Q1 2019 Earnings Call

Company Participants

- Arvind Sood, Vice President of Investor Relations
- David M. Reese, Executive Vice President, Research and Development
- David W. Meline, Executive Vice President and Chief Financial Officer
- Murdo Gordon, Executive Vice President, Global Commercial Operations
- Robert A. Bradway, Chairman and Chief Executive Officer

Other Participants

- Alethia Young, Analyst
- Carter Gould, Analyst
- Cory Kasimov, Analyst
- Geoff Meacham, Analyst
- Geoffrey Porges, Analyst
- Jay Olsen, Analyst
- Kennen Mackay, Analyst
- Kim Do, Analyst
- Matthew Harrison, Analyst
- Michael Yee, Analyst
- Ronny Gal, Analyst
- Salim Syed, Analyst
- Terence Flynn, Analyst
- Umer Raffat, Analyst
- Yaron Werber, Analyst
- Ying Huang, Analyst

Presentation

Operator

My name is Ian and I will be your conference facilitator today for Amgen's First Quarter 2019 Financial Results Conference Call. All lines have been placed on mute to prevent any background noise. There will be a question-and-answer session at the conclusion of the last speakers' prepared remarks. In order to ensure that everyone had a chance to participate, we would like to request that you limit yourself to asking one question during the Q&A session. (Operator Instructions)

I would now like to introduce Arvind Sood, Vice President of Investor Relations. Mr. Sood, you may now begin.

Arvind Sood {BIO 4246286 <GO>}

Okay, thanks, Ian. Good afternoon, everybody. Thanks for joining us today on our first quarter call. Special welcome to those who are new in their coverage of our Company, including Jay Olsen of Oppenheimer; Yaron Werber of Cowen; and Do Kim of BMO.

So we go into 2019, having put in place a strong track record of execution and we are well prepared for the challenges and opportunities ahead. I'm joined today by our Chairman and CEO, Bob Bradway, who will provide a strategic overview of our business and the environment we operate in. After Bob's comments, our CFO, David Meline will review our financial results for the first quarter. Our Head of Global Commercial Operations, Murdo Gordon will then review our product performance, followed by our Head of R&D, Dave Reese, who will provide a pipeline update.

We will use slides to guide our discussion today and you should have received the link separately. Just a reminder that we will use non-GAAP financial measures in today's presentation, and some of the statements will be forward-looking statements. Our 10-K and subsequent filings identify factors that could cause our actual results to differ materially.

So with that, I would like to turn the call over to Bob.

Robert A. Bradway {BIO 1850760 <GO>}

Okay, thank you Arvind and let me add to Arvind's welcome to all of you joining the call today. We entered 2019 with a strong track record of execution and an improved ability to innovate, compete and grow over the long term. We feel now well positioned to capitalize on the growth opportunities presented by our newer products in our pipeline, even as we effectively defend our mature products against emerging and expected new competition.

As you know, drug prices are being challenged around the world, and we therefore have said for some time that we expect volume driven growth to be important to our long-term success. And in Q1, we once again demonstrated our ability to grow unit volumes, especially for our newer products like Prolia, Repatha and Aimovig, as well as for our six hematology oncology products that are in early phases of their life cycle.

I believe our performance outside of the U.S. where we have faced biosimilar competition for over a decade is instructive. There, our business generated 15% unit volume growth in the first quarter, as growth of our newer products more than offset the erosion of our mature brands from biosimilar competition. We remain confident in the life cycle management strategies we have in place to defend our mature brands, and we believe there is considerable upside potential with our newer products that will drive attractive long-term growth.

As a leader in bone health with Prolia, we know that there is a need for an additional innovative therapy for women who are at high risk for fracture from postmenopausal osteoporosis. In Q1, we added EVENITY to our portfolio of first-in-class innovative medicines with approvals in Japan and earlier this month in the U.S. Post menopausal osteoporosis remains a highly under-diagnosed and under-treated disease with potentially devastating consequences from fractures, many of which are predictable and preventable. And we're excited to be at the forefront of offering innovative products to the millions of women worldwide, who may benefit from them.

I want to take a moment to highlight our biosimilars business, which we think represents a compelling opportunity to leverage our world-class biologics capabilities. This business is now annualizing at more than $200 million this year, with KANJINTI and AMGEVITA off to strong starts in Europe and select other international markets. We expect other launches this year and we see biosimilars making important contributions to our revenue profile moving forward, especially as pressure on drug pricing creates increased demand for lower cost treatment options. Murdo will discuss our full product portfolio in some detail shortly.

Looking to the future, we are rapidly advancing a robust pipeline of innovative medicines, many of which have the potential to be first-in-class or best in class therapies. In oncology alone, we're capitalizing on our industry-leading BiTE portfolio and targeted therapies across a number of important disease areas, including multiple myeloma, AML as well as various solid tumors. As you know, oncology programs can move very rapidly from proof of concept to registration, and we're excited about what we're seeing. You'll hear more from Dave Reese on our pipeline in a moment.

Our strong balance sheet and cash flows enable us to provide significant returns to our shareholders, through buybacks and dividends, even as we invest in long-term volume driven growth opportunities around the world. Our financial strength also gives us the ability to consider a wide range of business development opportunities, consistent with our areas of strategic focus, while remaining disciplined to ensure we earn solid return for shareholders.

We just say a few words also about healthcare reform and drug pricing. Simply stated, we are in favor of policies that provide more patients with greater access to better health care. And we continue to work with the administration and Congress to advance policies that harness the competitive power of the marketplace, encourage innovation and improve access to new therapies for patients. For example, we're supportive of the administration's proposal and move from back end rebates to upfront discounts in order to lower out-of-pocket costs for patients.

Even in the face of net price declines as we experienced last year, patients are not seeing the benefits or rebates. In fact out of pocket cost for patients have been rising in recent years, which underscores the need for the administration to move forward with its final rule. We're just close with one final message, which is that we will build on our recent transformation successes and have the resources and determination to take advantage of the many opportunities in front of us to meet our competitive challenges and to deliver long-term growth.

Now let me invite David to share his remarks on the first quarter.

