# Q4 2019 Earnings Call

## Company Participants

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

## Other Participants

- Alethia Young, Analyst
- Brian Skorney, Analyst
- Chris Raymond, Analyst
- Cory Kasimov, Analyst
- Do Kim, Analyst
- Evan Seigerman, Analyst
- Geoffrey Porges, Analyst
- Jay Olson, Analyst
- Kennen MacKay, Analyst
- Matthew Harrison, Analyst
- Michael Yee, Analyst
- Mohit Bansal, Analyst
- Robyn Karnauskas, Analyst
- Ronny Gal, Analyst
- Salim Syed, Analyst
- Terence Flynn, Analyst
- Umer Raffat, Analyst
- Yaron Werber, Analyst

## Presentation

### Operator

My name is Ian and I will be you conference facilitator today for Amgen's Fourth 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 speaker's prepared remarks. (Operator Instructions). I would now like introduce Arvind Sood, Vice President of Investor Relations. Mr Sood, you may now begin.

## Arvind Sood {BIO 4246286 <GO>}

Okay. Thank you, Ian. Good afternoon everybody. Thanks for joining us today. So 2019 was the year and that we made significant progress on our strategy and took steps that position us well for what will surely be a special year in 2020 as we celebrate our 40 anniversary.

What better gift to celebrate this important milestone than to get back to revenue growth. So, our Chairman and CEO, Bob Bradway, will lead the discussion today. We are also joined today by our new CFO, Peter Griffith, who will provide a financial update on our results for Q4 and full year 2019 and provide guidance for 2020. 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. We will also 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 results, actual results, to differ materially. So with that, I would like to turn the call over to Bob. Bob?

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

Okay. Thank you, Arvind and good afternoon everyone and thank you for joining our call. Heading into 2020, we feel ready for the challenges of a new year and we're feeling encouraged by the progress we made in 2019. Once again, this past year, we met and exceeded our financial targets. We advanced key elements of our long-term growth strategy and we serve more patients around the world with our growing portfolio of medicines.

2019 was the transition year, we had long been preparing for as many of our off-patent legacy products faced new competition. I believe we managed this transition well, as evidenced by the fact that we delivered earnings growth in 2019 and will return to top line growth in 2020.

In 2019, drug prices in the U.S. actually fell overall for the first time since 1974. In anticipation of this challenge, we re-positioned the company's expense base and embedded productivity initiatives over the past several years that are serving us well.

In addition, we reshaped our product portfolio committing to medicines that can deliver growth for us primarily through volume increases rather than price increases. Products like Repatha, Aimovig, Prolia, Evenity, and most recently Otezla. In 2019, we delivered 3% volume growth globally and 19% volume growth outside the United States. We're seeing especially strong performance in our Asia-Pacific region, albeit from a small base. Over the next decade, we expect this region to account for as much as 25% of Amgen's growth.

For the full year in 2019, volume in the region grew 62%. Over two-thirds of that growth came from our joint venture with Astellas in Japan, the world's third-largest

pharmaceutical market. Just a reminder that this collaboration reverts fully to Amgen on April 1st, enabling us to do business in Japan, through a wholly-owned subsidiary for the first time.

Our strategic collaboration in China with BeiGene closed a few weeks ago and we're excited by what our two companies can achieve together in the world's second largest pharmaceutical market.

2019 was also a watershed year for us, for our biosimilars business. We've delivered our first several biosimilars to market on time and on budget and we believe we are in the early innings of what can be an important growth opportunity for us over time.

Through the end of Q4, the business was already annualizing at over $1 billion and we will add to our portfolio later this year with the launch of Avsola, our biosimilar to Remicade. We also expect that Amgevita, our biosimilar to Humira in Europe and other parts of the world will benefit from our recent acquisition of Otezla.

A key pillar of our growth strategy continues to be bringing to market first-in-class or best-in-class medicines that deliver a large effect size for patients suffering from serious illnesses. The world is growing older, wealthier, and more urban and these mega trends mean that the world will need more biopharmaceutical innovation, not less. We intend to be a leader and delivering that innovation. We expect several important data readouts from our pipeline in 2020. We expect data for AMG 510 or KRAS G12C inhibitor for tezepelumab in allergic and non-allergic asthma for omecamtiv and heart failure and look for Otezla in mild-to-moderate psoriasis.

In addition, we'd expect to generate some important data across our BiTE portfolio in 2020 as well and Dave Reese will provide details on all of this shortly.

Last year, we also expanded our commitment to discovery research, strengthening our world-leading human genetics capabilities through a number of collaborations while adding large scale proteomic data as well. We remain excited about how our approach is enabling us to identify and pursue new targets and the patients who stand to benefit most from them.

Everything we see in our company and across the industry continues to make us feel that we're living in an incredible age of biotechnology innovation. Across diseases, we're seeing more and more reason to be optimistic about the next breakthrough for patients. At the same time, we know that governments and individuals who are struggling with how to pay for these breakthroughs. We accept responsibility to be part of the solution, both in advancing innovation that really matters and in providing innovative ways for patients to get access to it. In an election year, there is bound to be much discussion about health care and we look forward to engaging with other stakeholders to promote market-based solutions that promotes innovative medicines and affordable access to them.

Just as we recognize that we need to be a constructive stakeholder to help sustain the robust ecosystem that exists for biotechnology innovation in the U.S., so to do we

recognize and accept the need to be part of the process of addressing other environmental, social, and governance matters that are of concern in our communities today.

To that end, several years ago, we set targets for reducing our carbon emissions and water consumption by the year 2020. Having hit those targets in 2019, a year earlier than planned, we are now developing a next set of goals that we will share later this year. These goals will include a further commitment to our next generation manufacturing technologies, which have a much smaller environmental footprint than traditional biologics manufacturing and enable us to operate at a lower cost too.

Now, let me turn over the call to our new CFO, Peter Griffith. You'll recall that Peter joined us in October, and he will take you through the details of our performance in 2019 and our outlook for 2020. Peter, over to you.

## **Peter Griffith** {BIO 4299061 <GO>}

Thanks, Bob. Let me begin by saying how happy I am to join Amgen at such an exciting time in the company's 40-year history. I also want to take a moment to thank, David Meline, the Amgen team, as well as many of you on the call who have helped me transition into the role. Over the last several months, I've enjoyed meeting many of our investors as well as members of the analyst community and I look forward to the continued dialog and engagement.

Now, let's turn to the fourth quarter financial results on Page 6 of the slide deck. Revenues at $6.2 billion decreased 1% year-over-year in the fourth quarter. In the quarter, we saw worldwide product sales declined 2% to $5.9 billion as our portfolio transition with declines in our mature products substantially offset by our growth and launch products.

We are particularly encouraged by the strong 21% volume driven growth from our ex-U.S. markets, which gives us confidence as we continue our global expansion including into China, which will also benefit from our collaboration with BeiGene, which closed earlier this month.

