

## Q3 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

- Christopher Raymond, Analyst
- Cory Kasimov, Analyst
- Do Kim, Analyst
- Evan Seigerman, Analyst
- Geoff Meacham, Analyst
- Geoffrey Porges, Analyst
- Jay Olson, Analyst
- Kennen MacKay, Analyst
- Matthew Harrison, Analyst
- Michael Yee, Analyst
- Mohit Bansal, Analyst
- Ronny Gal, Analyst
- Salim Syed, Analyst
- Terence Flynn, Analyst
- Umer Raffat, Analyst
- Yaron Werber, Analyst

### Presentation

#### Operator

My name is Ian, and I'll be your conference facilitator today for Amgen's Third 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 speaker's prepared remarks. In order to ensure that everyone has 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. Thank you, Ian. Good afternoon, everybody. Thanks for joining us today. So we have a lot of ground to cover, so I'll keep my comments very brief. I'd like to begin by acknowledging those who are new in their coverage of our company, with the most recent being Geoff Meacham, who is now at Bank of America Merrill Lynch. Also we want to correct an oversight on my part from our Q2 call as I inadvertently forgot to acknowledge Evan Seigerman of Credit Suisse who initiated back in the second quarter. A warm welcome to both Evan and Geoff.

Okay, so onto our Q3 results. Continued execution on our strategy, launch progress, and pipeline advancement are some key themes that come to mind as I think about our third quarter results. To discuss these in some detail, I'm joined today by Bob Bradway, our Chairman and CEO. After Bob's comments, our CFO, David Meline, will review our financial results for the third quarter and provide updated guidance for 2019. Our Head of Commercial Operations, Murdo Gordon, will then review our product performance; followed by Dave Reese, our Head of R&D, who will provide a pipeline update. We will use slides to guide our discussion today and a link to those slides was sent separately.

Just a reminder that we'll use non-GAAP financial measures in today's presentation and some of the statements will be forward-looking statements. Our 10-K and the subsequent SEC 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. Bob?

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

Okay. Thank you, Arvind, and good afternoon, everyone. I'll begin the call today with some comments about our third quarter performance while also touching on the industry environment and how we're responding to it strategically. Several years ago we realized the need to transform certain aspects of our business to stay ahead of the curve and position ourselves for a sustained long-term growth. Anticipating pressure on drug pricing, for example, we emphasized the importance of innovative medicines that can grow over time through volume and access increases and that's what we're seeing again in the third quarter from brands like Prolia, Repatha, and Aimovig generating double-digit volume increases.

It's not just these brands that are exhibiting volume growth, a number of our specialty products, including Parsabiv, KYPROLIS, and BLINCYTO also registered double-digit volume increases. And in aggregate for our portfolio this is the seventh quarter in a row that we've reported volume growth globally. We think that bodes well for our long-term outlook.

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As you're aware, drug prices have indeed come under pressure in the U.S. for the first time in more than 40 years as the Council of Economic Advisers recently reported CPI Prescription Drug Index actually declined over the previous 12 months by 0.7%. This broad price decrease in 2019 is consistent with our own experience. Against this backdrop, a flow of innovative medicines that address major unmet medical needs will be more important than ever. As Dave Reese will discuss in a moment, we're excited about our pipeline and we're investing to rapidly advance it. Thanks to a set of productivity capabilities embedded throughout our organization, we've been able to increase our R&D spending this year, up 8% in the third quarter while keeping overall expenses flat.

We've been especially focused on building differentiated capabilities in discovery research. For example, we think recent collaborations with the UK Biobank and Intermountain Healthcare will enable us to extend our industry-leading human genetics capabilities. Over time, we expect a better understanding of human genetics will enable us to dramatically improve both R&D cycle times and success rates. And with our Nuevolution deal completed earlier this year, we're positioning Amgen for what we anticipate will be a new era of multi-specific drug development, focusing initially on targeted protein degradation.

We made a strategic decision several years ago to build a branded biosimilars business, leveraging our world-class biologics development and manufacturing capabilities. Our first three biosimilars, AMGEVITA, KANJINTI, and MVASI generated about \$173 million in the third quarter and are annualizing at approximately \$700 million. We expect our growing portfolio of reliable, high-quality biosimilars to be an important growth opportunity for us in the years ahead. The demand for quality health care is growing globally, and this has led us to steadily expand our geographic presence. In the third quarter, our product sales outside of the U.S. grew by 15%, with volume growth of 23%. We expect sales outside the U.S. to account for an increasing percentage of our total product revenues over time.

We're excited, for example, to have recently launched Repatha in China, our first product entry into the world's second-largest pharmaceutical market. We expect this to become an important market for us through time, just as we can now see Japan emerging as an important new opportunity for us. In 2020, we look forward to assuming full ownership of our very successful collaboration with Astellas in Japan, the world's third-largest pharma market. We think our portfolio of products is well suited to the needs of an aging population in China and Japan, in particular.

And finally, let me reiterate that we're excited about our planned acquisition of Otezla as announced in August. Amgen has been a leader in the treatment of inflammatory diseases for decades. With Enbrel, our recent launch of AMGEVITA in Europe, and pipeline opportunities like tezepelumab, Otezla will significantly strengthen our inflammation portfolio. It will also enhance our geographic segments as we are acquiring global rights to the product, which is approved in more than 50 markets worldwide. We expect the Otezla acquisition to close before the end of the fourth quarter, giving us an asset that will add to our long-term growth. Of course, we look forward to welcoming the Otezla team to Amgen. Our capital allocation priorities remain intact. We will continue to invest in the growth of our business internally and through business development aligned

with our stated strategy while also providing attractive returns to our shareholders through a growing dividend and continued share repurchases.

Before I turn the call over to David, let me just note that I'll say a few words about him and his planned retirement at the end of our call. David, over to you.