David W. Meline {BIO 6397419 <GO>}

Okay. Thanks, Bob. The first quarter marked another period of solid performance for the Company, as we delivered mid single-digit volume growth globally, while we increased investment in the business and delivered year-over-year non-GAAP EPS growth in the first quarter. Turning to the financial results on Page 6 of the slide deck. Worldwide revenues were $5.6 billion in the first quarter, with worldwide product sales of $5.3 billion, declining 1% year-over-year as strong unit demand for our newer products was offset by declines in our mature products including small molecule generic competition again Sensipar.

On the revenues, at $271 million increased $60 million driven by royalty income growth. As we continue to make incremental investments to rapidly advance our innovative pipeline, and maximize the value of our marketed products, our non-GAAP operating expenses increased 11% year-over-year. This also contributed to our non-GAAP operating income result at 9% lower than previous year. On a non-GAAP basis, cost of sales as a percent of product sales increased by 2 points to 14.7%, driven by higher manufacturing costs and product mix, partially offset by lower royalty expense.

As mentioned last quarter, for the full year, we continue to expect year-over-year cost of sales expense to be flat to up depending on sales volume. First quarter research and development expenses of $859 million, were 16% higher due to increased investments in support of our multiple differentiated early stage oncology programs. Research and development expense as a percent of product sales was 16.3% for the quarter. For the full year, we currently expect R&D spend on an absolute basis to rise in single-digit percentage terms in 2019.

SG&A expenses increased 5% on a year-over-year basis, primarily driven by support for our newly launched products, including Aimovig, EVENITY and our biosimilar AMGEVITA and KANJINTI. For the full year, we continue to expect SG&A spend to decline as launch expenses normalize and we continue with our resource allocation discipline. We remain on track to meet our initial 2019 operating expense guidance of in-line versus 2018 on an absolute basis. Our operating expense guidance anticipates several important factors, including, one, that we continue to benefit from our productivity program; two, that we make appropriate investments in support of our in-line portfolio; three, that we advance our innovative and biosimilar programs; and four, that we continue to increase our global presence where we're experiencing rapid volume growth.

Other income and expenses were a net $158 million expense in Q1. This was favorable by $24 million on a year-over-year basis. The non-GAAP tax rate was 14.6% for the quarter, an increase of 0.9 percentage points, primarily due to prior-year tax benefit associated with the inter-company sales under U.S. Corporate Tax Reform. Non-GAAP net income declined 10% and non-GAAP earnings per share increased 3% year-over-year for the first quarter to $3.56 per share.

Turning next to cash flow and the balance sheet on Page 7. Free cash flow was $1.7 billion. This was lower than first quarter last year driven by lower net income and an increase in sales deductions paid to customers following higher third and fourth quarter 2018 sales. I note that Q2 will be negatively impacted as we make one-time tax payments of approximately $1 billion included in our second annual repatriation tax payment.

We continue to provide significant cash returns to shareholders consistent with our commitments, as we deployed $3 billion in Q1 to repurchase 15.9 million shares at an average price of $191 per share. Given our attractive share price, we plan to repurchase an incremental 1.5 billion to 2 billion of our shares in Q2. Additionally, our first quarter dividend increased to $1.45 per share, an increase of 10% over last year. Cash and investments totaled $26.3 billion, a decrease of approximately $5.9 billion from the first quarter of last year. Our debt balance stands at $33 billion as of March 31st, carrying a weighted average interest rate of 4% and an average maturity of 10.8 years.

Turning to the outlook for the business for 2019 on Page 8. We remain on track with our plans to continue to invest to advance our pipeline including our early oncology programs, build out our global presence and drive long-term volume growth. In light of our Q1 performance, we are raising our 2019 guidance. Our revised revenue guidance is $22.0 billion to $22.9 billion versus previous guidance of $21.8 billion to $22.9 billion. This continues to reflect a range of outcomes related to Sensipar generic competition as well as the evolving competitive dynamics associated with the rest of our in-line portfolio.

With regard to our non-GAAP earnings per share guidance, we are revising the outlook to $13.25 to $14.30 per share versus previous guidance of $13.10 to $14.30 per share. Further, we are maintaining our non-GAAP tax rate guidance of 14% to 15% and we continue to expect capital expenditures of approximately $700 million this year. This concludes the financial update, I will now turn the call over to Murdo.

Murdo Gordon {BIO 18450783 <GO>}

Thanks David and good afternoon everyone. You'll find product sales information starting on Slides 10 and 11. We're off to a solid start in 2019 with continued volume driven growth across our portfolio of newer products. While we successfully execute life cycle management strategies in our more mature brands. Moving to first quarter results. Let me start with Repatha on Slide 12. Given the dynamic nature of the PCSK9 class and our confidence in Repatha, I want to provide some detail on its performance and growth prospects.

Q1 sales grew by 15% year-over-year as we hold leading share of the PCSK9 class. Worldwide unit growth was 81% year-over-year with 90% unit growth in the U.S. The growth is attributable to increasing prescribing death by cardiologists, increasing prescribing breadth [ph] by primary-care physicians and increasing patient fulfillment following the introduction of lower list price Repatha.

In Medicare lower list price Repatha is now available to more than 60% of seniors. The next step is to make the lower list price version available to a majority of Part D patients at

a lower fixed co-pay versus the current co-insurance structure. While this is underway, it's expected to improve early next year as Part D plans update for 2020. Currently only 6% of Medicare patients are at a low fixed co-pay level of about $50. For patients covered by commercial insurance, approval rates have improved by 11 points year-over-year as we continue to secure improved payer utilization management criteria through contracting. We will continue to work with health plans, PBMs and the U.S. administration to get lower list price Repatha to patients more rapidly, and we remain committed to discontinue our original list price Repatha once we see sufficient coverage in the market, which could be between now and the beginning of 2020.

With regard to pricing the blended net price for Repatha in the U.S. declined in Q1 due to annual contracts that took effect in January. We are optimistic that we will see a positive impact on volume growth and reported net sales over the longer-term. Outside of the U.S., we continue to work with country authorities to optimize access and are pleased with our first ever launch in China. Overall, our priority remains to help the large underserved population of high-risk cardiovascular patients that can benefit from Repatha.

