we're going to be focused on over the months ahead.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, John, and maybe I can provide some color to your question about Upjohn. It's a good question and I receive a lot this question and I understand the reasons. Right now, as I said nothing has changed other than Upjohn performed very well in the first quarter. Always I said that our focus it is to make sure that we stand up this business in a way that will operate effectively and effectively means that in a very new, lean, construct with management relocated in China where most of the opportunities are as evident from the first quarter but also where most of the challenges will come as we know that there are some reforms that the governments are taking into this business. So right now, I'm very, very pleased with the way that the whole thing is evolving. If we think that we could separate down the road, yes, it is a possibility, but this is not what is in my mind right now. First, we need to make sure that we have a strong stand-alone business. So we are working to make sure that operates Upjohn fully as a subsidiary within the company.

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

Great, thank you, Albert, and John. Next question please, Operator?

Operator

Your next question comes from Geoff Meacham from Barclays.

Q - Geoffrey Christopher Meacham {BIO 21252662 <GO>}

Good morning, everyone. Thanks for the question. Mike or Albert, just wanted to see if you have any additional color on the recent Tanezumab long-term data, just in particular the RPOA rates and I know you're awaiting FDA feedback. But would it be the totality of the data so far or the unmet need is still warranting a filing at this point. And then another one on BD somewhat, so on the gene therapy front, you guys are obviously progressing a number of programs, hemophilia DMD, a lot of BD activity in this area recently, so the question is, has the decision to buy versus build, or partner changed for Pfizer over time. It does seem like post the Bamboo deal you guys have a working platform that really could add multiple indications quickly. I just wasn't sure what the strategy is there. Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Right. I will ask Mikael and John to comment on Tanezumab. So John, why don't you start and then maybe, Mikael, you can give a little bit of scientific information?

A - John Young {BIO 17639257 <GO>}

Yes. So look, thanks for the question, Geoff. Obviously we've released a fairly significant commentary on the study in our press release. I wouldn't comment on that, but I think, let me just say for Tanezumab, we are continuing to analyze the clinical profile based on the ongoing Phase 3 development program in both OA and chronic lower back pain. That

includes in totality five Phase 3 studies and nearly 7,000 patients and we plan to review the totality of the data with regulatory authorities and we'll assess potential next steps for Tanezumab and as we engage with regulators we will be in a position to provide an update in the coming months.

A - Mikael Dolsten {BIO 16368411 <GO>}

That was very well-summarized, John, and of course it's a very large data set from this recent Phase 3 and previous Phase 3. So it's a real opportunity to put together the totality of data together with our partner, Lilly, and have a discussion with regulatory agency about that data set and the pain landscape.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Mikael, and then maybe I can give you an answer to your question about gene therapy, it is yes, as you said gene therapy is an area but -- of significant focus for us and this is an area that we started much earlier and our strategy was to combine our clinical expertise in the said therapeutic areas together with biotech expertise as they were developing specific projects and very early we realized that in this category the bottleneck is going to be manufacturing. This is why Pfizer embarked into significant investments to build the platform in manufacturing, which is progressing very, very well. As we look to the future, we plan to do both, to grow our platform organically through projects that we're developing and inorganically through the licensing and partnership that we are going to make. And actually the last partnership that we announced was in the gene therapy field for the Wilson disease, which is a liver disorder. We believe actually that exactly because of our track record of having successful partnerships, but also because we have built a significant manufacturing capability, we will become a partner of choice for Biotechs that they will see that the combination will unlock value for that.

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

Great. Thanks for those responses, can we move on to the next question please. Thank you.

Operator

Your next question comes from Andrew Baum from Citi.

Q - Andrew Simon Baum {BIO 1540495 <GO>}

Thank you. Couple of questions, please. Firstly, you referenced the, the pending ACIP review for Prevnar 13. Given the replacement serotype drift that we've seen because the pediatric vaccination. I know that your numbers in guidance includes -- no change in their recommendation. What's your level of confidence? And if high, which it seems to be, exactly why is it high given the meeting has been scheduled to discuss it? And then second, in reference to Eliquis. Could you talk to what you see as the likely impact on realized pricing and volumes for Eliquis sales within your Medicare book of business assuming rebate reform takes place as the administration seems to be pushing for at the beginning of 2020? Many thanks.