## **David W. Meline** {BIO 6397419 <GO>}

Okay. Thanks, Bob. Overall, we're pleased with the strong performance in the third quarter as investments in support of our newer products continue to deliver volume driven growth, including over 20% in our ex-U.S. markets, enabling stable performance again this quarter.

Turning to the financial results on Page 6 of the slide deck. Worldwide revenues at \$5.7 billion declined 3% year-over-year. Worldwide product sales at \$5.5 billion declined 1% year-over-year as growth for our newer products was slightly outpaced by declines in our mature brands impacted by increasing competition due to patent expirations. Other revenues declined \$120 million year-over-year due to a prior year milestone payment. We expect full-year other revenues of between \$1.1 billion and \$1.2 billion.

Non-GAAP operating income of \$2.8 billion declined 6% from prior year. Non-GAAP operating margin was 51% for the third quarter as we continued to make incremental investments in our products and pipeline to drive growth and maximize shareholder value. Consistent with prior guidance, third quarter non-GAAP operating expenses were flat year-over-year. We expect full-year 2019 operating expenses on an absolute basis to be up slightly versus 2018. As a reminder, we expect to see a 15% increase in non-GAAP operating expenses in Q4 versus Q3 reflecting the typical pattern for the business.

On a non-GAAP basis, cost of sales as a percent of product sales was flat year-over-year at 13.9%. We continue to anticipate 2019 full-year cost of sales on an absolute basis to be slightly up based on volume growth reflecting our industry-leading manufacturing capability. As you begin to model 2020 financials, note that we expect cost of sales as a percent of product sales to be generally consistent with 2019.

Third quarter research and development expenses of \$977 million were 8% higher year-over-year due to increased investments in support of our early and late-stage oncology programs. Research and development expenses as a percent of product sales was 17.9%. For the full-year 2019, we continue to expect the R&D spend trajectory on an absolute basis to increase by a high single-digit percentage as our pipeline advances. As communicated in our August call, we highlighted that we expect 2020 R&D investment to increase by about \$500 million as we invest in our innovative pipeline programs and new Otezla indications.

SG&A expenses decreased 5% on a year-over-year basis in Q3, driven primarily by reduced general and administrative expenses and productivity efforts. We expect that for the full year, SG&A expense on an absolute basis will decline year-over-year. With regard to 2020, in addition to the \$600 million to \$700 million increase related to the Otezla

acquisition, we also expect SG&A expense for the base business to increase modestly year-over-year as we continue to expand our international business, including China and Japan, grow our biosimilar business, and begin product launch preparation for our advancing innovative oncology and non-oncology pipelines. These investments will exceed the benefits of our 2020 productivity initiatives.

Other income and expenses were a net \$199 million expense in Q3. This is favorable by \$23 million on a year-over-year basis. We expect full-year 2019 expense of about \$675 million. Looking ahead to 2020, we expect OI&E net expense to increase, reflecting a cash drawdown for the Otezla acquisition. The non-GAAP tax rate was 15.2% for the quarter, a 2.2 point increase versus the third quarter of 2018, primarily due to a prior year tax benefit associated with intercompany sales under U.S. corporate tax reform. Non-GAAP net income decreased 8% and non-GAAP earnings per share decreased 1% year-over-year for the third quarter to \$3.66 per share.

Turning next to cash flow and the balance sheet on Page 7. Free cash flow for the third quarter of 2019 was \$3.2 billion. This was in line with the results from the third quarter last year of \$3.1 billion. Consistent with our principles, we continue to provide significant cash returns to shareholders. In Q3, we deployed \$1.2 billion to repurchase 6.2 million shares at an average price of \$188 per share. We plan to repurchase an incremental \$1 billion to \$1.5 billion of our shares in Q4. Additionally, our third quarter dividend was a \$1.45 per share, an increase of 10% over last year.

Cash and investments totaled \$20.9 billion, a decrease of approximately \$9 billion from the third quarter of last year, primarily due to share repurchases and debt repayments. Our debt balance stands at \$29.8 billion as of September 30, a reduction of \$4.6 billion from a year ago as we paid down maturing debt.

Turning to the outlook for the business for 2019 on Page 8. We remain on track with our plans to deliver solid results while investing for the future. With regard to our updated outlook for 2019 revenue, we are increasing our revenue guidance to \$22.8 billion to \$23 billion from our prior range of \$22.4 billion to \$22.9 billion. This reflects solid revenue performance as well as ongoing competitive dynamics associated with Neulasta and other legacy products. We're also increasing our 2019 non-GAAP earnings per share guidance to \$14.20 to \$14.45 per share from the previous \$13.75 to \$14.30. In terms of the non-GAAP tax rate, our 2019 guidance range of 14% to 15% is unchanged. We expect capital expenditures of approximately \$650 million this year. Note that our guidance excludes the impact of the Otezla acquisition, which we expect to close by year end. As we approach the end of 2019, we are pleased with our progress, again, this year. As is customary, we will provide full 2020 guidance on our January call.

This concludes the financial update. I now turn the call over to Murdo.

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

Thanks, David, and good afternoon, everyone. You will find product sales information starting on Slide 10. In the third quarter, volumes grew by 3% year-over-year, which

represents, as Bob mentioned, the seventh consecutive quarter of volume growth. Net selling prices declined 4% year-over-year resulting in reported net sales declining by 1%. We have a stable outlook for our base business in 2020, and with the anticipated addition of Otezla, we expect revenue growth next year.

Now let me share some product detail, starting with Prolia on Slide 12. Prolia delivered another strong quarter with 18% growth year-over-year driven by volume coming from increasing rates of new patient growth as well as strong repeat rates. Recall that Prolia experiences consistent seasonal trends. The launch of the EVENITY, which has been recognized by the osteoporosis community as a highly innovative therapy, is off to a solid start as sales more than doubled sequentially. Worldwide, 8.9 million fractures due to osteoporosis occur each year, that's a fracture every three seconds. In the U.S., there are approximately 2 million patients who have had an osteoporosis-related fracture and are at greatest risk of having another fracture within the next one to two years. We believe EVENITY is an important option to offer these patients. Within the U.S., we've received a permanent reimbursement J-code, which should facilitate uptake. In Japan, which currently represents the majority of EVENITY sales, uptake has been very encouraging. EVENITY creates a solid foundation in Japan upon which we anticipate adding Otezla and that will keep us in the ability to deliver on our international expansion strategy.