Now onto Prolia on Slide 13. Prolia delivered another strong quarter with sales increasing 20% year-over-year driven by 17% volume growth. As a reminder, given a 6-month dosing interval Prolia exhibits a seasonal sales pattern with Q1 and Q3 representing lower sales than Q2 and Q4. Overall market penetration of the addressable patient population is only in that mid 20% range, indicating significant potential for improved diagnosis and treatment. With this unique profile and through increasing investment, we expect Prolia will remain a very consistent growth driver.

I'd like to take the opportunity to comment on our recent approval and launches of Evenity in the U.S. and Japan in conjunction with our partners UCB and Astellas. The World Health Organization calls osteoporosis a global epidemic as there are fewer diagnosed and treated patients in the U.S. then a decade ago. In the U.S. alone osteoporosis is responsible for 2 million fractures. And given the aging population annual direct costs of osteoporosis are expected to reach $25 billion by the year 2025.

Evenity has convenient once-monthly physician administered dosing for 12 months and strengthens Amgen's a leading position in bone health with two highly innovative molecules that are complementary. We are confident in our ability to continue to penetrate this market. Our U.S. sales force is trained and is already promoting the product. Meanwhile, our launch in Japan, through our joint venture with Astellas is off to a strong start.

Now onto a Aimovig on Slide 14. To begin the unmet need for migraine is substantial. There are approximately 4 million individuals in the U.S. alone who take preventative medications for migraines. However, compliance, as well as 75% discontinued therapy after only a year. Approximately 200,000 new patients in the US have now tried Aimovig since it launched less than a year ago and there remains a significant opportunity for growth as CGRP penetration of the overall market is low. We expect this number to expand considerably, given the 26% sequential TRX market growth for CGRP inhibitors in Q1. Prescriber breadth is consistently increasing has over 22,000 physicians have now prescribed Aimovig since launch. We are particularly encouraged the primary care

adoption is steadily rising with nearly 8,000 prescribers to date. We also have indicators that our recently launched direct to consumer program is increasing patient awareness for Aimovig.

Now, let me take a few minutes to help you understand Aimovig's performance in Q1. First, Amgen is the market leader with 40% share of new to brand prescriptions and 60% share of the total prescriptions exiting Q1. Aimovig benefit from strong market access conditions with over 75% approval rate for new patients in both commercial and Medicare Part D plans.

Regarding net selling prices, we experienced a decline that is the net result of two dynamics. Recall that during the early launch phase of the product, a majority of paid prescriptions were reimbursed at near list price. Currently, the proportion of our business under commercial contract and receiving discounts is near 70%. Meanwhile, the proportion of paid versus free prescriptions increased to 60% at the end of the first quarter. Looking forward, we expect to see strong CGRP market growth well competing effectively for share. Offsetting this, Aimovig patient persistence will continue to be dynamic given competing free product offerings in the market.

We expect net prices to stabilize in 2019, as the majority of coverage decisions have been made. Additionally, the proportion of free prescription should continue to decline over the remainder of 2019. We are confident in the potential for Aimovig to positively impact patient lives and the recent launch of the single 140 milligram auto-injector will further enhance the patient experience.

Moving to our hematology and oncology business. The portfolio of XGEVA, KYPROLIS, Nplate, Vectibix, BLINCYTO and IMLYGIC collectively totaled $1.2 billion in the quarter, growing 8% year-over-year. Looking at additional details for some of the larger brands within this portfolio, let's start with XGEVA on Slide 16. In Q1, XGEVA grew 6% year-over-year, primarily from volume as we gradually see share increasing to just above 60% in the U.S. We recently received preferred status over zoledronic acid in castration-resistant prostate cancer, in the recently revised NCCN guidelines, reinforcing XGEVA superiority in this indication.

Moving to KYPROLIS, which grew 10% year-on-year, driven primarily by growth in key markets including the U.S,, which had 12% growth. Our team continues to emphasize KYPROLIS overall survival benefit, and we are pleased to see increased adoption of the once-weekly dose approaching close to 20% of share of KYPROLIS use in the U.S. Onto Enbrel, sales increased 4% year-over-year of which 2% was non-recurring, which included a positive 10 point impact from changes in accounting estimates, offset partially by 8 points from unfavorable inventory changes. During Q1 rheumatology market growth accelerated by 12% versus the 6% on average over the last eight quarters. Share trends continued, and we recognize a limited benefit from net selling price in the quarter, which we expect to persist for the full year. We continue to invest in Enbrel and including the Enbrel Mini with AutoTouch, a multi-use device, which continues to receive positive feedback from physicians and patients.

Next to our filgrastim brand starting on Slide 19, in Q1 Neulasta sales declined 12% year-over-year, which included a $98 million purchase from BARDA. We exited Q1 with approximately 90% share of the long-acting segment, with OnPro holding share at close to 60% of the segment. Insurance coverage of Neulasta also remain strong in the U.S. with close to 90% of commercial lives and 99% of Medicare lives covered. Currently, we are seeing increased competition in medium size clinics and small non 340B hospitals and are prepared for additional U.S. entrants in 2019 should they receive approval.

Outside of the U.S., Q1 year-over-year sales declined 12%. We now face three long-acting biosimilar competitors in a number of countries in Europe and expect additional entrants during 2019, which will likely accelerate the pace of decline. More broadly, we remain confident that our experience, established record of quality, dependable supply and innovative solutions, such as OnPro will serve us well as we compete account-by-account.

Turning to Slide 20, NEUPOGEN sales were $73 million in Q1 '19, sequentially U.S. Q1 results benefited from $7 million of accounting adjustments and NEUPOGEN exited the first quarter with roughly 30% share of the short-acting segment. Since the introduction of NEUPOGEN biosimilars in the U.S., costs to the healthcare system for short-acting filgrastim has come down meaningfully.

Switching to nephrology starting on Slide 21, Q1 Epogen sales declined 10% due to lower net selling price. The first quarter benefited from approximately $20 million of large end customer purchases. Given our contractual pricing commitments with DaVita, net price will continue to decline for Epogen in 2019. Aranesp declined 9% year-over-year in Q1, driven by lower volume due to increased competition. We expect Aranesp sales to continue to decline at a faster rate in 2019 versus 2018 with both long-acting and short-acting competition in the U.S. Parsabiv continues to experience solid growth. Independent and mid-sized dialysis providers utilize Parsabiv for a majority of their calcimimetics patients, while FMC and DaVita are gradually increasing adoption.