Foreign exchange had a 1% negative impact to fourth quarter worldwide sales on a year-over-year basis. Other revenues at $316 million were up $87 million versus Q4 2018.

Our Q4 non-GAAP operating income at $2.6 billion decreased 4% from prior year. Non-GAAP operating margin was 44.6% for the quarter, compared to 45.3% in Q4 of 2018. As previously indicated, our operating expenses reflected the typical underlining -- underlying fourth quarter pattern, increased investment in our rapidly evolving oncology pipeline portfolio and additional operating expenses associated with the Otezla acquisition, which closed in Q4. These increases were partially offset by continued favorable expense impacts from our productivity initiatives across all operating expense categories. Other income and expenses were a net $65 million expense in Q4, representing $132 million of year-over-year favorability. This favorability was driven by gains generated from liquidating bond investments to fund the Otezla and BeiGene

transaction and favorable market value fluctuations of publicly traded securities held in our venture's portfolio, partially offset by lower interest income due to reduced cash balances.

The non-GAAP tax rate was 14.9% for the quarter, a 1.6 point increase versus Q4 2018, primarily due to a one-time prior-year tax benefit associated with intercompany sales under U.S. corporate tax reform. Non-GAAP net income was $2.2 billion and non-GAAP earnings per share increased 6% year-over-year for the fourth quarter, supported by a 7% reduction in share count versus Q4 2018.

Next, I will review our 2019, full-year results on Page 7 of the presentation. Our 2019, full-year revenues decreased 2% to $23.4 billion, while our non-GAAP earnings per share grew 3% to $14.82 per share. For the full year, we saw a 1% decline in worldwide product sales to $22.2 billion. Volume growth in markets outside the U.S. was 19% year-over-year. Other revenues at $1.2 billion were down $56 million year-over-year.

For the full year, non-GAAP operating income at $11.2 billion decreased 6% from the prior year and our non-GAAP operating margin was 50.2% for the year, down from 52.6% in 2018. In total, non-GAAP operating expenses increased 3% year-over-year to $12.2 billion. This growth was driven by Research and Development investments, launch product support, and the addition of Otezla to our business, partially offset by our productivity program.

Other income and expenses were favorable by $250 million on a year-over-year basis due primarily to gains in 2019 from liquidating bonds to fund the Otezla and BeiGene transactions, partially offset by lower interest income resulting from reduced cash balances.

The non-GAAP tax rate was 15% for the full year, up 1.5 points versus 2018. Again, primarily due to a one-time prior-year tax benefit associated with intercompany sales under U.S. corporate tax reforms.

Turning next to cash flow in the balance sheet on Page 8. For the full year 2019, Amgen continued to generate strong cash flow, reflecting a diversified portfolio of products coupled with an industry-leading cost structure. Free cash flow was $8.5 billion in 2019 versus $10.6 billion in 2018. The decline driven by lower net income, timing of working capital, and an advance tax deposit. In 2019, we returned a total of $11.1 billion to shareholders through dividend payments totaling $3.5 billion and $7.6 billion used to repurchase $40.2 million shares at an average of $190 per share. And this followed the $21.4 billion return of capital to shareholders in 2018.

Cash and investments totaled $8.9 billion at the end of 2019, a decrease of $20.4 billion from the end of 2018. This decrease was primarily driven by the Otezla transaction, cash return to shareholders in the form of dividends and share repurchases as well as debt repayment. All partially offset by free cash flow generated during the period. Debt outstanding at year-end totaled $29.9 billion and carries a weighted average interest rate of 3.7% with an average maturity of 12 years.

Now turning to the outlook for the business for 2020 on page 9. 2020 and will be another important year for Amgen, as we continue to invest in the pipeline to generate innovative and differentiated molecules build out the global business and support the growth of our new products. As previously discussed in anticipation of this opportunity and continued downward pressure on net prices, we developed a productivity capability to enable us to fully invest from a position of strength.

Our 2020 revenue guidance is $25.0 billion to $25.6 billion and our non-GAAP earnings per share guidance is $14.85 per share to $15.60 per share. GAAP earnings per share guidance is $10.85 per share to $11.65 per share, which divergence from non-GAAP EPS, primarily due to the amortization of intangibles related to our Otezla acquisition. Our non-GAAP tax rate guidance is 13.5% to 14.5% and once again, we expect capital expenditures of approximately $700 million this year, including our industry leading environmentally friendly next generation manufacturing facility in Rhode Island.

Let me mention several key assumptions embedded in our guidance. First, our revenue guidance range reflects continued strong worldwide growth from products including Prolia, Evenity, Repatha, Aimovig, Otezla and our biosimilar portfolio. At the same time, we expect increasing competition against our filgrastim and ESA franchises, as well as Sensipar.

Next, with regard to net selling prices, we experienced a 5% decline globally in 2019. For 2020, we expect to again experienced low to middle single digit declines globally. We expect our volume growth to more than offset the net price declines. Overall, as previously stated, excluding Otezla, we expect our base business to be stable in 2020 on a year-over-year basis. As you model revenue in 2020, note that historically the first quarter represents the lowest product sales quarter of the year. As a percent of the full year, product sales for the first quarter should look similar to the percentage we saw in Q1 of 2019. Murdo will explain further in his remarks.

With respect to other revenue, we expect about $1.1 billion for the full year 2020, as we anticipate increased competition against our royalty product portfolio. From an operating expense perspective, overall we expect 2020 total non-GAAP operating expenses to grow in the low double-digit percentage range year-over-year on an absolute basis. As previously communicated, we reiterate the following three assumptions. Non-GAAP R&D investment to increase as we invest in our advancing innovative pipeline programs and new Otezla indications partially offset by R&D recoveries received from our BeiGene collaboration.

Second, non-GAAP SG&A expense to increase due to the acquisition of Otezla as well as modest incremental investment in support of our base business, as we continue to expand globally, including China and Japan. Grow our biosimilars business and begin product launch preparation for our late-stage pipeline.

Non-GAAP cost of sales as a percent of product sales to be generally consistent with 2019. We expect all expense categories to continue to benefit from our productivity program. We anticipate non-GAAP other income and expense to be a net expense in a range

between $1.2 billion and $1.4 billion. This is primarily driven by lower interest income as a result of cash used to fund the Otezla and BeiGene transactions as well as our 20.5% share of BeiGene's results based on current publicly available consensus estimates.

I know that our 20.5% share of BeiGene's results will be booked one quarter in arrears in accordance with the equity method of accounting and therefore begins in Q2, 2020. As you know, on April 1, 2020, Amgen will purchase the 49% of shares in Amgen Astellas BioPharma that are held by Astellas for a nominal fee, making the company a wholly-owned Amgen subsidiary.

First, let me say how excited we are about this transition as it marks the achievement of a long-term strategic objectives. We look forward to further leveraging this platform as we seek to bring Amgen's new medicines to patients in the third largest pharmaceutical market. From a financial perspective, we anticipate limited near-term financial impact resulting from this transition.