Next on to Repatha on Slide 14. Q3 sales grew by 40% year-over-year as we continue to be the market leader in the PCSK9 class. Worldwide unit growth was 87% year-over-year driven by the U.S. New to brand U.S. prescriptions are steadily improving growing at 58% year-over-year. Although we're pleased with the growing use of Repatha in helping to lower LDL cholesterol, the fact still remains that cardiovascular disease is much too common in our society today. Every year 30 million people globally will suffer a heart attack or a stroke. Approximately 7 out of 10 adults in the U.S. with cardiovascular disease have elevated LDL-C despite optimal lipid-lowering treatment.

The importance of lowering LDL-C levels as a means to lower the risk of cardiovascular event in high-risk adults is increasingly recognized by professional cardiology societies, including the American Heart Association, the American College of Cardiology, and most recently the European Society of Cardiology, which now recommends LDL-C levels of less than 55 milligrams per deciliter in high-risk patients and less than 40 milligrams per deciliter in patients with two prior cardiovascular events. PCSK9 inhibitor is like Repatha can play a critical role in helping patients achieve their cholesterol-lowering objectives. Removing barriers for PCSK9 use is an important factor in ensuring this health crisis is effectively addressed. In the U.S., we're pleased that access is improving, as 72% of commercial plans now require physician attestation only and that's up from just 23% last year.

Additionally, more plans are removing specialty pharmacy mandates moving Repatha to more accessible retail pharmacies, which now fill a majority of Repatha prescriptions. Overall in the U.S., commercial approval rates increased from 39% to 59% and the abandonment rate for Medicare patients has improved meaningfully. Affordability is a concern for Medicare patients, and in 2020 approximately half of all Medicare patients who are prescribed Repatha will have an affordable copay of less than \$50. Although the blended net price of Repatha in the U.S. declined in Q3 2019 versus the previous year,

partly due to contracting for better access and partly with the advent of the lower list price Repatha, net selling price was relatively stable sequentially. With lower list price Repatha now representing over 50% of total prescriptions, the original list price SKU will no longer be available for sale effective December 31 of 2019.

Now on to Aimovig on Slide 15. On a quarter-over-quarter basis, unit volume grew 12%, although reported net sales declined by 20%, primarily due to \$19 million of unfavorable changes in accounting estimates for sales discounts in prior periods. These adjustments result from a higher proportion of our paid business coming from the lower-priced Medicaid population than initially anticipated. As a reminder, we reported \$20 million of favorable changes in accounting estimates in Q4 of 2018, demonstrating the impact on net price of early variability and source of business.

Considering 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. Each week approximately 7,000 patients start a CGRP therapy and to date more than 260,000 patients have been prescribed Aimovig. Additionally, the number of prescribers is consistently increasing as more than 30,000 physicians have now prescribed Aimovig since launch, including 10,000 primary care prescribers. Aimovig is the market leader with 50% of total prescriptions exiting Q3. Regarding pricing, we're pleased to see the transition of patients from our free drug program to paid demand is progressing nicely, increasing from 74% in Q2 to 81% at the end of Q3. Additionally, our recent agreement with CVS Caremark rounds out our strong access position going into 2020.

Moving to our hematology and oncology business. The portfolio of six brands collectively totaled \$1.2 billion in the quarter, growing again by double-digits at 12% on a year-over-year basis. As for some of the larger brands within this portfolio, XGEVA grew 10% in Q3 year-over-year driven by volume. As a reminder, the NCCN guidelines recognize XGEVA with preferred status over zoledronic acid in castration-resistant prostate cancer, reinforcing XGEVA's superiority in this indication.

KYPROLIS grew 15% year-on-year, driven primarily by 12% volume growth, with the breadth of prescribers continuing to increase. We continue to invest behind KYPROLIS and add to the growing body of clinical evidence demonstrating KYPROLIS's important role in the treatment of multiple myeloma as a recent results of the CANDOR study indicate, and you'll hear more on this from Dave Reese.

Moving on to Enbrel. Sales increased 6% year-over-year driven by increases in net selling price and changes in accounting estimates offset by unit volume declines of 2% due to continued competition. Q3 results included a benefit of approximately \$60 million in changes in accounting estimates related to sales discounts. We're making investments in Enbrel, including the ENBREL Mini with AutoTouch device, a multi-use product, which continues to receive positive feedback from rheumatoid arthritis patients. Overall, we expect volume trends to continue while we anticipate a modest benefit from net selling price on a full-year basis in 2019.

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We're investing substantially behind our Inflammation portfolio, which has been strengthened by the reaffirmation of Enbrel's intellectual property, our pending addition of Otezla, our biosimilars of AMGEVITA and ABP 710, which is our biosimilar to REMICADE, the potential of tezepelumab for asthma, as well as a number of other assets that are earlier in the R&D pipeline.

Now onto some of our more mature brands on Slide 20. In Q3, Neulasta sales declined 32% year-over-year with a 31% decline in the U.S. Exit share of Neulasta in the U.S. was comparable to Q2 just under 80% in the long-acting segment with Onpro unit volume declining slightly on a sequential basis. We're encouraged by how well Onpro has performed so far, demonstrating the confidence that our customers have in the reliability and quality of our supply, along with our broader commercial services. We anticipate that additional competitors could launch in the U.S. sometime in the future, but the timing is uncertain, reflecting the complexity of developing and manufacturing molecules in this space. Looking forward, recall that Q4 of 2018 benefited from a \$55 million BARDA order that we do not anticipate repeating this quarter. Finally, outside of the U.S., Neulasta declined 40% due to increasing competition.