A - Albert Bourla {BIO 18495385 <GO>}

All right, why don't you Angela answer the ACIP question?

A - Angela Hwang {BIO 20415694 <GO>}

So, our adult PCV13 vaccination program has been extremely effective and it's difficult for me to speculate on the ACIP vote because that's still coming up in June. But I do want to emphasize that Pfizer strongly supports the continuation of the current adult vaccination program. This is because there are actually important serotypes such as serotype 3 and serotype 19A that still have not reached acceptable protection levels. So keeping the current recommendation will prevent numerous individual cases of pneumonia, hospitalizations and other outpatient treatments. Direct vaccination is important because there are also underserved populations still in our country where the disease risk is high. And just to give you a couple of examples. Those that are living in rural communities have 50% less coverage than those that live in suburban areas or there is a 24 point gap among the low socioeconomic adults. I think you've also seen through the recent news reports the importance of direct vaccination for adults as well as for public health and we also are looking forward to the filing of our next generation pneumococcal vaccine, where we received FDA breakthrough to exit designation. We expect to file this by the end of 2020 and so it underscores the importance of an uninterrupted adult vaccination program.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you. Andrew, you asked also about the Eliquis and how we think this will perform in the Medicare population particularly given price and volume. First of all, I would say that Eliquis had the phenomenal performance I think I'm thinking highly about the profile of this product. But 36% growth is really something that we feel - make us feel very proud and actually in the U.S., the growth was even stronger 38% but the U.S., it's part of the business, right. So it is a very, very well diversified geographical brand. And I think that the pricing pressures, the growth is coming predominantly those 38% from volume, and all our strategies it is how to make sure when the diagnosis rates are more accurate and people and physicians understand the profile of the products that they can make the right choices when they choose to prescribe a medicine like that. So given that everything is a predominant growth, it is volume and I think very good about the growth prospects of this product going forward.

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

Thanks. Albert and Angela, can we move to our 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 wanted to focus on two broad topics. First on Ibrance's adjuvant, can you quantify for us how large an opportunity you think that is? And given the significance of it, I have to ask, is there an interim this summer? And

secondly on DMD gene therapy, my question is, do you think you have a best-in-class asset? And I ask partially because I don't see this asset listed in your 15 blockbusters by 2022 which should theoretically be a very realistic possibility even if the pivotal were to start in early 2020, so just wanted to reconcile both of those. Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you. Angela, I think you can deal with the Ibrance, the market, the potential of -- and also let me say that -- on the studies, yes, there is an interim analysis as with all studies, but the studies are designed to come to full completion. So we expect that the studies will be completed. And we expect that this completion will happen next year, although it is event-driven, so we need to see how the events will evolve. But, Angela, let's speak about the commercial opportunity, and then, John, maybe you can give the clarification about DMD because what we have in 15 in 5, it was not the gene therapy molecule. Please.

A - Angela Hwang {BIO 20415694 <GO>}

Sure. So, we have the two Phase 3 studies ongoing in the high risk early breast cancer population, the first is the PENELOPE, which enroll patients with high risk early breast cancer previously treated with the neo-adjuvant therapy and then we have PALLAS which enrolled patients with the high risk early breast cancer stage 2 and 3, we're optimistic about both of these studies because of the ability to meet unmet need but also to your question more directly if successful we will have the ability from both of these programs to double the number of patients that are eligible for Ibrance.

A - John Young {BIO 17639257 <GO>}

Yes, and thanks for the question about DMD again. Obviously the 15 in 5 or up to 15 in 5 portfolio reflected the portfolio that we had at that time and plainly one of the sort of good things in our industry is that a portfolio is never static and so I think as we begin to see data readout from our DMD gene therapy program, the profile of that medicine will become clear to us and to clinicians and to importantly to patients. So we would really see this having the potential to be an additional complement to that portfolio that we described last year. So I think it's obviously premature for anybody to describe the relative profile of respective or other comparative gene therapy assets, the data is still emerging, it's still in relatively small patient numbers and obviously for us and other players in this field, we will see the totality of data as it emerges over the months and years ahead. But we feel cautiously optimistic about that program. As I mentioned in my comments earlier on, we look forward to presenting some clinical data from that later on this year.