Now, with regard to capital deployment, our actions will continue to reflect the following principles. First, we will invest in our business to expand our pipeline of innovative medicines and to seek to drive long-term volume growth globally. We will also invest in prudent external business development opportunities.

Second, we remain committed to returning capital to shareholders in the form of growing dividends, including the 10% increase in the first quarter of 2020 or $1.60 per share, as well as continued share repurchases. We will continue to take an opportunistic view towards the timing of share repurchases within '20. We expect share repurchases within a range of $3 billion to $5 billion and have an authorization outstanding in the amount of $6.5 billion.

And third, we remain committed to maintaining an optimal capital structure in order to minimize our weighted average cost to capital and retain our investment grade rating. Consistent with our usual practice, our guidance today does not include the impact of potential external business development activities.

So in summary, we delivered another year of strong financial results in 2019 and we remain confident in the outlook for Amgen's success in 2020 and beyond. This concludes the financial update. I will now turn the call over to Murdo.

## **Murdo Gordon** {BIO 18450783 <GO>}

Thanks, Peter, and good afternoon everyone. I'll take a few minutes to reflect on 2019 and then review Q4 in greater detail. In the 40 years since incorporation, Amgen's product portfolio and geographical footprint has changed dramatically. On our 40th anniversary, we reflect on the pioneering innovative spirit of our early Amgen employees that transformed the treatment of disease. Our mission to serve patients remains unchanged and it motivates us every single day. Our accomplishments on behalf of patients in 2019 give us further confidence about our future as we enter 2020.

To summarize 2019, for the full year year, we grew volume by 3%. The growing proportion of our portfolio posted 35% year-over-year volume increases. This portfolio is diverse and includes products such as Prolia, Evenity, Repatha, Aimovig, Otezla, Amgevita, our six hematology and oncology brands as well as MVASI and KANJINTI.

Finally, our international business contributed 19% volume growth in 2019. Notably, year-over-year revenues for our businesses in China and Japan grew nearly 8 fold. These markets are long-term growth engines for Amgen and our collaboration with BeiGene along with our acquisition of Otezla will accelerate our expansions in the second and third largest pharmaceutical markets.

Now moving to fourth quarter results. Volumes grew by 3% year-over-year. In Q4, net selling prices declined 4% year-over-year, resulting in reported net sales declining by 2%. As Peter mentioned, we have a stable outlook for our base business for 2020 and with the addition of Otezla, we expect revenue growth this year despite projecting continued declines in net selling price on a portfolio basis.

Now getting into product details, Prolia delivered 15% growth year-over-year, driven by higher volume from increasing rates of new patient growth and strong repeat injection rates. Recall that given twice a year dosing, Prolia experiences consistent seasonal trends. Evenity posted $85 million in the fourth quarter, driven by strong uptake in both Japan and the U.S. Every year, worldwide 8.9 million fractures occur due to osteoporosis. That's one fracture every three seconds and only 20% of women who experienced a fracture are treated with a bone-building medicine. Given the under-penetrated nature of this market, we continue to focus on ensuring postmenopausal women receive appropriate screening, diagnosis, and treatment. With Prolia and Evenity, we have excellent treatment options to offer these patients.

On to Repatha, Q4 sales grew by 26% year-over-year, as we continue to be the leader in the PCSK9 class worldwide unit growth was 67% year-over-year and new to brand U.S. prescriptions are steadily improving growing at 61% year-over-year, we've taken significant steps and have made major progress in improving access and affordability for Repatha.

We removed the original list price offering. We simplified and improved prescription approval rates and commercial plans and we have increased the percentage of Medicare patients up to 70% that can access Repatha at a more affordable co-pay. Although the blended net price of Repatha in the U.S. declined in Q4 versus the previous year, net selling price was relatively stable sequentially.

For 2020, we expect a step down in Repatha's net selling price in Q1 based on our contracting to obtain broader access with stabilization thereafter.

Now onto Aimovig on Slide 16. On a year-over-year basis, volume grew 27% while net sales grew 3%. As a reminder, Q4 2018 benefited from $20 million of favorable changes in accounting estimates impacting the year-over-year comparison on a quarter-over-quarter basis. Unit volume grew 9%.

To date, almost 300,000 patients have been prescribed Aimovig by more than 33,000 prescribers. Considering that there are 4 million migraine patients in the U.S. who are eligible for CGRP treatment, Aimovig has significant potential remaining to penetrate this market and we expect to drive volume growth over the course of 2020.

Aimovig leads in both new to CGRP prescriptions and total prescriptions, which exited Q4 with a 48% TRx share. Aimovig has exceptional access with over 80% of prescriptions paid and over 92% of the lives covered. As a result of this broader access, we expect net price to decline slightly on a full year basis for 2020, when compared to the full year 2019. Additionally, Q1 has lower sales in subsequent quarters due to the impact of benefit plan changes, insurance re-verifications, and greater co-pay expenses as patients, work through their deductibles.

We'll move to Parsabiv on Slide 17, which grew by 49% year-over-year in the fourth quarter. Independent and midsize dialysis providers already utilize Parsabiv for a majority of their calcimimetic patients while FMC and DaVita continue to increase adoption.

Next onto Otezla. With the help of the dedicated professionals that have joined our team from Celgene, we will continue to drive strong sales growth and launch potential new indications for Otezla. During the period since acquisition closed, prescription momentum continued with 13% year-over-year growth. Our seamless integration efforts, combined with planned label and geographic expansion gives us confidence in our ability to grow Otezla at low double-digit compound annual growth rate over the next five years.

For the approximately five weeks post closing in 2019, Otezla sales were $178 million. We expect first quarter sales to be proportionally lower than in the remaining quarters of the year. The quarterly pattern for Otezla in 2020 should approximate the historical pattern over the last number of years.

Moving on to Enbrel sales increased 2% year-over-year driven by a $66 million favorable change in accounting estimates and increases in net selling prices, partially offset by unit volume declines. Volume trends in 2020 are expected to be similar to those in 2019. As for net selling price, we project limited benefit in 2020 versus 2019 due to less favorable contract terms.

With two highly complementary products, targeting psoriasis and psoriatic arthritis, we see an opportunity to strengthen their positions in the market; more broadly, we're increasing our focus in inflammation through our broad portfolio, which includes our biosimilars, Amgevita, and Avsola. Our late-stage asset tezepelumab and a number of other earlier assets in the R&D pipeline.

Now to our hematology and oncology business, which is highly integrated with our oncology biosimilars that I'll discuss later. Our innovative portfolio of six brands XGEVA, KYPROLIS, Nplate, Vectibix, BLINCYTO, and IMLYGIC collectively totaled $1.2 billion in the quarter, growing 10% year-over-year.