Turning to Sensipar. As a result of some at risk small molecule generic launches, you can see on Slide 24 that our U.S. Q1 sales of $135 million are significantly lower than recent quarters. Given the intrusion of these at risk launches that have now occurred, we expect U.S. sales in Q2 to be lower than Q1. Going forward performance will be dependent on the outcome of legal proceedings and the rate of consumption of generic inventory across periods.

I'd like to close by highlighting the strong performance of our biosimilars. We're uptake of our European launches for KANJINTI and AMGEVITA is progressing as we anticipated. We're planning for multiple new launches from this portfolio over the next few years and look forward to bringing the value of these assets to patients and the healthcare system.

In summary, I'm pleased with the solid execution and dedication of our team, as our portfolio evolves in 2019. We are successfully launching new products, driving volume growth and demonstrating the value of our mature brands. We are also now establishing a strong presence in the biosimilars market with customers who appreciate the high

quality of Amgen services and product supply. I'm confident that we are prepared to maximize the opportunities to bring Amgen's products to a greater number of patients.

Now let me turn it over to Dave Reese.

David M. Reese {BIO 19782623 <GO>}

Thanks, Murdo and good afternoon everyone. We are off to a rapid an exciting start to 2019 in R&D with progress across our pipeline. I'll begin with our oncology portfolio. We continue to advance our BiTE platform with approximately a dozen molecules now in or close to the clinic. In hematologic malignancies at ASCO, we will provide an update on the dose escalation trial of our first-generation BCMA BiTE molecule AMG 420. We are now enrolling patients in a dose expansion study.

We also expect some of the first clinical data from our new generation BiTE platform by the end of the year with AMG 701, an extended half-life BCMA BiTE molecule. Our enthusiasm is high for our BCMA BiTE molecules, as well as our CD38 bispecific and MCL1 programs, as we pursue our commitment to develop therapies that can make a meaningful impact in the treatment of multiple myeloma.

Other presentations at ASCO will include the first in human dose escalation study of AMG 212, a BiTE molecule directed against prostate specific membrane antigen or PSMA, which is highly and specifically expressed in the majority of human prostate tumors. This clinical study was conducted by (inaudible) through a license they had with Micromet, prior to our acquisition. We believe the data from this trial provide proof of concept for the target and BiTE specific T-cell engage or approach in solid tumors and we have introduced a new half-life extended BiTE molecule AMG 160 into clinical testing for prostate cancer. AMG 160 is now progressing briskly through dose escalation.

As with all of the targets for which we have both first generation and half life extended BiTE molecules in clinical development, we'll preferentially advance the half life extended molecule, if we observe comparable safety and efficacy between the two formats. One final note on our BiTE programs. Recently, we have seen intriguing early clinical evidence of potentially enhanced activity for BiTE molecule in this case in-situ [ph] when given in combination with a PD-1 inhibitor. We anticipate sharing a larger data set within a year or so. There is substantial evidence that T-cell activation leads to up regulation of the PD-1 axis, providing a rationale for this combination. Based on these biologic and clinical insights, we are incorporating early checkpoint inhibitor combinations into many of our BiTE programs and I'll have more to say on this, as studies initiate and we accrue data.

I'd like to turn now to a program of great interest our KRAS G12C program, AMG 510. By way of background, perhaps mutations occur in about 25% of all human cancers and the specific KRAS G12C mutation occurs in about 14% of lung adenocarcinomas and most common form of non-small cell lung cancer. It also occurs in about 4% of colon cancers, a couple of percent of pancreatic tumors and low frequency in various other cancers. KRAS is going to target of active exploration since it was identified as one of the first

oncogenes, but it remained un-druggable due the lack of traditional small molecules binding pocket on the protein.

The G12C mutation produces a very shallow groove, which allowed us to elegant medicinal chemistry to design an irreversible small molecule inhibitor that locks KRAS into its inactive state. I've spoken in the past on how we are improving productivity and accelerating the timelines of drug development here at Amgen and AMG 510 is an excellent example. When we knew that we could generate an inhibitor to a key oncogene that has been un-druggable for over 30 years, we accelerated pre-clinical development and advanced the programs from discovery to first in human trials in well under a year.

Our presentations at AACR demonstrated that we have a highly specific molecule with good drug-like characteristics that can be dosed orally once a day. We also showed in pre-clinical models at AMG 510 may act synergistically with other agents. A particular interest the pre-clinical data of AMG inflamed -- AMG 510 inflamed tumors in part by up regulating Class 1 MHC expression and enhanced sensitivity to checkpoint inhibition.

We look forward to the opportunity to share the initial data from our first in human dose escalation study in patients with solid tumors containing KRAS G12C mutations at the upcoming ASCO meeting in Chicago where we will also be hosting an investor event. There have been a lot of questions on the extent of the data that will be available and what I would say here is that you should expect basic exposure data and the cumulative efficacy and safety data we've got to date. While we have been in the clinic for only about eight months, we have completed dose escalation and our expanding enrollment at the target dose.

Moving forward, we will also be exploring AMG 510 in combination with checkpoint inhibitors, based on the pre-clinical work I've described in various targeted therapies and we are currently moving ahead to include a combination with the PD-1 inhibitor in our expansion study. Based on the early clinical data and feedback from our investigators, we very optimistic on the potential for AMG 510 to address unmet medical need and look forward to seeing many of you at ASCO.

Finally, in oncology, we recently began recruiting patients in a combination study of venetoclax plus AMG 176, our intravenous MCL1 inhibitor in non-Hodgkin's lymphoma and AML after seeing strong pre-clinical evidence of synergy. We're also rapidly advancing our oral MCL1 inhibitor AMG 397 through dose escalation in patients with hematologic malignancies. We expect initial clinical data from these programs later this year, along with several other programs. In our accompanying presentation, you can find an overview of our hematology and oncology clinical portfolio.