Switching to nephrology starting on Slide 21. Q3 EPOGEN sales declined 15% due to lower net selling price, which is a function of our contractual pricing commitments with DaVita. Meanwhile Aranesp declined 5% year-over-year in Q3 driven by lower volume due to increased competition. We expect Aranesp's sales to continue to decline at a faster rate with both long-acting and short-acting competition in the U.S.

Turning to Sensipar on Slide 23. As a result of some at-risk generic launches, year-over-year sales declined 73% to \$109 million for the quarter. Given the ongoing legal proceedings, there remains uncertainty about the magnitude of future U.S. Sensipar sales. Parsabiv grew by 54% in the third quarter. As a reminder, independent and mid-sized dialysis providers already utilize Parsabiv for a majority of their calcimimetic patients, while FMC and DaVita are slowly increasing adoption. On a quarter-over-quarter basis, trends were impacted by purchasing patterns, which included a larger purchase in Q2.

Our biosimilars recorded sales of \$173 million in Q3 and are noted on slide 25. Our biosimilar strategy continues to come to fruition with two successful launches in Europe and two recent launches in the U.S. Our global sales are already annualizing at approximately \$700 million with the adoption of KANJINTI and MVASI in the U.S. and continued growth of KANJINTI and AMGEVITA outside the U.S. The uptake is a result of customers recognizing the quality and importance of Amgen's supply chain as well as our commercial capabilities and services. Our experience in commercializing innovative products along with our established presence in existing commercial resources in these therapeutic areas provides us with a productive operating model. These factors helped to reduce costs to the health care system, while also generating a return for shareholders. When looking at factors for success in the U.S. in terms of access, we have attained coverage in the majority of national commercial accounts and are making good progress in Medicare accounts.

As of Q4, we've received reimbursement codes for both KANJINTI and MVASI and believe this will be a catalyst for further uptake. When looking at prescribers, we've seen



very encouraging adoption rates in the clinic segment while non-340B hospital adoption is showing signs of acceleration. Outside the U.S., we continue to see important differences between products and markets in terms of uptake and price erosion. Some markets are 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 will benefit from and synergize nicely with the addition of Otezla.

In summary, we plan to continue to drive volume uptake of our more recently launched products while defending our mature brands to deliver better outcomes for patients and the healthcare system.

Now let me turn over to Dave Reese.

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

Thanks, Murdo, and good afternoon, everyone. As we've previously discussed, our key strategic priorities in R&D include increasing our success rates, improving our speed to market, and ensuring access and use for our innovative products. A core component of this strategy is the use of human genetics and allied genomic and proteomic technologies.

Following on our collaboration with Intermountain Health disclosed last quarter, we were pleased to announce that we joined a public-private consortium to complete the whole-genome sequencing of nearly 0.5 million individuals in the UK Biobank. deCODE with the Wellcome Sanger Institute will perform sequencing to rapidly generate data in this most ambitious whole genome project to date. We believe in the power of human genetics to transform medicine, have built an industry-leading platform, and anticipate well over 2 million participants in our databases at the conclusion of these products -- projects.

In inflammation, our collaboration with AstraZeneca on tezepelumab continues to advance. Enrollment in our Phase 3 study in adults and adolescents with severe uncontrolled asthma has completed, and we expect the primary analysis in late 2020. We also recently began enrolling patients in the Phase 2 study of tezepelumab for the treatment of COPD, and we continue to recruit patients in our Phase 2 atopic dermatitis study. Also in inflammation, we are enrolling patients in a Phase 2 study of AMG 570 for the treatment of systemic lupus erythematosus or SLE. AMG 570 is a first-in-class bispecific antibody peptide conjugate that targets ICOS ligand which modulates T cell function and B cell-activating factor or BAFF. These two inflammatory mediators are elevated in SLE, and we believe AMG 570 has the potential to provide clinical benefit for patients suffering from this disease.

Finally, we continue to enroll proof-of-concept studies with AMG 592, our IL-2 mutein designed to enhance regulatory T cell function in autoimmune diseases, and we expect data from these trials beginning in 2020. In bone health, we were pleased that the CHMP issued a positive opinion for EVENITY in the treatment of severe osteoporosis in postmenopausal women at high risk of fracture and with no history of myocardial

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infarction or stroke. This is an important step and along with our partner UCB, we look forward to the European Commission's final decision later this year. Working closely with the Ministry of Health, Labor, and Welfare and the Pharmaceuticals and Medical Devices Agency in Japan, EVENITY's prescribing information was updated by making the potential cardiovascular risk more prominent and adding information to help ensure its proper use.

Turning to oncology. I'll begin with AMG 510, our first-in-class KRAS G12C inhibitor. We have the opportunity to present data from 76 patients in our first-in-human monotherapy study at the World Lung and ESMO conferences where we reported responses in multiple tumor types with no dose-limiting toxicity. In our monotherapy program, our Phase 2 study in non-small cell lung cancer continues to enroll briskly since initiation in August. We have also rapidly enrolled an initial Phase 2 cohort of colorectal cancer patients at the target dose, and as the data mature, we will determine the development path in colorectal cancer.

We are also moving forward with a suite of Phase 1b combination studies, including PD-1, MEK, and other targeted therapies. Our next clinical update will be in 2020 when we have accumulated a meaningful amount of data from these Phase 2 and combination studies.

In our BiTE development programs, two BLINCYTO Phase 3 studies in pediatric patients with acute lymphoblastic leukemia at first relapse were stopped early due to the treatment benefit of BLINCYTO when substituted for a portion of the standard chemotherapy blocks. These results have the potential to be practice changing since patients with high risk relapsed ALL have a poor prognosis with standard therapeutic approaches. Later this year we will be presenting data on AMG 673, a half-life extended BiTE molecule targeting CD33 and AML; AMG 596 directed against EGFRviii and glioblastoma; and we anticipate data for AMG 701, our half-life extended BCMA BiTE molecule next year.