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

Thank you, John and Angela for the background. Next question please?

Operator

Your next question comes from Louise Chen from Cantor Fitzgerald.

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

I don't think we can hear you, if you are asking a question maybe you are in mute.

Q - Louise Chen {BIO 6990156 <GO>}

Hold on, un-mute the phone. Can you hear me, okay now?

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

Very well.

Q - Louise Chen {BIO 6990156 <GO>}

Okay, sorry about that. Okay, so thanks for taking my questions, I have a few here. So first question I had was on Tanezumab, just curious how the recent data impacts you thinking with respect to the CLBP in cancer pain indications and then secondly on Tafamidis, how do you expect the initial launch to go if you do get approval this year, what is your anticipation for adoption, payer coverage, physician and patient awareness and then last question is on your business development comments, just curious if you have any interest in primary care or you more focused on specialized medicine? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you. John, what about Tanezumab?

A - John Young {BIO 17639257 <GO>}

Yes, thanks for the question Louise. I mean I think we've probably covered this mostly in our comments earlier on. So we obviously have shared fairly detailed press releases at each of our Phase 3 studies readout and I think what we are just saying overall is we're going to look at the totality of the data from all of our Phase 3 studies, we have round about 7000 patients worth of data, we're still in the process of analyzing the clinical profile and understanding its potential value across different indications. Our next step is obviously most importantly going to be to discuss that data with regulators and we will be in a better position to be able to provide you with an update once we have done so.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you. Angela, very exciting news for Tafamidis' potential launch, so tell us.

A - Angela Hwang {BIO 20415694 <GO>}

Yes, we are very excited about Tafamidis and that's because it's a transformative therapy for ATTR-CM and today it treats a fatal and a rare disease where there are no therapies or no alternatives but it also addresses a large burden on the healthcare system because of the complications and the hospitalizations that arise from this disease. We do see this though as a rare disease, so approximately 100,000 patients in the U.S. But as you know today it is severely underdiagnosed. We estimate approximately a less than 1% diagnosis rate because of their lack of treatment and the use of invasive heart biopsies to drive the diagnosis. So, as you can see diagnosis is going to be key to growing this market. At launch therefore we're going to be focused on creating suspicion of this disease by

cardiologists and patients through educating them around the signs and symptoms of cardiomyopathy.

We also need to increase the utilization of non-invasive methods such as scintigraphyversus a heart biopsy for diagnosis. So as you can see, this will all take time because we need to educate both physicians and patients on these red flag symptoms. We need to drive the utilization of scintigraphy and we also need to advocate for the changes in treatment guidelines which will help to drive both diagnosis and treatment. But as Pfizer, we are confident about our capability to build this market because we have a track record of success in creating new markets. And just to bring up an example from Xalkori, you may recall that at the time of launch of Xalkori the diagnosis rate of the ALK mutation was only 1%. But today it is 80% to 90%. So Tafamidis has excellent data, it has a compelling patient benefit. Pfizer has deep expertise and a commercial footprint in cardiology. So we look forward to bringing all of these capabilities to bear in launching this important medication to the patients who need it.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Angela and maybe I can make some comments about your question Louise about if we would be interested to also in-license primary care potential candidates in medicine and the answer is of course yes. But let me be clear and specific what we mean. We have specific criteria what we are interested in licensing in, so it's not just a blind thing to have given to people go in-license things. But those criteria involve that the potential of medicines need to be breakthroughs. It's to be significant science that can create significant improvement in current standards of care. And they need to be within the areas of expertise of Pfizer, so that we can add value to it. It's just not to go on with the in-licensing. But we can add value.

And we have six areas of expertise right now that they are all from that aspect, from my perspective, are treated equally. Those are areas that we know we have the best science in the world that they can make fewer mistakes as we're selecting products. And this is where we have the scientific expertise to develop potential in licensing assets in the best possible way because the development path plays a key role in our working the value of a molecule and primary care is definitely one of the areas of significant expertise of us from the long way that goes way back but also in the current days as we are having some of the best scientific programs running in metabolic diseases and other primary care conditions in our research centers. So the answer is yes, and the criteria that we are going to implement I hope I made them clear.

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

Great, thank you, Albert. Next question please?