Moving to our other therapeutic areas. As a leader in bone health, we were pleased to receive approval of Evenity as Murdo noted in the U.S. for the treatment of osteoporosis in postmenopausal postmenopausal women at high risk for fracture based on the (inaudible) disease characteristics or a history of fracture. Post-menopausal osteoporosis, a silent epidemic that affects women and societies around the world leads to approximately 2 million fragility fractures per year in the United States alone. Despite this,

it remains an under-diagnosed and under-treated disease with only 20% of these women receiving any type of osteoporosis treatment post fracture. Evenity is the first and only anabolic therapy with a unique dual effect that both increases bone formation and to a lesser extent reduces bone resorption.

The patients who need to rapidly increase bone mineral density in 12 months, Evenity can reduce the risk of a first or subsequent fracture and in particular clinical fractures, some symptomatic breaks that often lead to disability. In cardiovascular disease, we expect to complete enrollment of our omecamtiv mecarbil Phase III cardiovascular outcome study by mid year and recently passed an interim futility analysis with no recommended changes to the study. AMG 890 Lp (a) SiRNA also continues to progress and we anticipate sharing data later this year or early next year.

We recently received a pediatric indication for Corlanor for the treatment of stable symptomatic heart failure due to dilated cardiomyopathy in patients aged six months and older who are in sinus rhythm with an elevated heart rate. And finally in migraine as Murdo noted, we received approval for our single 140 milligram Aimovig auto-injector or pre-filled syringe in the U.S., following inflammation, we began enrolling a Phase II atopic dermatitis study with tezepelumab. I'm also pleased to report that our Phase III study for ABP959, our biosimilar Soliris is enrolling patients.

I'll close by thanking our staff for advancing our exciting pipeline and continuing to deliver for our patients. Bob?

Robert A. Bradway {BIO 1850760 <GO>}

Okay, thank you. Let's open the line up now for questions and perhaps I can ask our operator to remind you what the procedures are for submitting your questions. Thanks.

Questions And Answers

Operator

(Operator Instructions) Our first question is from line of Matthew Harrison from Morgan Stanley.

Q - Matthew Harrison {BIO 17603148 <GO>}

Great. Good afternoon. Thanks for taking the question. Dave, I was hoping to ask two part on KRAS. So I guess the first thing is, it seems like you 0progressed through the dose escalation period fairly rapidly. You know, is that because you have the MTD faster than you were expecting or are there other factors such as faster enrollment in play? And then how should we view the fact that you're pushing forward here with combinations with PD-1? It's part of that, that the monotherapy efficacy that you've seen is below what you were expecting or you think you can drive efficacy substantially higher with those combinations? Thanks.

A - David M. Reese {BIO 19782623 <GO>}

Thanks, Matt for the questions around the KRAS program. Let me take them in order. In terms of the dose escalation, I think we'll present the clinical data at ASCO. We had a planned dose escalation in the Phase I trial, we were able to move through that very quickly based on tolerability. We had quite brisk enrollment, based on pre-identification of patients at most of our centers and were pleased to have been able to move along in the eight months in a population that is a fraction of lung cancers and other tumors. In terms of the combination, as I've indicated before, I think, based on the clinical setting these molecules may find a home is either monotherapy or in combinations, it's early days and we're moving quickly to investigate both of these approaches. As we move forward and the combinations will be not only with PDL-1 inhibitors based on some of the pre-clinical data that I described in terms of the KRAS inhibitor inflaming tumors and up regulating MHC-1 expression, but also data we've generated on other components of the pathway. So I think all of those will be pieces of what we explore going forward. This program is moving as quickly as almost any I've ever seen here at Amgen.

Operator

And our next question is from the line of Terence Flynn from Goldman Sachs.

Q - Terence Flynn {BIO 15030404 <GO>}

Hi, thanks for taking the question. Maybe Bob would love your perspective. Just on the proposed Part B demonstration project. In particular, do you anticipate that the IPI proposal could remain here or do you expect there could be any changes? Thanks a lot.

A - Robert A. Bradway {BIO 1850760 <GO>}

Well, it's a proposed rule as your question implies Terence, and that enables quite a bit of commentary and the administration as we see something like 4,000 comments from different groups including quite a wide range of physician groups and patient groups that were concerned about the proposal. it won't surprise you to know that we are concerned about it and we've expressed that concern as well. We're not interested in seeing patient access to innovated new medicines and physician choice impaired by potential rule like this.

So we and others in the innovative industry have expressed that to the administration and I think if you compare the situation in the United States where patients have access to innovative medicines very rapidly. In fact, if you just look at cancer 95% of the new cancer medicines are available to Medicare patients here in the U.S. and that compares to about 65% of the same medicines being available in France and by the way in France there available some 21 months later, so in cancer patient that can mean the difference between life and death. So we are not in favor of a rule like this that might have the effect of diminishing access to innovation and impairing investment and innovation over the long term.

Having said that, we have been working with the administration around other proposals that we think can help address the concerns of the administration and we'd like to continue to do that. So we think there are some things that the administration could

pursue that would enable the government to get access to the market prices and still enable physicians and patients to use the medicines that they think are appropriate for these diseases.

Operator

And our next question is line of Ying Huang from Bank of America Merrill Lynch.

Q - Ying Huang {BIO 16664520 <GO>}

Hi, thanks for taking my questions. My first question has to do with the Neulasta. So year-over-year sales came down by 12%, units went up by 1%, inventory went down 3%. So, by my math, the net price is probably coming down by roughly 10%. Can you comment on the pricing trend for the rest of the year for Neulasta? And then can you quickly provide an update on the Enbrel panel ruling against Sandoz? Thank you.

A - Murdo Gordon {BIO 18450783 <GO>}

So Ying, I'll take the first one and then I'll ask Bob perhaps to talk about the other question regarding Sandoz and Enbrel. I think overall, we're pleased with how we're performing in the market despite two biosimilar competitors against Neulasta. In particular, we see good durability of our Onpro business, which is holding at around 60% share of the long-acting filgrastim franchise. We also continue to compete at an account-by-account level and we defend as you point out, significant volumes. What will drive further price erosion and potentially share erosion is the number of new competitive entrants and we are following that very closely going forward.

A - Robert A. Bradway {BIO 1850760 <GO>}

On the court case nothing to report, as you know, we're waiting for the Judge to rule and nothing new to report there.

Operator

And our next question is from line of Geoffrey Porges from Leerink Partners.