As for some of the larger brands within this portfolio, XGEVA grew 7% in Q4 year-over-year driven by 4% volume growth. KYPROLIS grew 6% year-over-year driven by volume led by a 12% increase in the U.S. -- in U.S. sales. Nplate grew 15% year-over-year driven by volume. Our investments in R&D for Nplate have resulted in two innovations. First, we recently launched a smaller presentation at 125 mcg in support of in Nplate's pediatric indication, as the product is administered with weight-based dosing. This new presentation will also help to minimize general product wastage for ITP patients across all indications. Second, Nplate received approval in October for the treatment of early ITP, which gives us the chance to serve patients earlier in the course of their disease and provides the opportunity for treatment free remission.

Now onto our more mature brands, in Q4 Neulasta sales declined 43% year-over-year with a 42% decline in the U.S. Recall that Q4 of 2018 benefited from a $55 million BARDA order, which did not repeat in Q4 of 2019. Coinciding with the emergence of U.S. biosimilar competition, the most recent CMS published ASP for Neulasta reflects a 10% reduction. Bear in mind that ASP is calculated two quarters in arrears.

On a volume basis in Q4, U.S. Neulasta retained an exit share of 74% of the long-acting segment with Onpro holding an exit share of 55%. We are encouraged by Onpro's durability demonstrating confidence that our customers have in the reliability and quality of our supply, along with our broader customer services. We now face a third biosimilar competitor in the U.S. and other potential competitors remain and development. As you model, Neulasta sales for the first quarter, recall that Q1, 2019 benefited from a $98 million BARDA order that we do not project to recur in 2020.

Finally, outside the U.S., sales declined 48% in Q4 and we expect those trends to continue.

Switching to Nephrology, starting on slide 25, Q4 EPOGEN sales declined 20% primarily due to lower net selling price from our contractual commitments with DaVita, which calls for a further price reduction in 2020.

Meanwhile, Aranesp declined 10% year-over-year driven by lower volume due to increased competition. Regarding Sensipar, recall that in the U.S., there were several at risk generic launches in 2019 that resulted in year-over-year sales declining 76% to $107 million in the quarter.

In 2020, supplemental patent protection certificates for cinacalcet expire in France, Germany, Italy, Spain, and the United Kingdom, which will likely result in a significant decline in ex-U.S. sales in 2020.

I'll close the product section with our biosimilar portfolio, which is highly integrated with our innovative business throughout the company. As examples, a majority of these products were made with the same manufacturing network as our innovative brands. We also leverage the same supply chain for distribution. And on the commercial side, we continue to identify synergies in commercializing our biosimilars alongside our innovative

products, making it a highly efficient selling model and allowing us to rapidly apply learnings across our portfolio.

We also offer the same provider and patient services as with our innovative portfolio. These advantages are increasingly important as we now face additional biosimilar competition to KANJINTI and MVASI and expect other competitors to enter during 2020. Our Q4 biosimilar portfolio comprised of KANJINTI and MVASI in the U.S. and Amgevita, KANJINTI and MVASI outside of the U.S. recorded sales of $258 million.

In the U.S., KANJINTI and MVASI each recorded $79 million of sales and we've seen very encouraging adoption rates in the clinic segment and hospital adoption is accelerating. Given the early stage of launch, there is also some inventory stocking during the quarter. Ex-U.S. sales from our biosimilars where $100 million led by Amgevita. We continue to see important differences between products and markets in terms of uptake and price erosion with some markets experiencing strong uptake at more discounted pricing levels, while other larger markets including Germany and France exhibit a more balanced and sustainable opportunity.

Here again, we're able to leverage our expertise and footprint in oncology, while Amgevita efforts synergized nicely with Otezla. In summary, 2019 was a solid year given the evolution of our product portfolio. In 2020, we plan to drive volume uptake of our growth portfolio of products, now including Otezla while defending our mature brands. Let me now turn it over to Dave Reese.

## **David M. Reese** {BIO 19782623 <GO>}

Thanks, Murdo and good afternoon everyone. As we enter 2020, we are looking forward to important clinical data from programs across our three therapeutic areas, inflammation, oncology, and cardiovascular disease. I'll say more about oncology in a moment, but I'd like to take the opportunity upfront to express our enthusiasm for the BeiGene collaboration. We're off to a good start and look forward to working together to advance the global development of our pipeline of innovative oncology molecules.

I'll now begin my quarterly review in inflammation. We expect Otezla data this year from a Phase 3 study in over 500 patients with mild-to-moderate psoriasis that have failed topical therapy. This patient population has no approved oral therapy available and we are confident that Otezla may provide a much needed treatment option. We're working with the CHMP toward a Behcet's indication in Europe and with the FDA on inclusion of the scalp psoriasis data in the U.S. label this year. There are also ongoing studies for new indications, including pediatric psoriasis and we're evaluating additional studies to expand the opportunity for Otezla.

I'll also remind you that later this year, we expect Phase 3 data from our TSLP antibody, tezepelumab in development with AstraZeneca and severe uncontrolled asthma.

In bone health, along with UCB, we were pleased to receive European approval for Evenity for the treatment of severe osteoporosis in postmenopausal women at high risk of

fracture. Evenity is the first new osteoporosis medicine approved in Europe in the last decade, a testament to the need for a new therapy that can rapidly build bone.

Turning to oncology and hematology, we continue to rapidly advance the development program for AMG 510, our first-in-class KRAS G12C inhibitor. We enrolled the potentially pivotal Phase 2 monotherapy study in advanced non-small cell lung cancer in approximately three months and look forward to sharing data later this year when we have at least six months follow-up on all patients. I previously mentioned that we had enrolled a cohort of advanced colorectal cancer patients in our Phase 2 monotherapy study. Based on the data we have generated to-date, we have opened the study to further enrollment and we'll assess our potential development path in colorectal cancer as additional data become available.

We also expect to present additional data later this year from our first-in-human monotherapy study in solid tumors, where we will have more information on duration of therapy as well as data and tumor types other than lung and colon cancer. We also expect initial data from our Phase 1 combination study with KEYTRUDA in advanced non-small cell lung cancer.

We are enrolling advanced colorectal and non-small cell lung cancer patients in our MEK inhibitor combination study as well as treatment-naive non-small cell lung cancer patients in our ongoing Phase 1 monotherapy study. We continue to plan additional studies primarily combination trials and we'll provide updates as the program progresses.

We remain enthusiastic about our BiTE platform in 2020 will be an important year. Based on emerging evidence of anti-tumor activity in both hematologic malignancies and solid tumors, we are growing increasingly confident in the half-life extended format. As we advance our BiTE clinical programs in different tumor settings, we are gaining important insights into dose and schedule and management of adverse events such as cytokine-release syndrome.

These insights will guide customized development approaches, depending on the target and underlying disease biology. Over the course of the year, we anticipate sharing data from some of these programs and I'll provide further guidance on expected data presentations as these molecules advance. We are now pursuing two half-life extended BiTE programs for gastric cancer and recently initiated a first-in-human study for AMG 199, which is directed against MUC17, a target widely expressed in gastric cancer.

Gastric cancer, as you know is highly prevalent in East Asia, where we have a growing presence through our impending Japan subsidiary and collaboration with BeiGene. As I previously discussed, we intend to present the data for AMG 701, or half-life extended BCMA BiTE when we have a meaningful dataset, most likely in the second half of this year.