Operator

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

Q - Jason Gerberry {BIO 17237298 <GO>}

Hey, good morning. Thanks for taking my questions. I guess just firstly coming back to the Tafamidis launch. Can you give us a sense of what you view as maybe the best analogs for driving this diagnosis and treatment rate above this 1% level. I guess on the one hand it looks like there's a largely an educational element to this with a lot of these patients basically sitting in the cardiologist office just not diagnosed but you also have a drug that's pretty easy to dose no monitoring. So I'm just kind of curious, if there are any analogs that you guys have thought about. I wouldn't think that Xalkori would be the greatest analog but correct me if I'm wrong. And then secondly on DMD gene therapy, it sounds like you haven't dosed any patient at the intermediate dose, I was curious sort of the rationale for having an intermediate dose, was that more of a safety consideration or just seeing the above normal expression levels achieved with Sarepta program had a lower dose than your high dose was the decision ultimately to just have the optionality around a lower dose? Thanks.

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

Thank you. Angela, why don't you deal again with Tafamidis question. There is a lot of interest in this product and they understand why.

A - Angela Hwang {BIO 20415694 <GO>}

Yes, sure. So actually we do think that Xalkori is a great analog for what we see coming up for diagnosis in -- for Tafamidis in cardiomyopathy. Today, this is a disease where the symptoms and the signs and symptoms are easily, I guess it could be confused with heart failure. So I think the ability for us to be able to find diagnostic approaches that will help us to really identify and to isolate who, specifically the cardiomyopathy patients are going to be really important. I think that there are some symptomatic attributes that we plan to be educating around at the time of launch. But really, what we need is the ability to leverage technology such as scintigraphy as an alternative to what exists today, which is a hard biopsy, which is extremely invasive.

And I think that the ability to use scintigraphy will allow us to more readily diagnose these patients, I think the qualitative attributes, the symptoms will allow us to create suspicion around what the right pool of patients might be. But the definitive diagnosis really needs to come with scintigraphy. There are 15,000 scintigraphy machines within cardiology offices today and 32 centers of excellence. So I think that this effort around education and awareness building is going to be key to both bring patients to the doctors' offices, but also to highlight the importance of these symptoms to prescribers and then to eventually diagnose and to treat. So as we said, I think we have deep expertise and capabilities in doing this, but that you can imagine with a disease that is so undiagnosed and up till now has had no therapeutic options. This is going to take time for us to really educate and to bring the full benefit of Tafamidis to bear.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Angela. And Mikael please, if you can comment on dosing strategy with a DMD development program, and maybe you can provide any color you would like about this breakthrough medicine?

A - Mikael Dolsten {BIO 16368411 <GO>}

Thank you very much. Yes, we worked with our Bamboo colleagues in carefully designing this AV9 vector that contains muscle relevant with specific promoter for expression of the trans gene. And the protocol was designed intentionally based on our experience of many gene therapy programs to allow some flexibility, which was the basis for dosing at 1E to the 14 and 3E to the 14 to gain experience across a reasonable dose range in what will be the expression of the trans gene the tolerability and clinical performance for young boys that, as Albert alluded to earlier, we're aiming to have a transformative outcome. Now we look forward to share data at the PPMD meeting in Orlando this late June. We think it is a good meeting for that purpose. It's one of the largest Duchenne muscular dystrophy gathering where both key scientists attend and patient representative. As you know, these types of devastating rare disease you work very closely with the leading scientists and patient groups. So we look forward to be there and share data set as John alluded to earlier.

Q - Jason Gerberry {BIO 17237298 <GO>}

Thank you very much, Mike.

A - Albert Bourla {BIO 18495385 <GO>}

Right. Thank you for that background also. Next question, please?

Operator

Your next question comes from Alex Arfaei from BMO Capital Markets.

Q - Alex Arfaei {BIO 15433937 <GO>}

Good morning and thank you. A couple of follow-up questions on Tafamidis. Congratulations on the approval in Japan; it was faster than we expected. We focused a lot in the U.S. market, but could you also comment on the ex U.S. opportunity for tafamidis? And following up on the diagnosis rate commentary, my understanding was that you are also working on blood tests to make diagnosis even easier. Could you give us an update on those efforts as well as your potential launch readiness in case of earlier approval in the U.S.? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Alex. Angela again, you are the ex U.S. opportunities and on the testing?