In the KYPROLIS program, as Murdo mentioned, the Phase 3 CANDOR study investigated KYPROLIS, dexamethasone, and DARZALEX KdD versus the KYPROLIS-dexamethasone doublet in relapsed or refractory multiple myeloma. The study met its primary progression-free survival or PFS endpoint with KdD reducing the risk of progression or death by 37% compared to KYPROLIS plus dexamethasone alone. The median PFS for KYPROLIS plus dexamethasone was 15.8 months, although median PFS for KdD was not yet reached. These data demonstrate that these two potent therapies can be effectively combined and may provide a potential treatment option for patients who have relapsed but need a REVLIMID sparing regimen. We look forward to discussing these results with the regulators.

In hematology, FDA approved an updated indication for Nplate that expands treatment to newly diagnosed and persistent adult patients with ITP who've had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. We have also begun enrolling a Phase 3 Nplate study for the treatment of chemotherapy-induced thrombocytopenia.

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Before leaving our therapeutic areas, I'd like to say a few words about a decision we've made to reshape our neuroscience research efforts. We believe that in order to compete effectively, we need to make investments in the areas and platforms that will position us for long-term success. In careful evaluation of our pipeline and the challenges inherent in developing drugs for major neurologic diseases, we have made the decision to end our neuroscience research and early development programs with the exception of programs centered on neuro inflammation that will be pursued by our inflammation TA. This was a very difficult decision, and we know it will be a disappointment for our staff and the scientific community. Over the years many people at Amgen have devoted time and energy toward developing medicines for patients with neurologic conditions, and I'd like to thank and acknowledge them for their efforts.

In particular, bringing Aimovig to migraine patients as the first and innovative new class of medicines was a tremendous achievement. Aimovig is making a meaningful impact on the lives of migraine patients around the world, and we will continue to actively support the program, including ongoing clinical development. At the same time, we are exploring other models to capitalize on our genetics capability and advance our broader efforts in neuroscience and we'll provide guidance on those activities in the future.

Let me conclude with a quick update on biosimilars. Our Phase 3 non-Hodgkin's lymphoma study of ABP 798, our biosimilar Rituxan, has successfully completed and we expect to submit a BLA in the U.S. in Q1 2020. And finally, the FDA review of ABP 710, our biosimilar REMICADE, continues to progress towards the BsUFA target action date in December. Bob?

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

Okay. Thank you, David. Let's turn over now, Ian, to you and perhaps you can open up the lines for questions and remind our callers of the procedure that will follow. Thanks.

## Questions And Answers

### Operator

(Operator Instructions) Our first question is from the line of Ronny Gal from Bernstein. Ronny.

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

Good afternoon and thank you for taking my question. I'd like to start actually with the last comment you made about ending neuroscience. I'm sure it was a difficult decision and a lot of us are following you through other companies, and we've seen some really interesting breakthroughs, especially when it comes to nucleic acid-based medicine. Can you talk a little bit about that decision -- your decision? The other option obviously was to double down and go even more innovative. What drove that decision in terms of your thinking? And if you can kind of like coach it in terms of how you feel about the neurology market and what it takes to succeed in it will be great?

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

Dave, why don't you take a shot at that, and I'll offer any thoughts at the back-end?

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

Yeah, Ronny, so this was a very difficult decision. And as you pointed out, there are new therapies becoming available, some of them nucleic acid based. Many of those I think are targeted at orphan or niche diseases and consistent with our desire to generally target diseases with a large public health impact, based on what we felt was the state-of-the-art in terms of understanding the pathogenesis of major diseases, especially neurodegenerative diseases and our overall portfolio, we made that decision to end our early neuroscience research efforts. As I mentioned, we are looking at ways to maintain a hand in neuroscience through alternative models and we'll discuss some of that in the future. We believe the genetics will ultimately drive progress in this area, and we'll continue to work with deCODE to generate insights. Bob?

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

I would just add, Ronny, just on the last point. Half the genes in the body are expressed in the brain and only the brain, and we think we have some unique resources to try to capitalize on insights around that. And as Dave suggested, we'll be exploring potentially different models for doing that with venture capital and perhaps academic institutions as well. And I think more broadly we're focusing our efforts on where we think we can be successful. So we're focused, as you know, in cardiovascular disease, inflammatory disease, and cardiovascular disease and oncology, of course. So those are the areas that we're focused on and expect to be successful advancing molecules in those areas over the coming years.

**Operator**

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

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

Hi. Thanks for taking my question. Just wanted to ask about Otezla. As you look past the closing of the Otezla acquisition, how do you think about the disruption -- potential disruption to the ongoing commercial operations of Otezla and how long it would take to fully onboard the drug and its components?

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

Yeah. Thanks, Do. It's Murdo here. We've met with our potential future colleagues several times now around the world at different forums. We met at a few all-staffs and town halls. We've extended conditional offers of employment, and we're really pleased by the uptake there. From Japan to the U.S. and the rest of the world, we see an eager, highly-engaged workforce that's very interested in joining Amgen. So I would say that we expect minimal disruption, if any, to ongoing operations. I mean we did set patient continuity as our North Star in this integration and everybody's been very focused on following that.

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

Great. Thank you.

**Operator**

And our next question is from the line of Chris Raymond from Piper Jaffray. Chris?

**Q - Christopher Raymond** {BIO 4690861 <GO>}

Yeah, thanks. Just on the Repatha pricing, I know you announced a while back that you're phasing out the higher priced SKU at beginning of next year. But it's been I think just over a year I guess since you announced this move to have the dual SKUs. And it looks like so far this transition has been a pretty decent success, I mean, look at numbers, they're relatively stable in the U.S. So I guess I'm just wondering if commercially if there have been some learnings from this conversion and actually in this move that can be applied maybe to other areas where perhaps there is like a healthy distributor margin where a high list price perhaps can impact Medicare patient access? Thanks.