We've also made several regulatory submissions in oncology, including the KYPROLIS CANDOR study in the U.S., KYPROLIS plus dexamethasone in China for relapse and refractory multiple myeloma and BLINCYTO in China for relapsed-refractory AOL. We look forward to working with BeiGene to advance these important medicines.

In cardiovascular disease, along the Cytokinetics, we look forward to the data from the omecamtiv mecarbil Phase 3 outcome study in the fourth quarter of this year. While the heart failure treatment landscape is expected to change based on recent data from other drug classes, we believe significant residual unmet medical need remains in this global epidemic. Also in cardiovascular disease, our LP(a) siRNA, AMG 890 continues to advance and we expect to initiate Phase 2 development in the first half of the year.



Finally, on biosimilars, we're pleased to receive U.S. approval for Avsola, our biosimilar Remicade and to make our U.S. regulatory submission for ABP 798, our biosimilar Rituxan. I'm also pleased to announce that we are initiating a Phase 3 study with our 7th biosimilar ABP 938, our biosimilar aflibercept or EYLEA. Bob?

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

Okay. Thanks, Dave. Ian, why don't we open the lines up for questions now and please remind our callers of the process.

## Questions And Answers

### Operator

(Operator Instructions). Our first question is from line of Jay Olson from Oppenheimer & Co. Jay?

### Q - Jay Olson {BIO 18027199 <GO>}

Hi. Congrats on the quarter and thanks for taking the question. You talked a little bit about net pricing dynamics for Aimovig. Could you maybe elaborate a little bit on how you expect the competitive dynamic to shape up in the CGRP space and any long-term data, you could potentially leverage there? Thank you.

### A - Murdo Gordon {BIO 18450783 <GO>}

Thanks for the question. Jay, it's Murdo here. We're very pleased with Aimovig's market access position now with over 92% of covered lives, having access to Aimovig at a very affordable co-pay. We're also pleased with the addition this year of CVS, last year we did not have CVS as a benefit -- with Aimovig as a benefit and we do as of the beginning of this year and we've already seen an acceleration in our new patient uptake.

We are happy that the percentage of patients that are receiving paid prescriptions now of Aimovig is above 80% and that bodes well for the future growth of this category because we've got highly effective medicines that have an impact, a significant impact on the reduction of migraine days on migraine sufferers and we have a lot of them, there is 4 million eligible patients out there in the U.S. and they're able to access Aimovig at a very affordable co-pay.

So that's good for the future outlook of the category, obviously because we did contract to secure that additional access, there will be a reduction in our net selling price that

you'll see in Q1 and then we expect it to be relatively stable over time. Now, because this is a retail benefit product, you do see some fluctuations, as you make true-ups in the mix of your product that comes through Medicaid commercial or to some extent Medicare Part D. But overall, we would expect post Q1 stability in net selling price.

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

All right. Let's go to the next question, Ian.

### Operator

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

### Q - Michael Yee {BIO 15077976 <GO>}

Great. Thanks for the question. I had an R&D question for David. Of course there is a lot of attention on AMG 510, you made a lot of great comments about how you quickly enrolled the study and we're going to get data later this year. One of the things I picked up on was your comments about first-line lung, can you just maybe make a comment about how that advances or how that progresses or how you go about a first-line strategy that's obviously a huge opportunity. So maybe just comment about where that monotherapy study goes and where you can go with first-line? Thank you.

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

Yeah. Thanks, Michael. That is intended to provide a potential treatment option for patients who are not eligible for other first-line lung therapies or unwilling to take such therapies. I think it will provide incredibly valuable clinical information on response to the drug in a previously untreated population. We've just started enrolling that, so over the course of the year as we generate data, we'll provide guidance as to when we may have some things to share.

### Operator

And our next question is from line of Chris Raymond from Piper Sandler. Chris.

### Q - Chris Raymond {BIO 4690861 <GO>}

Hi. Thanks for taking the question. Just on M&A priorities. So by that was kind of struck a couple of weeks ago in San Francisco, you guys talked about renal as maybe an area of interest in terms of building out the pipeline and you're offering and obviously augmenting what is a pretty formidable business now, but I think the wording that I heard you say, Bob was that any asset you bring in, would have to be game changing. So maybe two parts. Can you talk about the reasoning for this sort of focus on renal or at least articulating that to us and then what are you really looking for in terms of the game-changing therapy? Thanks.

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

So, Chris, just to remind you we -- we have six commercial franchise areas, of which nephrology is one obviously that was our first and we've been a leader in that area now for several decades. We have a number of important products for nephrologists today and we intend to continue to serve the needs of patients and physicians and providers et cetera in that community.

We have not found in our own discovery research efforts that we've been able to find the kinds of game changing innovation that we want to invest in from a discovery standpoint. So we're not investing in discovery research in nephrology right now, but we are going to look for business development opportunities there and in general our strategy when it comes to the business development is to look for medicines that make a big difference for patients suffering from these diseases.

So we'll look for innovation and large effect size. I don't know that I use the word game changer, but if I did, that's what I was intending to reflect the notion of large effect size innovative medicines. So to the extent, there are some in the industry or otherwise medicines, where again we think because of the historical investment we've had it with this community patients that we can add real value, we'll look.

## Operator

And our next question from line of Brian Skorney from Robert W. Baird & Co. Brian.

## Q - Brian Skorney {BIO 15993204 <GO>}

Hey, good afternoon guys. Thanks for taking the question. One quick one -- actually two quick ones on housekeeping, just it looks like compared to last quarter, you saw a 6% decline in Neulasta market share. Can you just break out how much of that was Onpro loss and can you also talk about how Onpro price has been impacted by the biosimilars have been able to maintain price so far or have you taken greater discounts to maintain that share? Thanks.

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

Okay. Those are good questions for Murdo. Why don't you go ahead Murdo.

## A - Murdo Gordon {BIO 18450783 <GO>}

Yeah. Thanks, Brian. The majority of the share decline is from the prefilled syringe. Onpro exited at a 55% share of long-acting filgrastim and continues to hold up well in terms of share. We have had a contract out there that provides some discount to Onpro, but it's a more modest discount, then you would see on the prefilled syringe.

## Operator

And our next question is from line of Evan Seigerman from Credit Suisse. Evan.

## Q - Evan Seigerman {BIO 18922817 <GO>}

Hi, all. Thank you for taking my questions. One on biosimilars. So what are some gating factors to achieve, I think it's multi-billion or you had at one point, said greater than $3 billion in sales across the franchise and if there were to be implementation of an international pricing Index are most favored nation clause for Medicare Part D, how would this potentially impact your biosimilars business? Thank you, guys.