Q - Geoffrey Porges {BIO 3112036 <GO>}

Thank you very much. And first question David, just on the KRAS. Could you help us understand how -- in terms of expectations, how treatment response to this particular intervention should compare to other mutations in lung cancer that we're accustomed to seeing for example (inaudible) EGFR, just as it's likely to be as economical if you like in those mutations? And then secondly, Murdo, if you could just give us a little bit more color on Aimovig in particular. It does look as though you've come under some pressure in terms of share of new prescriptions. Is that a one-time event in the first quarter that we are seeing in the prescription data or has it been a step down because of the contract and is this the new baseline? Thanks.

A - David M. Reese {BIO 19782623 <GO>}

Sure, I'll go ahead and start with the question regarding KRAS biology. I think there's probably no specific answer for that Geoff. In some tumors, this mutation will be a trunk mutation, a driver mutation and we may well expect monotherapy activity in other tumors based on the other suite the molecular alterations that are present. You may need combinations or another approach. I think these are all things we'll sort out. We will be doing extensive molecular profiling on the tumors as we move forward to try to sort out the best predictor of response and resistance.

A - Robert A. Bradway {BIO 1850760 <GO>}

Yes. And Geoff, considering the huge unmet need in migraine, we continue to feel good about the opportunity to grow new prescription base and to continue to compete effectively for share. As you know we're still the market leader with 60% TRx share, around a 40% NBRx share. We have nice coverage across commercial and Medicare Part D payers, and we continue to drive good increases in the percent of patients that have -- that are paying for their Aimovig through commercial insurance benefits. So what we are seeing in our trends in our total prescriptions, is some effect of the bolus of patients that we secured when we first launched into the market and working then through the free drug to paid transition. We are also trying to understand what the persistence is in the CGRP category. We saw that it was between 20% and 30% and clinical trials will be looking to see how that shapes up in the real world as we move forward.

Operator

And our next question is from line of Kennen MacKay from RBC Capital Markets.

Q - Kennen Mackay {BIO 18821382 <GO>}

Hi , thanks for taking the question. Quick R&D question. You mentioned tezepelumab Phase II moving forward in atopic derm. How did tezepelumab miss the primary endpoint in the prior Phase 2A and in AD? And what sort of the difference in how you're thinking about this in AD or how has this about? Thanks

A - David M. Reese {BIO 19782623 <GO>}

I think we've gained a greater understanding of the approach to the disease, the variance in background medications. This is a disease that also has a waxing and waning natural history. And so we have with -- our partners have designed a subsequent Phase II study that we think will rigorously evaluate the utility of tezepelumab in AD.

Operator

And our next question is from the line of Carter Gould from UBS Equities.

Q - Carter Gould {BIO 21330584 <GO>}

Good afternoon guys. Thanks for taking my question. I want to change the pace for a second, ask one, on the omecamtiv progress you've been making. Specifically, if there are any additional planned interim analysis either for a futility or stopping early for efficacy?

And then just maybe your initial thoughts on how this -- you think this may be positioned in HF maybe alongside Entresto? Thank you.

A - David W. Meline {BIO 6397419 <GO>}

Sure, this is Dave. I'll take that question. So, typically in these trials there are interim analysis for efficacy. They are event driven and we'll communicate at the appropriate time, as we might expect those data. I think one of the things that excites us about omecamtiv is that, its mechanism of action is novel. We think it's orthogonal to many of the existing therapies and should be able to be added to existing background therapies. To me that's one of the potential great attractions of the drug for advanced heart failure.

Operator

And our next question is from line of Yaron Werber from Cowen & Company.

Q - Yaron Werber {BIO 19486720 <GO>}

Great, thank you. So David, I have also follow up on KRAS, can you give us a little bit of a sense? Was this a typical three-by-three dose escalation or you doing inter-patient escalation and would you break out the results by tumor type as well? And then I have a quick question on Sensipar.

A - David M. Reese {BIO 19782623 <GO>}

Yes, what I'll say is all of those questions will be answered at ASCO and I don't want to get out in front of our investigators and steal their thunder, but will provide greater detail in the Phase I presentation.

A - Arvind Sood {BIO 4246286 <GO>}

What was your second question Yaron? You wanted to ask a second question about Sensipar.

A - David M. Reese {BIO 19782623 <GO>}

Yaron, your line is still open. Can you hear me?

Q - Yaron Werber {BIO 19486720 <GO>}

Yes. Sorry go ahead.

Okay, great. Can you give us a sense or the launches for Sensipar? Are they Zydus and Piramal and are they still subject to the litigation coming up in June? Thank you.

A - David W. Meline {BIO 6397419 <GO>}

Yes, so what I'd say, this is Meline. So, first point is, if you look at the guidance that we offered this afternoon, what we've given you is, while it's a bit narrower, it's still quite broad. And the reason for that is the uncertainty around, will we have additional launches

this year or not? And of course that is driven by the fact that we do have litigation that's still going on and we expect that the conclude here sometime in the coming months. So hence the breadth of the guidance.

Operator

And our next question is from line of Do Kim from BMO Capital Markets.

Q - Kim Do {BIO 15104361 <GO>}

Good afternoon and thanks for taking my question. I wanted to ask about the Humira biosimilar market in Europe. We know that biosimilars in the European landscape is fairly mature. But with so many competitors out there, how are you seeing, how the market for Humira will shape out? And how do you position your biosimilar with so many competitors?

A - Murdo Gordon {BIO 18450783 <GO>}

Yes, thank you Do for the questions. It's Murdo. What we're seeing in Europe in general in the biosimilars market is more rapid penetration of the biosimilars of the innovator compound. So higher biosimilar penetration in general across a number of different categories. Our shares are more or less in line what we had anticipated and price is a little lower. So we are seeing higher volume due to that penetration offsetting somewhat lower prices and the prices you have to be a little bit careful. Most of the interest and news that we read about on pricing, particularly in the case of the Humira biosimilar were related to tender prices in some smaller European markets and those were pretty significant winner-takes-all price reductions. What you're seeing in the broader marketplace at the National Formulary level and at regional formularies are better prices holding up quite well. And we foresee the biosimilar business to be a significant revenue driver for some time to come.

Operator

And our next question is from line of Jay Olsen from Oppenheimer.