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

Yeah, Chris, if I understand your question correctly, you're looking to see if there is any lessons learned to apply to other products.

**Q - Christopher Raymond** {BIO 4690861 <GO>}

Other therapeutic areas, yes.

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

Yeah, in the specialty category. I think -- look, I think lessons have already been learned from Repatha. I think we applied them to the launch of Aimovig and how we priced that product. I think that that's been a major reason for why patients have been able to access Aimovig at relatively affordable co-pay levels. I'm also pleased with the progress we've made on the commercial side with Repatha. I think, where it's less clear to us, and it's still an area of work-in-progress, is how we are advancing the evolution of access to Repatha at a fixed co-pay preferred tier benefit in Medicare Part D. We're happy that we're going to next year with roughly half of the lives in Medicare Part D being able to access Repatha at an affordable less than \$50 co-pay. But we think that number should be much higher. And we think that national plans and PBMs should be moving to add Repatha as a preferred benefit. So it's a very fragmented health care system with a lot of different actors in the supply chain. And I think that improvements can be made and we along with other companies in our industry and our partners on the insurance and PBM side will hopefully come up with better solutions going forward.

**Operator**

And our next question is from the line of Geoff Meacham from Bank of America. Geoff?

**Q - Geoff Meacham** {BIO 21252662 <GO>}

Afternoon, guys. Thanks for the question and glad to be back Arvind. Just had one for Murdo on Aimovig. It's probably the highest-profile launch I think at Amgen with a lot of prior discussion from you and others on the big unmet need in millions of eligible patients. But when I look at your Slide 15 and I understand the impact payors have on adoption, but why isn't there more of a tipping point more than a year into the launch? And you look at Lilly they've seen good growth as well but no real inflection point either. So the question is what do you think is holding back the class and how could you help accelerate the launch from here? Thanks.

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

Yeah. Thank you, Geoff. Look, it's still very early days and we're pleased with the uptake, over 260,000 patients treated so far with Aimovig since launch. We are really -- if you think about it, we are really only now reaching a point in the market where good access has been provided. We're now at 81% of our prescriptions being paid through some insurance benefit. We're also really only scratching the surface, as you mentioned, looking at roughly 4 million eligible patients in the U.S. alone. So there is a number of activities. We are investing heavily in direct-to-consumer promotion. We have a very extensive and sophisticated digital campaign along with, as we have done since the very early days of our work in migraine, been able to activate a lot of the different patient organizations in this area.

So I think given the benefit that patients are experiencing with Aimovig, given the way in which it's transforming the lives of migraine sufferers, and we see the letters coming in from patients. There is really -- we have a lot of confidence that this market will evolve. And I think throughout the course of 2020, we're looking for changes in the number of new patients that are coming into the CGRP category on a weekly basis. We're running at around a 7,000 patient per week clip, new patients to CGRP. We're hoping that that grows into double-digit throughout the course of next year.

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

And just add a clinical perspective. The drug works. We've got data out to four years now in some patients, and we think that that foundation will simply lead to increased uptake over time. So we remain very optimistic about the prospects for this what's really a transformative medicine.

**Operator**

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

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

Hi. Thanks for taking the question. Maybe just two for me. Murdo, just wanted to confirm that you said -- I think I heard this correctly that for 2020 you're expecting revenue growth for next year ex-Otezla. And then wondering what that assumes for overall price. And David, on margins, any reason why we would expect a step down versus this year? And then on the pipeline, obviously, there was some competitor KRAS data yesterday at a conference. Just wondering if you can offer your perspective. Thank you.

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

Terence, thanks for the opportunity to clarify. What I said was our base business will be stable going into 2020 and with the anticipated addition of Otezla we will grow.

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

David, I think you've been pretty comprehensive with margins. Do you want to add anything to Terence?

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

No. I've tried to give a preview in terms of the components of cost for next year. And so combination of what we're doing with revenue and those costs I think gives that answer. And I think importantly, we've said in the past and we continue to believe that the Company's overall capability in terms of delivering profitability is very good and will continue.

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

Dave, I think there was a third question in there about KRAS.

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

Yeah, mainly related to this molecule called KRAS. Of course, we're aware of the data. I'll let others comment on those data. As I mentioned, we are enrolling very briskly in our Phase 2 non-small cell lung cancer program. We've enrolled a cohort in colorectal cancer in Phase 2 that we believe will inform the development pathway there. And we've got a wide-ranging combination therapy program that's opening up. So I think 2020 will be a very data-rich year for the KRAS program and we'll understand where to go from there.

**Operator**

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

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

Hi, all. Thank you for taking the question. And I want to congratulate David on his retirement and wish him the best. And I have a question for the other David, following up on what Terence just asked. So we have seen a lot of KRAS data recently, much of it remains pretty early. But looking ahead, what is your view on the eventual role of 510 as monotherapy in lung cancer? Or do you ultimately believe that this is probably best served as in combination maybe with chemo or a checkpoint? Just to get your thoughts there on how we think about potentially moving that up line. Thank you.

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

Yeah, Evan. Thanks. And that's a great question. I think the ongoing clinical program is really designed to answer that question. In monotherapy key things that we will be looking at in the dataset over time in addition to the response rate will be, importantly, duration of response and then I think progression-free survival or median progression-

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free survival. Many of the patients that we've treated to-date are third, fourth, fifth line patients where response rates to single agent chemotherapy are quite low with progression -- median progression is often on the order of a few months. And so those are some of the benchmarks that we'll be looking at in terms of monotherapy.

In terms of combinations in different indications, tumor cells can have very different wiring. And I think over time as we generate these datasets, we will determine in individual settings whether monotherapy or combination therapy is most appropriate. And then finally, of course, we do have a keen interest in advancing the drug into earlier lines of therapy where we would hope that the magnitude of benefit will be greater, and we will be orienting the development program in that direction as well.