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

I can take a stab at the first part of your question and Murdo, I invite you to jump in. But since we made those undertakings before you were part of the team Murdo, the notion that we articulated was that we were going to advance the portfolio of up to 10 biosimilars that we expected that these could be an attractive growth opportunity for the company and we're off to a good start, as you heard me say earlier, at the end of the fourth quarter, we are annualizing in excess of $1 billion. So we're off to a good start. We're on time. We're on budget with these programs and the gating item is simply product approvals and product launches. So we remain enthusiastic about our chance to earn a return from these products and and it adds to the specifics of IPI, just to say in general, we obviously would be concerned we think quite a few other stakeholder groups would as well about the disruption that IPI would represent to the innovative biopharmaceutical industry and we think there are better ways to evolve our system in a way that ensures patients have access to medicines at affordable prices, but Murdo feel free if you want to add anything specific about IPI in biosimilar landscape.

## A - Murdo Gordon {BIO 18450783 <GO>}

Nothing on IPI, but I think you summarized it well and on biosimilars, the only thing I would say is I'm thankful to have inherited this portfolio and for the decisions that were made prior to my arrival. I think this is a strong business opportunity. It's been one, we've been able to realize very good competitive share in Europe and we're off to a very good start in our early launch in the U.S. and I look forward to being able to launch more products.

## Operator

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

## Q - Kennen MacKay {BIO 18821382 <GO>}

Hey. Thanks so much for taking my question and congrats on the end of the year-end 2019. I totally agree it was transformative. Maybe for Murdo, I was wondering if you could talk a little bit about the synergies you're seeing or expecting between selling of both Otezla and Enbrel and whether there were any tailwinds there to year end formulary rebating or contracting negotiations, we should think about in pricing or access in the year ahead?

## A - Murdo Gordon {BIO 18450783 <GO>}

Thanks for the question, Kennen. Yeah. We're excited about potential synergies between Otezla and Enbrel, and quite frankly by extension our biosimilars business coming into the inflammation category. Too early to comment on specifics, but we continue to work

through our contracting strategy, promotional strategy even things as simple as possibly expanding into primary care promotion because we have a fairly large primary care footprint and then clearly our international geographic expansion is augmented by having Otezla joining our portfolio with potential new markets where perhaps Otezla was slated to be launched by distributors when we have a full blown affiliate in some of those markets. And then the last pieces of course synergies as we go into some of the new indication areas. So I'm excited about building those. Our teams are working hard to realize those synergies, and I feel optimistic that we'll be able to be more specific in upcoming quarters.

## Operator

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

## Q - Umer Raffat {BIO 16743519 <GO>}

Hi. Thanks so much for taking my question. I am just extraordinarily confused today on the guidance, but I'll limit my question two specific things perhaps. First, Peter on the OINE line, if you can bear with me for a second, you mentioned $1.2 billion to $1.4 billion and I was trying to think it through and I thought to myself $30 billion debt at just above 3% rate, so that's $1 billion as an interest expense, minus about $100 million of the interest income. So that's $900 million, so when you guide to $1.2 billion to $1.4 billion, that's effectively implying $300 million to $500 million for BeiGene. But my understanding was you're only booking 20% and I'm just trying to understand is BeiGene's implied net income $1.5 billion to $2.5 billion or am I thinking about that wrong, because that sounds so much higher than what BeiGene does. That's number one.

And secondly on revenues. I noticed -- I know the business is being implied flat year-over-year outside Otezla, so I just want to understand better what the pushes and that pulls are there and perhaps also I think it mentioned biosimilars doing $1 billion in 2020 annual 4Q '19 alone was north of $1 billion run rate, so just trying to understand all this. Thank you very much.

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

Okay Umer. Let's try and go through that, I think there were three questions there. So Murdo, you want to take the first two on the revenue, just clarify what we said and then Pete, you can help clarify the other interest and expense line.

## A - Murdo Gordon {BIO 18450783 <GO>}

Sure. So yes, we have guided that our base business will be stable year-over-year, obviously there are a range of outcomes on that portfolio and we continue to work hard across a number of opportunities to do as we've done historically and that is to outperform. I would say that Otezla has come in and we have seen very good seamless integration of that team and that performance of that product and the growth trajectory continues with -- without any interruption through the fourth quarter and we're seeing strong weeks early in the New Year.

On biosimilars, it's very early in the launch of those two products, where we are annualizing as you pointed out at over $1 billion based on fourth quarter and we expect to be able to continue to accelerate that business.

### A - Peter Griffith {BIO 4299061 <GO>}

Umer, Peter here. Thanks for your question. I would take you to the fact that our total debt at the interest rate I talked about in my remarks at 3.7% average maturity 12 years, by the way, I mentioned that too. That plus the 20.5% of BeiGene's results for 2020, the publicly available consensus estimates are what we're guiding to. So when you work through those two, you should get pretty close to our $1.2 billion to $1.4 billion for 2020.

### Operator

And our next question is from line of Robyn Karnauskas from SunTrust Robinson Humphrey. Robin.

### Q - Robyn Karnauskas {BIO 15238701 <GO>}

Hi. I don't want to beat a dead horse, but I guess I'm confused too just by this lack of growth given that your slides have outlined, Neulasta, you've lost like half Onpro's holding, you're growing like a bunch of different products. So what is the one thing you think that is going to prevent you from growing more this year and not just having a stable business year-over-year, like that's sort of what I'm struggling with the most, just help me understand that because the way you describe, it looks like more growth of the top line. Thank you.

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

Sorry Robyn, repeat the last piece -- last piece of your question.

### Q - Robyn Karnauskas {BIO 15238701 <GO>}

Sure. The way you're describing our your business is in your slide performance basically is that you're growing many parts of the business and the part that is declining is Neulasta, it seems to be potentially stabilizing with Onpro. So what is preventing you from growing beyond what you're guiding, is there one particular thing, I think most of us sitting there saying why can't you grow more than what you've outlined given the picture that you painted of the business being actually quite strong.

### A - Peter Griffith {BIO 4299061 <GO>}

So I would agree with your last comment, the picture of the business does look quite strong. We're pleased with what we've been able to achieve, particularly in the back half of last year.

As I mentioned earlier, some of the Neulasta stability with Onpro has been at the expense of contracted terms, which lowered the net price of that total portfolio inclusive of Onpro and we would expect with additional competitors against Neulasta in the biosimilar space that there will be further net price erosion in the long-acting filgrastim category and of

course, overall in our total portfolio worldwide, we would expect single digit net price declines for the year.

Now, that goes up against what I talked about throughout the call is we have a number of really strong growth drivers in a young portfolio, very diverse products, and we have guided a wide range on revenue and it's my hope that the strong execution we saw in the back half of last year continues into this year and we can achieve a good growth profile, not just in Otezla but in the base business.



## Operator

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

## Q - Terence Flynn {BIO 15030404 <GO>}

Hi. Thanks for taking the question. Omecamtiv is a product you guys haven't talked a lot about recently obviously some Phase 3 data coming later this year, Dave, you mentioned it in your, in your remarks as well in terms of kind of the change in treatment landscape, but just curious if you could remind us of the puts and takes for the program, as we think about the probability of success here and what would really get you guys excited that type of data? Thank you.