A - Angela Hwang {BIO 20415694 <GO>}

Right. So, yes, with the Japan launch was very recent. And I think that the opportunity there sets us up well, for the kind of launches that we expect to see around the world, as you say, it's not just the U.S., it's Japan, it's also rest of world. In terms of rest of world, I think the filings have been submitted and unable to comment on those for now because we are still awaiting for commentary from the regulatory agencies, but I think that my general comment about Tafamidis is really one that I mentioned earlier, which is the critical aspect of this is diagnosis. It really is a rare disease. It is severely underdiagnosed

today because of the lack of options. And so, critical to our ability to drive Tafamidis growth anywhere in the world, is the ability for us to be able to find the patients and then be able to screen them and to be able to diagnose them and then send them on to treatment. So I see that these trends are pretty consistent wherever we are around the world.

A - Albert Bourla {BIO 18495385 <GO>}

Mikael is a great physician, but you are as well. Can you please comment a little bit on the diagnosis opportunities for this Tafamidis?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yes, I want to just punctuate that. The growing availability of scintigraphy technician based, makes it increasingly easy to get the diagnose after suspicion often raised by clinical symptoms, and echocardiogram. We are also in parallel looking at potential future blood markers. But right now, I think there should be no really hindrance to fast and easy diagnosis based on clinical sign scintigraphy. And in addition, we have made work on diagnostic algorithms, including artificial intelligence to be able to advise on typical algorithms that makes a heart cardiomyopathy, more likely to be TTR related, than unrelated.

A - Albert Bourla {BIO 18495385 <GO>}

Yes. It's amazing how much work is happening right now in this field and particularly how AI also can help identify potential people that potentially could suffer from this disease. And we had some multiple discussions with payers as well and a lot of them, they're having high interest to exploit this opportunity because when we say 1% is diagnosed, we don't mean that the 99%, they are just untreated. Usually, all of these patients are presented with heart failure symptoms and they are treated for the wrong reason and they're going of course doesn't work because the doctor haven't identified the disease, the real cause of their cardiac issues and then they have treated it and failed and treated it and failed and then eventually, there's a fatal event. So payers are highly interested to diagnose this disease, I think. But as Angela said, this is the key and we know how to do it very well. But it will take time to pick up these diagnosis rates, but we will do.

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

Great. Thanks for that context as well. Next question, please?

Operator

Your next question comes from Navin Jacob from UBS.

Q - Navin Jacob {BIO 20931208 <GO>}

Hi, Navin Jacob, UBS. Thanks for taking the questions. A few, if I may. Interesting slide on your treatments beyond up to 15 in 5, 2 in particular stood out the oral GLP-1 and the HER2 ADCs. Could you provide any context for how far along those assets are particularly the oral GLP-1, are those Phase 2 assets, Phase 1 assets? Any color would be helpful. And

then, I'll add to the questions on Tafamidis. With regards to the payer discussions, are most of those related to traditional contracts or are you exploring outcomes based contracting? And if so, to what extent is that? Do you think that outcomes-based contracting is will be a broad mandate or is it more of a experimental type of situation. And then finally, if you have any color on resolution of the sterile injectable manufacturing issues, is the resolution still expected for end of 2019? Thank you very much.

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

Thank you very much. Mikael, let's start with you, and with the Beyond 15 in 5?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yes, I really appreciate your interest in the beyond 15 in 5, which of course covered the next period beyond 22 of the up to 15 in 5. So for the oral GLP, that's been an area where we have deployed some unique chemistry. And I'm very pleased to say that we are right now concluding a Phase 1b trial in diabetic patients and I've seen some very encouraging performance of that drug related to control of diabetes and bodyweight and we look forward to share those and will swiftly move into a larger Phase 2 trial for diabetes. To the best of our knowledge, this is the only true small molecule that have come this far and shown this promise in PK and pharmacodynamic favorable effects. The next generation HER2 ADC is based on site directed conjugation of adjuvant inhibitor and has been going through dose escalation and showed promising signs of activity. We continue to optimize those and expect to go into Phase 2 expansion cohort relatively soon including potential combination with PD-1 agents.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Mikael. Let me give you a very brief comment on Tafamidis and then I will ask Frank to take the manufacturing question. On Tafamidis, as you know breakthroughs requires a breakthrough approach is also commercial and we believe that we want to, we believe that Tafamidis is also suitable product given that we have a strong clinical outcomes data for value based agreements. So we are discussing and with multiple payers. It's too early to comment because also we are in the middle of the year and usually contract starts from the beginning of the year. Nevertheless there is significant interest and discussions between ourselves and payers on agreements that will really value the value that the product brings to patients. So, Frank, on manufacturing?