## Operator

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

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

Great. Thanks for taking my question. Maybe, David, I was going to maybe just ask you another follow-up KRAS question. Just piggybacking on what you said, assuming that monotherapy is where you're going to go into in terms of a potential filing path from the Phase 2 in lung cancer, what is your latest thinking? Is 50% response rate, a PR with a six-month durability, is that really where the latest bogey is for a TKI that's fairly directed or is there a chance to file if the data refers to 4.5, 5 months durability, if that's going to be what ends up. And then just a question on your formulation. Can you give us a sense, is that -- what's the size of the tablets in the current 960 mg dose? Thank you.

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

Yeah, sure. So in terms of the monotherapy, I don't know that I would want to put a stake in the ground there and it depends also on the patient population in prior lines of therapy. The patients that we have treated to-date have all 100% have received platinum-based combination chemotherapy and the very large majority, 90% or so, have received a prior checkpoint inhibitor. Beyond that, there are very few available therapies. And so I think it's against that backdrop that we will be looking at the efficacy and safety results. In terms of the dosing, the 960 milligrams is eight tablets. We have not had any reports of tolerability issues. And quite frankly, that part is a non-issue in the program right now.

## Operator

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

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

Thanks. Question for David Reese as well. On BCMA you've commented that you expect half-life extended data perhaps in early 2020. I wanted to ask your confidence on the ability for that program to move forward to a pivotal, what you're looking for, what's the hurdle, is there any chance that that doesn't move into a pivotal? Maybe just comment on that update and what you're looking for. Thanks so much.



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

Yeah. So I think, in addition to standard and efficacy and safety, we will be looking at how the molecule stacks up in what's a crowded treatment landscape. Based on what we've seen from the continuous infusion, BiTE molecule AMG 420, we remain quite enthusiastic about the platform. In general, our approach in the BiTEs after we've done dose finding and an expansion cohort, our intention will be generally to progress to a registration phase of the program and that would be our goal for AMG 701. All of this, of course, contingent on data that we generate.

**Operator**

And our next question is from the line of Matthew Harrison from Morgan Stanley. Matthew?

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

Hey, great. Good afternoon. Thanks for taking the question. I wanted to ask Murdo on biosimilars. You gave us a nice sort of round out of some of the market dynamics. I was hoping maybe you could just talk a little bit more detail about what you're seeing in the oncology launches versus the inflammation launches and maybe just give us some sense for what the breakdown of the revenue mix is right now?

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

Yeah. Thank you, Matthew. We're pleased with the U.S. oncology uptake. I think what's really important to note is Amgen's capabilities across our company are known for our strength in biologics manufacturing and providing a reliable quality supply to customers. So I think that first box that you would anticipate oncologists would be concerned about is well checked with the capabilities at Amgen and we've proven that on our innovative side, and now we're demonstrating that with being the innovator total portfolio and first to launch with our biosimilars. I think from a behavioral standpoint, providers in the oncology market are more than willing to try high-quality biosimilars, and we're seeing good adoption. We're able to open accounts relatively quickly.

So our breadth in the community oncology market is good. We've provided good coverage in terms of payor reimbursement. And now what we're working on is our non-340B and 340B hospital coverage and now that we've got permanent J-code -- or permanent coding in for reimbursement, we're in really good shape. So I think oncologists have behaved very consistent with what we had expected, given some of the uptake that we've seen on the supportive care side with the long-acting filgrastim franchise. And I think we're looking forward to continuing to supply those community oncologists providers and academic oncology cancer centers with good commercial services and good patient support as well as that quality and reliable supply that we're known for.

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

Different region, Murdo, but do you want to comment on the experience with inflam in Europe?

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

Yeah, we've seen very quick uptake and penetration of the biosimilar into the innovator compounds with AMGEVITA. We've been pleased to see that despite having multiple products early in the launch of that, all launching at the same time that we've been able to settle in on price points that are good for our profitability. And as I mentioned earlier, we're also excited now that we've got on the ground inflammation focused, customer-facing organization. The addition of Otezla to that is very efficient one as we go forward.

**Operator**

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

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

Thank you very much. And just sort of a couple of follow-ups for Dave, if I may. Dave, I'm sure in reviewing the competitor's data will not have been lost on you that your competitor has a half -- a longer half-life but a greater dosing frequency as well. So wondering in the context of that, will you be studying BID dosing with 510 in any of the studies. And then could you just talk a little bit about ongoing research? I mean, this field is obviously exploding. Does Amgen have a continuing research investment in KRAS, and do you have backup molecules that you believe could have some of the attributes that competitor's molecules that are emerging appear to have? Thanks.

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

Thanks, Geoff. Those are both good questions. I would -- to start, I would say that when we were developing AMG 510, we outlined a set of target parameters for the molecule that we wanted to achieve biochemically, in terms of pharmacokinetics, et cetera. Most importantly is the ability to inhibit the target over a dosing interval of 24 hours. We have we believe a wealth of data suggesting that with a covalent inhibitor, a couple hours of exposure above a threshold leads to complete inhibition of signaling over that dosing interval, and we're convinced that our 960 milligram dose achieves that and in fact is well above that target threshold.

Now that said, of course, it's very common in small molecule development programs early in the clinical development program to explore alternative doses and schedules, and we will do that as part of the clinical pharmacology program going forward, including split dosing such as BID. And then finally, as you noted, the field is exploding. That's a fact that is not lost on us. We have a variety of preclinical efforts ongoing there, which we'll be happy to talk about at the right moment in time. I think it's important, as you follow this field, to keep in mind that not all of those molecules are directly KRAS inhibitors but inhibit other signaling or co-signaling molecules in the pathway or have slightly different mechanisms of action. And as we've seen in oncology over the last several decades, we would expect sort of plethora of different approaches around these targets.