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

Yeah. Sure Terence. This is Dave. I'm happy to address that. I mean, as I mentioned in my remarks, heart failure is a global epidemic, what makes us continue to have excitement in omecamtiv, it's a first-in-class mechanism of action, it's the only drug ever introduced that actually acts directly on the heart cell to improve contractility or the heart's pumping function and we're conducting what'll will be a definitive 8200-patient or give or take trial in patients with advanced heart failure, it's a fairly sick population, where we're going to be looking for mortality benefit and a variety of other clinical outcome measures that improve. So I think there is a large amount of residual unmet medical need and obviously where this fits in a train changing treatment landscape will depend on the profile that emerges from that Phase 3 trial.



## Operator

And our next question is from line of Ronny Gal from Bernstein Research. Ronny.

## Q - Ronny Gal {BIO 15022045 <GO>}

Good afternoon and congratulations on the nice 2019 and got one housekeeping and one question. The quick one is, I was wondering if you could give us your comment on the Medicaid block grant that just was announced today. Does that has any relevance to you and then generally, where do you expect it will impact the drug industry.

And second, David, I was wondering if you could give me your -- your view on the modest lung catering paper suggesting in the targeting the active GDP bound form of KRAS is

better than trapping the GDP KRAS in the inactive form in terms of preventing tumors and tumor resistance to those agents.

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

Good. Well let me -- I'll knock off the Medicaid piece first Ronny, for those who are on the call who aren't aware, CMS released some guidance earlier today, so we and others are still chewing through it. I think you'll have very limited impact at first read of it for us, but it's likely to be relevant for those states that didn't opt into the ACA in the first instance and we'll go through it as well, I'm sure others in our industry, more closely to see whether there are any specific issues, for our business, but it didn't seem to me Ronny that that was going to be a concern for us in 2020. Dave, you want to tackle the one please.

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

Yeah. I'm sure you don't want to address that one, Bob. So, we look -- for those who aren't familiar, Ronny's referring to paper that came out within the last month or so that suggests that also targeting the GDP bound form of KRAS G12C would be required for signaling inhibition. We read the paper with interest, of course, I'll make a couple of observations. First, I would say our own data with AMG 510 suggest that at the appropriate doses and doses that we can achieve clinically, we can completely suppressed signaling throughout a dosing interval.

It is also my understanding or belief that the G12C inhibitor used in that paper may have been a little less potent and one thing that we've learned over 40 years in oncology is that if you in completely inhibitor target, you very quickly breed resistance. So I would say, I feel very confident based on the preclinical data that we've generated with AMG 510 and we're of course profiling tumors across our clinical program to try to generate signatures of response and resistance. This is the sort of thing that we'll look at. But I don't see anything in the literature as of yet that dissuades me from the approach we're currently taking.

## Operator

And our next question is one of Mohit Bansal from Citi. Mohit.

## Q - Mohit Bansal {BIO 18070890 <GO>}

Great. Thanks for taking my question. And a quick question on Otezla in mild-to-moderate psoriasis, it seems like you will have data later this year, but given that net of tax rate is kind of a standard of care in that particular market and is a generic, what sort of challenge do you anticipate placing baseline in that market and how do you think about navigating those challenges there? Thank you.

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

Yeah. Well, let me start Mohit and then I'll ask Murdo to jump in. So in mild-to-moderate psoriasis, there are currently no approved oral therapies. The only thing really available to patients right now is topical therapy, many of them will not ultimately experience disease control with those topical therapies and so we think there is a real opportunity for Otezla

in that area. There are up to nearly 6 million patients with mild-to-moderate psoriasis in the United States alone. So that gives you a sense of the size of this opportunity and actually the prevalence of the disease. Murdo.

## A - Murdo Gordon {BIO 18450783 <GO>}

Yeah and Mohit, the only thing I would add is, yes, there is some methotrexate use there, but it's largely a topical business as Dave described and it's largely a patient population that gets very little relief. And this is really a patient population that is in the sweet spot for Otezla. The other thing I have to say is that our new colleagues when building out their positioning strategy for Otezla and their payor strategy have done a very, very nice job of positioning the access and reimbursement for Otezla as a post topical pre-biologic option. So I think for the mild-to-moderate population if we're successful in securing that indication that same payor strategy will be continued. So, I feel confident that we're in good shape there for another source of growth for Otezla going forward.

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

So Ian, I know we've got several calls or several questions still queued up, so we will try to get through those apologies that were beyond the top of the hour here, but let's go onto the next question.

## Operator

Certainly. Our next question is from line of Matthew Harrison from Morgan Stanley. Matthew.

## Q - Matthew Harrison {BIO 17603148 <GO>}

I just wanted to follow up on a comment that Dave made earlier in the call, suggesting I think that -- that maybe you're seeing some activity in HLE-BiTE in both solid tumors and liquid tumors. Maybe you could just characterize for us what -- what data you have internally that gave you the confidence to make that statement? Thanks.

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

Yeah. Thanks, Matt. And I assume that someone would pick up on that statement. So what I would say is, I'm not ready to declare victory in any indication yet, but we're seeing the sort of pharmacodynamic activity and early suggestions of anti-tumor activity that are reminiscent of the early days of BLINCYTO and that give us encouragement that we're on the right track.

I'd also point out that we undoubtedly have the largest experience in the world in development of bispecific T-cell engagers, as I noted in my remarks, we've learned an enormous amount about dosing and scheduling appropriate management of adverse events and I think all of that is starting to come to bear right now and we're starting to see some of these hints in that in the HLE or half-life extended format. So again, I'm not ready to declare a victory, but we're seeing signs of encouragement and we'll be ready to share some of those data as the year goes on.

## Operator

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

## Q - Do Kim {BIO 18706913 <GO>}

Great. Thanks for taking my question. Just one on Aimovig, you've talked previously about expanding the primary care prescribing base. How would you go about doing that and could you do it with your current sales force?

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

Yes. Thanks, Do. We -- we are doing it with our current sales force. I think I talked about the 33,000 prescribing base and I think we're seeing some encouraging results, right now in the CGRP class, you see about 7,000 new patients coming into the class and into the category that are receiving a CGRP therapy and it's our goal to broaden that given that there are so many patients, who are persisting on oral therapies and older therapies that are just not as effective and in fact we see very high drop off and very low persistency on these older oral meds like topiramate and we are trying to change that care continue on that pathway in the way physicians treat chronic migraine sufferers and I think we're having some success. So the 7,000-patient per week number that we're seeing is one that we're looking to grow and we are applying all the right efforts, both in our digital campaigns, as well as our personal selling teams in the primary care community right now. So yes, the answer is, we have all the resources required to do that.