Q - Jay Olsen {BIO 16582659 <GO>}

Hi guys, thanks for the warm welcome and thank you for taking my questions. I'm curious about the Visalia CV [ph] outcomes trial for Repatha. Can you comment on the key differences between this outcomes trial and the 4a trial and how that study may impact long term commercial potential for Repatha? And then separately anything we should be looking out for next week in terms of data for Aimovig? Thank you.

A - Murdo Gordon {BIO 18450783 <GO>}

And Dave, you want to get both those.

A - David W. Meline {BIO 6397419 <GO>}

Yeah. Will let me, well, I'll half of the Repatha question and then Murdo will take the other one, I can address the that. So in terms of the Visalia, these are patients with known -- essentially known coronary artery disease, but who have not had an event. So they are very high risk. It's a population that numbers in the millions beyond what we were seeing in the target population studied in the 4a trial. We think it should add to the substantial body of evidence that we have with Repatha into an other high-risk population. Murdo, you may want to comment on the commercial component.

A - Murdo Gordon {BIO 18450783 <GO>}

Yes. We're continuing to work hard to penetrate that high-risk cardiovascular patient population and compete in that category. We are seeing the data are more similar than different to what we've already had in the public domain and we're really pleased with the 80%, 81% volume evolution. We continue to believe that more and more physicians are understanding the value of treating these higher-risk cardiovascular patients.

A - David W. Meline {BIO 6397419 <GO>}

And then in terms of our Aimovig data at the American Academy of Neurology meeting, which is starting in four or five days. We do have what I think are some very interesting data on long-term safety and efficacy data in both chronic and episodic migraine. The abstracts for those who are interested are up now in chronic migraine for example, we were able to show that roughly two-thirds of patients were able to convert to episodic migraine, meaning fewer than 15 migraine days per month and on average are depending on the population and the dose, the number of migraine headache days per month was reduced by 8 to 12 days per month. That's a very substantial clinical impact for these patients as you can imagine. So those data are coming out within the next week or so.

A - Murdo Gordon {BIO 18450783 <GO>}

Those data also support the launch of the new single 140 milligram dose of Aimovig, given that patients who got to the higher dose tends to do even better on conversion.

A - David W. Meline {BIO 6397419 <GO>}

Right. And there are, in those patients complete responders, which is remarkable in this disease.

Operator

And our next question is from the line of Michael Yee from Jefferies.

Q - Michael Yee {BIO 15077976 <GO>}

Hey, thanks for the question. Good afternoon. I guess I wanted to ask a question related to two ongoing litigation issues somewhat with the same Company, one is, if for some reason the IP does not go in your favor for some reason on Enbrel, what are the implications and what are the scenarios that we should know or for shareholders to know? And then maybe you can just comment on the separate litigation related to Aimovig. I

think it was a bit surprising to people, so maybe just comment on what the implications are there? Thanks so much.

A - Robert A. Bradway {BIO 1850760 <GO>}

Yes, sure Mike, I can understand that. On the first one, we feel pretty strongly about the IP case that was presented. So obviously if judgment were to go against us, we would immediately appeal. But on the Aimovig partnership, look, the first thing to underscore is that the teams in the field are committed to doing what's right for patients here and it's unfortunate that we have a dispute with our partner about this matter. But that's why we have this dispute resolution options specified in the contract like this. So we feel that are our partner is enabling a competitor product and so we want to pursue that matter in courts and that's where we are. But as I said, that will probably play out over a period of time. And in the meanwhile, both teams are committed to continuing to pursue this therapy for those patients who benefit from it.

Operator

And our next question is from line of Alethia Young from Cantor Fitzgerald.

Q - Alethia Young {BIO 17451976 <GO>}

Hey guys, thanks for taking my question, I just wanted to talk a little bit about the biosimilars that you have put out kind of in longer-term guidance around the $3 billion number. But I just wanted, now that we have some biosimilars in the market, how are you guys are thinking about the prospects? Do you think it is a more attractive business, less attractive or about the same? Just want you to kind of frame some of the puts and takes that you think about in simple longer-term value of that business? Thanks.

A - Murdo Gordon {BIO 18450783 <GO>}

Thank you, Alethia. I -- obviously, it's still very early days in the U.S. Based on our European experience and what we continue to believe the market outlook is in the U.S., I wouldn't change the long-range comments we've made. Historically, I think that they still hold up and we continue to pursue a number of really interesting and solid molecules and we continue to prepare for launches in the U.S. in the not too distant future?

Operator

And our next question is from line of Cory Kasimov from JPMorgan.

Q - Cory Kasimov {BIO 3009346 <GO>}

Hey, good afternoon guys. Thanks for taking the questions. Wanted to ask on Aimovig. I wonder if you could provide some color on the constipation issue that some docs and your competitors talk about with the drug. I guess I'm wondering how frequently that lead to discontinuations and what your might be doing to alleviate this, it certainly is millions of in fact initiative. Thanks.

A - Murdo Gordon {BIO 18450783 <GO>}

Yes, thanks for the question. We do hear about this issue and obviously we're always making sure that we provide necessary patient support and physician support around the safety and efficacy of our product. But we also think on this one, there is quite a large amount of rhetoric that's been created around this issue, given how the product performed in clinical trials. The stated incidence of constipation are labelled in, it'll even be reported in the long-term follow-up data AAN. So I think it's been well-characterized and in good, well-designed open-label and continuous clinical trials.

We're also pleased that many physicians, particularly the prescribers in the large-scale headaches centers are telling us that it's a relatively low incidence and that they have very little trouble having patients started on Aimovig and persisting. I think some of the other things we're seeing in persistence, and I mentioned that in response to an earlier question, just as we, given that we were the entire market for many months without competition, we are seeing some persistence effects in our continuing patient population that are different than what you might have concluded from looking at the clinical trials and that's a function of both people who are moving from one free trial offer to another and it's a function of people who are perhaps not pursuing commercial insurance and obviously there is a small component of that is switch away to other agents.

So there is a -- there is still an evolving understanding of how persistent patients are to your question on discontinuation of Aimovig. So -- and it will take many months to understand that you need at least a 12-month look back period that puts us in the 18-month to 24-month time frame before will be able to actually ascertain durability.