A - Frank A. D'Amelio

So, on the manufacturing, yes, we do plan on having significant improvements implemented by the end of 2019. But please also know along the way we've already implemented numerous preventative and corrective actions and we've seen a nice improvement in our overall supply to-date.

A - Albert Bourla {BIO 18495385 <GO>}

Okay. And I want to say Frank is always a man of few words and with a lot of actions. I'm very, very pleased with the way that under Frank's leadership and the new leadership he has, we are progressing on addressing the issues with manufacturing.

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

Thank you. Can we take next question please, Operator?

Operator

Your next question comes from Seamus Fernandez from Guggenheim.

Q - Seamus Fernandez {BIO 7525186 <GO>}

Thanks very much for the question. So just a couple of quick ones, can you just help us understand the number that you guys printed on EUCRISA this quarter as well as the sales for Xeljanz. What were the main impacts on both of those products? And then just as a second question if you guys wouldn't mind again this is a bit related to Xeljanz. Can you help us understand how differentiated the products in the dermatology Phase 3 clinical trials whether it be in alopecia or in atopic dermatitis. How differentiated those are from Xeljanz and perhaps from some of the other programs in development? Thanks so much.

A - Albert Bourla {BIO 18495385 <GO>}

Right. Angela, why don't you hit quickly the Eucrisa and Xeljanz question? And then we can leave time to Mikael, who is very passionate about the JAK portfolio to speak about it.

A - Angela Hwang {BIO 20415694 <GO>}

Okay, great. So let me start with some comments on Xeljanz. So as you can see Xeljanz had a 34% operational growth globally. In the U.S. Xeljanz grew 18% but actually the scripts grew 37%. So if you look at some of the Q1 effects some of that is due to higher rebating unfavorable channel mix and reauthorizations for patients that change insurance. And this is pretty typical of what we see every quarter. So I think we're really encouraged by the strong volume growth that we've continued to see in the U.S. and around the world for Xeljanz and it's all three of our indications strong growth from RA, exciting new launches for both PSA and UC and we're beginning to see some very, very strong market shares for UC as well coming out of the gate. For EUCRISA, specifically the number of EUCRISA patients in the U.S. for the first quarter was actually up more than 80,000 patients, so that's a 55% increase compared to where we were last year at this time. However, you do see revenues down slightly in Q1 and this is because despite the increased demand, we were negatively impacted by higher rebates in the U.S. So we need to continue to work on improving our formulary position and continuing to drive growth of EUCRISA in segments both in the U.S. as well as ex-U.S.

A - Albert Bourla {BIO 18495385 <GO>}

Mikael?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yes, So thank you for the interest in how we plan to grow the dermatology sector here. So for the atopic dermatitis where we are in Phase 3 and with a JAK1 inhibitor and the first readout of the JADE trial program is coming now in May and the second is coming this fall, we selected the JAK1 because we think JAK1 selective has the advantage that it covers

certain cytokines that are part of the disease pathophysiology IL-4, IL-13, similar as dupilumab. But on top of that, we cover IL-31 that relates to each phenomenon that bothers atopic dermatitis patients. And we saw a very profound and early relief of that in Phase 2 that we're obviously looking to confirm in our Phase 3 trial. While alopecia, it's a different type of underlying mechanism what we deal with cytotoxic cells destroying the hair follicles and the JAK3 selective inhibitor in what is worth we thought would be the best. And that was what we nicely recorded as a very effective agent in our Phase 2 trial, and it also has a very clean profile that most well-tolerated agent we have seen so far. So we look forward certainly to the Phase 2b pivotal study, and we also started a vitiligo study with this JAK3 inhibitor.