## Operator

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

## Q - Yaron Werber {BIO 19486720 <GO>}

Yeah. Great. Thanks so much. If you don't mind, Dave, just have a quick housekeeping and then a question for Murdo. On the housekeeping side, omecamtiv, can you just let us know is there one more final DSMB look before you look at the event rate and then for Murdo just curious about Repatha, it looks like it's beginning to grow now. But now, what's your expectation given that 70% of patients that have access to the new price -- the new formulation. Thank you.

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

Yeah. Yaron, so I'll take the omecamtiv question -- there is an -- as we've previously announced -- discussed, there is an interim analysis for efficacy that will occur, that has a very, very high bar, a very high bar in terms of the statistical stopping rule. So our expectation is that the trial will continue through to the primary analysis towards the end of the year.

## A - Murdo Gordon {BIO 18450783 <GO>}

Yes. And Yaron, on Repatha, just a reminder, a 100% of patients that are accessing the low-list price because we pulled the original list price off the market in December. And

we've been able to throughout the course of 2019, open up the commercial access where the majority of patients receive Repatha by their physicians prescribing it without the need for paperwork and utilization management criteria, so physician attestation only in commercial is the majority condition for how they can prescribed Repatha.

And then in Medicare Part D space, obviously that's a new event for us because we were mid-cycle when we lowered the price with the introduction of the low list price. So it's really something we're excited about as an accelerating potential for Repatha, as was mentioned roughly 70% of Medicare Part D lives now have access to Repatha at an affordable co-pay. So we're looking forward to seeing sustained growth going forward. Our teams are ready and I was just with our sales forces in Dallas and everybody is pretty excited about being able to treat more patients quite frankly the way they should have been treated all along.

## Operator

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

## Q - Geoffrey Porges {BIO 3112036 <GO>}

Thank you very much for taking the questions. A quick housekeeping and then one for Murdo. First, could you just give us an update Dave on where the C5 biosimilar program is, is that still active and then for Murdo -- Murdo, I'm impressed with the Evenity number, you're annualizing it sort of $350 million already, which I think is better than most of us anticipated. Could you talk a little bit about the reception, you're receiving and whether you really think this can become -- Forteo's obviously losing its exclusivity, can it become a Forteo-like brand given what you're seeing already? Thanks.

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

Yeah. Jeff, so I'll take the first part of that question relating to ABP 959 or Soliris biosimilar, the Phase 3 is actively enrolling and we'll provide guidance as we come to the conclusion of that trial when you can expect to see data.

## A - Murdo Gordon {BIO 18450783 <GO>}

Yeah. And Geoffrey, thanks for the question on of Evenity. We are pleased with the launch trajectory on Evenity, it's reflective really of 2 markets, Japan and U.S. primarily. The Japanese launch has been nothing short of a resounding success out there with our partners, Astellas and UCB, I think physician reception has been excellent.

We positioned the product for post-fracture high-risk patients and I think that that's gone really well and it's where the risk benefit equation seems to be one that most physicians are accepting off and we've done the same thing in the U.S., our launch is a little younger in the U.S., but nonetheless the trajectory has exceeded our own expectations as well. We just recently got our permanent J code in the U.S. and that's opening up the prescriber base as well. So I do think that we will have a very successful franchise on our hands and of course UCB will be commercializing with some help from us across Europe, thanks to the approval with the EMA there.

So overall, whether -- will it be as big as a Forteo, that remains to be seen. We are, I will remind you, slightly less expensive 30% on the low-end as much as 70% on the high end than our competitors in the category, it's a 12-month duration so it's not a product that you take for multiple years, it's a 12-month duration, but the new patient acquisition is clearly exciting.

## Operator

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

## Q - Alethia Young {BIO 17451976 <GO>}

Hey guys. Thanks for taking my question. I guess Parsabiv is another drug that's been doing quite well in spite of Sensipar, so maybe can you talk about -- should we expect continued kind of unit demand growth. I know you probably had some contracting obviously over the prior 12 months. But just maybe help us frame how to think about the next 12 months for Parsabiv? Thanks.

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

Yeah. Thanks, Alethia. The Parsabiv performance last year was fantastic. There are a number of patients who are benefiting from it. There is a change in reimbursement for Parsabiv going into -- coming into 2020 that may slow the rate of growth a little, but the range of possible outcomes is broad and it's really too early to call.

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

Okay. Ian, I think we've got two more calls, why don't we try to get them and then we'll wrap up.

## Operator

Very well. Our next question is from line of Salim Syed from Mizuho Securities. Selim Salim.

## Q - Salim Syed {BIO 16887281 <GO>}

Yes. Hi. Thanks guys for taking the question. Just one from me on omecamtiv, David, you mentioned that the landscape will be changing, you believe based on some of the recent data and I guess what I was looking for some clarity on when I presume you're talking about the SGLT2 space specifically that flows in and then from the commentary you provide, are you envisioning this to be -- the omecamtiv to be on top of SGLT2 or competing at the head and if there are any actually -- patients actually getting enrolled in the trial? Thank you.

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

Yeah. Thanks Salim. Yeah. So I was making reference to the SGL2 -- SGLT2 in particular, our sense is that the patients treated in those studies were probably a somewhat less sick population. So that may be a point of differentiation and then as we have intended all

along with our omecamtiv, given the lack of drug-drug interactions that we've seen now in the mechanism of action, it is intended to be an add-on to other therapies. Of course, in the Phase 3 trial, we will look at the number of patients who are receiving things such as SGL2, SGLT2 in the study.

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

Okay. Let's get the last question.

### Operator

And our final question is from line of Cory Kasimov from JP Morgan. Cory.

### Q - Cory Kasimov {BIO 3009346 <GO>}

Hi. This is Gavin on for Corey. Thanks for fitting us in. And I apologize if you answered this, but we are wondering what your assumptions are going into the double-digit growth for Otezla. Does this imply label expansion or is this just with the existing label and/or any comment on competitive concerns.

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

I think we've addressed that, but we will just reiterate for you Gavin, what we think.

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

Yeah. So we are assuming that we would secure additional indications in our assumption for double-digit going forward. We're also using historical growth rate and where we're sourcing a new patients right now. So I think that's pretty clear.

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

Okay, everyone. Thanks for your patience. Sorry, we went a little bit past the allotted hour, but let me just conclude by saying that we feel good about where we ended in 2019, managing through what was always going to be a transition year for us and we think we're on the cusp now of a period of new product revenue growth. So we look forward to that. And we look forward as well to important clinical data that is expected, particularly towards the second half of this year.

So I'd be remissive if I didn't just take a moment to thank as well the Amgen staff around the world, who continue to work so hard every day to deliver on our mission to serve patients. So thank you to them and we look forward to having chance to talk to all of you in April, after the first quarter. Thanks.

### A - Arvind Sood {BIO 4246286 <GO>}

Thanks, Bob. Thanks everybody for your participation. If you have any other questions you would like to cover, of course myself and the rest of the IR team will be around for several hours. Have a good day.

## Operator

Ladies and gentlemen, this does conclude Amgen's fourth Quarter 2019 Financial Results Conference Call. We thank you for joining us. You may now disconnect.