A - David W. Meline {BIO 6397419 <GO>}

And Cory from a clinical perspective, I would reiterate what Murdo said. What we hear from physicians, experts is that that they see it at a low incidence, it's clinically quite manageable, they don't really view it is any sort of barrier at all.

Operator

And our next question is from line of Geoff Meacham from Barclays.

Q - Geoff Meacham {BIO 21252662 <GO>}

Good afternoon guys. Thanks so much for the question. I just had a pipeline question for Dave. Broadly on the earlier pipeline you're still in and dose escalation for may for BCMA, for PSMA, for KRAS et cetera, but presumably, you've had some evidence of efficacy and I know it's data dependent, but is there a path to moving rapidly into a pivotal study, even if it's the registration phase? I just wasn't sure if this was even an option or there had been discussions with regulators on this? Thanks.

A - David M. Reese {BIO 19782623 <GO>}

Yes. Of course that will vary program by program. But what I would say in general is it, our goal in these programs, it will be to move as quickly as we can through dose escalation and then move into the expansion and potentially pivotal phases of the program. I think

given the target diseases and the potential regulatory paths, that's a realistic expectation and that's how we've planned many of the clinical development programs.

Operator

And our next question from the line of Umer Raffat from Evercore ISI.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi, thanks so much for taking my questions. I wanted to go back to KRAS again for a quick second. And basically ask -- based on everything you saw on the pre-clinical data, would you have expected to hit MTD by this third or fourth dose? And also you mentioned seeing cumulative efficacy at ASCO, is what do you intend to show? Should we be expecting a dose response? And then separately on Enbrel was curious what the net price trend was in the first quarter year-over-year adjusting for the accounting treatment? Thank you.

A - David W. Meline {BIO 6397419 <GO>}

Okay, I think there were several questions.

A - David M. Reese {BIO 19782623 <GO>}

So in relation to KRAS, again the clinical data will present. So I won't comment on the specifics of dose response. I will say that this is an irreversible inhibitor and our anticipation is that achieving adequate exposure for a period of time, probably a few hours over the course of the dosing interval, a day is adequate to poison the target and inhibit signaling and so our dose escalation was planned with that goal in mind. And we will present complete details in about a month at ASCO.

A - Murdo Gordon {BIO 18450783 <GO>}

And Umer on your question regarding Enbrel. We did have a strong quarter on Enbrel. It was primarily driven by a strong market across rheumatology and we did see some net price benefit based on net price increase as well as improved contracts in the New Year.

A - Arvind Sood {BIO 4246286 <GO>}

Okay. We have time for one or two more questions.

A - Robert A. Bradway {BIO 1850760 <GO>}

Yes, Ian, let's since past 6:00 PM on the East Coast, let's take two more questions.

Operator

Very well. Our next question is from line of Ronny Gal from Bernstein.

Q - Ronny Gal {BIO 15022045 <GO>}

Good afternoon guys and thanks for fitting me. Two if I may. Firstly, if you can break for us the relative sales of KANJINTI and AMGEVITA, just trying to keep track on those modules individually? And second on Aimovig, Murdo, you've mentioned that you're expecting net price stabilization of this molecule. And I was kind of wondering about this comment. It seems like that the payers have not really selected their preferred agency yet? Yes, I just added a (inaudible) backhand, so I was wondering, if there wouldn't be another step down in pricing expected when they choose to prefer agents. And then with oral is coming about a year out wouldn't that causes another step down in pricing at that point. So I'm just -- can you put this comment in context?

A - Murdo Gordon {BIO 18450783 <GO>}

Thanks. Ronny. Yes, we're not breaking out the biosimilar sales by brand yet, still a volatile market, but we are happy with both trends on both products going forward. We're also -- as you look at Aimovig, my comment, if you recall has two components to it. One is the net price reduction based on additional contracts that could occur throughout the course of the year, plus a rising percentage of prescriptions that are paid and the two offsetting one another, leading to a stable price at least for this year. And I think that would be my clarification to your question.

A - Arvind Sood {BIO 4246286 <GO>}

Let's take one last question, after which, Bob will make some closing comments.

Operator

And our last question is from line of Salim Syed fro Mizuho Securities.

Q - Salim Syed {BIO 16887281 <GO>}

Yes guys, thanks for taking the question. I guess one from me, multi-part one on Repatha and on the new CVOT trial. I guess maybe you could -- if you could just give us some color on what the genesis of the design of that trial was given -- it seems to mimic medicine companies are writing for [ph] almost like line-for-line? And should we be thinking about as a validation of (inaudible) value proposition in the marketplace as we think about long term Repatha sales? Thank you.

A - David W. Meline {BIO 6397419 <GO>}

Yes, I'll be happy to address that question. I mean that's -- we designed that study from a technical perspective, just the way we design any study based on the expected magnitude of effect, target population, all in the typical statistical calculations that go in clinical perspectives, that go into study design. We weren't using anyone else's trial or a template for that study. And I wouldn't call it validation of anything, but the internally consistent results from that trial alone.

Operator

Bob, would you like to make some closing comments?

A - Robert A. Bradway {BIO 1850760 <GO>}

Okay. Thank you. Well, in closing, we're off to a good start in 2019. And I hope you share our team's enthusiasm for our long-term prospects. We have a number of medicines in our in-line portfolio that can and we expect will benefit significantly more patients as we grow longer term. We have an emerging portfolio of branded biosimilars, which we've talked about and we think will be a new source of growth for us.

We're advancing a record number of potential new medicines in our pipeline, targeted at some of the most prevalent costly and serious diseases facing society today. Our financial strength, I think is evident again this quarter and are durable cash flows will allow us to continue to invest in the business, but also provide meaningful returns for our shareholders and deliver transformational innovation for patients. Most importantly, I wanted to just end by thanking our staff who are fully engaged and behind our mission and thank them for the work they did to get us off to a solid start in 2019.

We look forward to talking to all of you at the ASCO Investor meeting and then at the second quarter call in July. Thank you.

A - Arvind Sood {BIO 4246286 <GO>}

Great, thanks, everybody. If you have any follow-on questions, if we didn't get to your question, or if your comments you would like to discuss, feel free to reach out to me or other members of my team. Thanks again.

Operator

Ladies and gentlemen, this does conclude Amgen's first quarter 2018 financial results conference call. We thank you greatly for your participation. You may now disconnect.