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

All right. Thank you very much, Mikael. Our next question please?

Operator

Your next question comes from David Risinger from Morgan Stanley.

Q - David Risinger {BIO 1504228 <GO>}

Yes, thanks very much. So first I'm hoping that you can talk about your expectations for organic revenue growth prospects for your Upjohn division relative to the 1% that you printed in the first quarter. I just don't have a sense for how we should think about that, whether that will grow or since you put Lyrica in there, that it's about to decline. So if you could help us understand the growth prospects for Upjohn, that would be helpful. Second, with respect to your patents that could potentially be blocking Merck's 15-valent launch in coming years, could you please talk about those patents and your level of conviction that Merck cannot launch and then just a final tidbit what are your planned biosimilar launches in the U.S. in the second half of this year? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

So let me start with Upjohn and obviously Doug can cover the Merck patent situation and then Angela you can speak a little bit about the biosimilars. Our expectations for Upjohn in this year, of course, is going to be a decline, because they would be seriously affected by the loss of patent of Lyrica that will happen in the middle of the year. And that will affect their growth also next year, because they will have to face full-year LOE, which would be next year with only half a year LOE which is this year. Following that, I see Upjohn as a very stable to low -- single-digit growth on the top line, and much higher on the bottom line, and leverage bottom-line growth, but of course, that will be post 2020 year where the impact of Lyrica will be absorbed. Doug?

A - Doug Lankler {BIO 16615171 <GO>}

So we were pleased that the patent trial and appeal board denied Merck's IPR petitions on two of our U.S. patents covering compositions of pneumococcal vaccines. This patent stand is valid and will not expire until 2026. We believe that these patents and others in our portfolio present freedom to operate issues for Merck and its development of a 15-valent pneumococcal vaccine.

A - Albert Bourla {BIO 18495385 <GO>}

Very clear.

A - Angela Hwang {BIO 20415694 <GO>}

And then biosimilars, so we will have three biosimilar launches in 2019. Trastuzumab was already launched in the EU in the first quarter and we look forward to the launch of trials in Japan in the third quarter. Rituximab will also be launched in Japan and that will be in the fourth quarter and then finally Bevacizumab will be launched in both the U.S. and Japan in the fourth quarter. We've seen some nice uptake in the supportive oncology portfolio that we launched late last year and we look forward to the oncology biosimilar portfolio contributing to our growth.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Angela.

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

Thank you, and Operator, if we could take our last question, please.

Operator

Your final question comes from Steve Scala from Cowen.

Q - Steve Scala {BIO 1505201 <GO>}

Thank you. This is actually Kathy Miner on for Steve. Just a question on Bavencio please, we had been expecting Bavencio Phase 3 data in second line bladder this year, is this still possible. And then secondly is there any chance for an interim on the JAVELIN lung 100 this year and what is the PDL1 cut off for that trial? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Two questions Mikael for you.

A - Mikael Dolsten {BIO 16368411 <GO>}

Yes. So, thank you for showing interest in our Bavencio portfolio. So we expect late this year or possibly early next year as you know these are event driven trials that we will include the bladder, it's actually a first line trial, so it's quite an interesting trial where we have Bavencio as a maintenance therapy of the chemo. We'll also have PDL 1 high expression trial in lung, which if positive could be the second PDX available for monotherapy PD-L1 high lung and then we have a gastric first line also post-chemo patients in maintenance for Bavencio, so, quite nice remaining cohort and we look forward to review the data coming out of this. Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Mikael. And I think this concludes the Q&A session. Just I wanted to say that I found this session very productive. I'm very pleased that the vast majority of the questions with minus one or two, maybe, were focused on our pipeline and were focused on Tafamidis new launch products. And I don't remember any other session but Frank didn't receive any finance question, which is what happened today. I think this is exactly how science-based company when the results for the quarter are good, should be discussed in our earnings call. I'm very pleased about that. We continue to believe that Pfizer's position in the market is strong. We have great products, we have strong R&D and marketing skills, prudent capital allocation and perhaps most important, a clear path towards sustainable growth. Thank you very much and have a great day.

Operator

Ladies and gentlemen, this concludes Pfizer's first quarter 2019 earnings conference call. You may now disconnect.