**Operator**

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

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

Hi, thanks so much for taking my question. David, back to you again on KRAS as a surprise, we've seen two very different AUC disclosures on AMG 510 at the 960 milligram. It was 140 at ASCO the AUC and then the AUC declined to 65 at World Lung. So my question to you is, what do we know about the median AUC among patients that ended up being responders versus the median AUC among patients that were not responders? Thank you very much.

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

Yeah, Umer, thanks for that. I think I would point out that it's not unusual when you initially report Phase 1 results are often on just a handful of patients and with small molecules it's very typical to have quite large error bars around the various pharmacokinetic estimates. So to see those move over time is not surprising. And as I mentioned, we're still at a target exposure, and in our view Cmax here is probably the most important parameter, and we believe we're well above our target threshold for quite a number of hours, in fact essentially through the entire dosing interval. We believe we only need to be above it for a couple hours to extinguish signaling. So that's really what drove us forward in terms of dose selection in the program. And as I just mentioned, we'll continue to explore other approaches as part of the standard clinical pharmacology program.

**Operator**

And our next question is from the line of Salim Syed from Mizuho. Salim?

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

Yeah. Thanks so much, guys. And my congrats to David on his retirement. Just one for me on Neulasta if I may. So when I look at the NEUPOGEN ASPs over the last five years when the biosimilars launched, it seems like you guys have held your ASPs more or less flat over the last five years. Meanwhile the biosimilar ASPs for NEUPOGEN have come down substantially. And I'm wondering how you're thinking about that given what we're seeing with the Neulasta numbers declining pretty quickly. Should we be expecting a similar strategy here to be price disciplined or what breaks, price discipline can Sandoz do it if you could just opine on that? Thanks so much.

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

Yeah. Thanks, Salim. The general rule in these types of markets is that the more competition you have, the more number of players, the more price competition, you usually see. So I think it's too early to tell in the U.S. in at least the two oncology categories we're in with both bevacizumab and trastuzumab, and I think overall, we're pretty pleased with how price is holding in the long-acting filgrastim arena. I think what we continue to do is make sure that people understand our ability to supply a high-quality product with reliability of that supply along with our patient programs, we're able to hold onto share quite well. And there is usually some ability for the innovator to hold onto share even at a price premium, and that's usually in the 10% to 20% range.

**Operator**

And our next question is from the line of Jay Olson from Oppenheimer. Jay?

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

Oh hi. Thanks for taking the question. I'm curious about tezepelumab. Congratulations on completing enrollment of the 1,000-patient NAVIGATOR study. Can you describe the plans for submitting your BLA? You have a number of other studies running, including a steroid-sparing study in adults. What do you -- what data do you need and what is the timeline to file? And then as you contemplate commercialization, who are the target prescribers and how will tezepelumab fit into your commercial infrastructure? Thank you.

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

Let's take it into parts. Dave why don't you --

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

Yeah, I'll start. Typically we don't comment on regulatory filing timelines. I would point out, as you mentioned, the core of any filing package will be the NAVIGATOR study and there are a number of other studies that will provide supportive data. We expect -- those studies are 52 weeks in duration and so given that we completed enrollment to that trial, you can expect roughly a little after a year from last patient enrolled that the primary analysis reads out following that within the filing. Let me turn it over to Murdo who can address some of our commercial thoughts on the opportunity for tezepelumab.

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

Yeah. Clearly, we're working very closely with our partners at AstraZeneca who are very experienced in this area across respiratory, pulmonology, and even allergists which are our target customers for the at least the asthma indications. So lot of work being done there and we're looking forward to hopefully successful data and approval.

**Operator**

And our next question is from the line of Cory Kasimov from JP Morgan. Cory?

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

Hey, good afternoon, guys. Thanks for taking the question. I guess I'll skip another KRAS one. Instead ask on the BD front. So given that you recently announced a meaningful transaction for Otezla and now you have a CFO transitions going to be taking place, would it be fair to assume that you'd hit the pause button on other deals in the near to intermediate term or is it basically business as usual during this transition?

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

I think it's very much business as usual, Cory. We're very clear that our capital allocation priorities remain intact. We're continuing to look for ways to invest internally and externally and while also growing the dividend and buying back shares. So we've got an

active BD effort in those areas of our stated strategic focus therapeutically and geographically and we'll maintain that.

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

Yeah, Ian, as it's past 6:00 PM on the East Coast, why don't we take two last questions, after which Bob will make a few concluding comments.

**Operator**

Very well. Our next question is from line of Mohit Bansal from Citigroup. Mohit?

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

Great. Thanks for taking my question. And I would like to start with thanking David for all the help over the years. Moving to KRAS, we have recently learned that patients with LKB1 mutations do not respond well to checkpoint inhibitors and they also represent about 30% of KRAS-mutated cancer. So just wanted to see if this is an area you have looked at and could this be your entry as a first-line agent for your AMG 510? Thank you.

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

Thanks, Mohit, and that's a great question. So we've got a very active biomarker program. We are sequencing as many of these tumors as we can, and as we accumulate a larger number of patients who are both responders and non-responders, we will look to see if there are signatures -- molecular signatures that predict response or lack of response. The particular mutation that you called out is one, of course, that we will be keenly focused on. And as you mentioned, it seems to associate with relative resistance to checkpoint inhibitors. So I think there is a lot to learn. It took 40 years to get into the clinic with an inhibitor. We've been there a year. We are very rapidly generating data. I would think that when we present our clinical data next year, we will also be able to have a first pass at a fair amount of biomarker data as well.

**Operator**

And our final question is from the line of Kennen MacKay from RBC Capital Markets. Kennen?

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

Hey, thanks for squeezing me in, Arvind. Let me offer my congrats on the quarter and guidance raise, as well as congrats on the decision to pull the high-priced Repatha from the market by New Year's Eve. And on that note, just a question for Murdo. Repatha share of the PCSK9 market has increasingly gained over probably 1.5 or over the last couple years. I was wondering if you could comment on what you see is the big driver for that, and also how you're thinking about the potential competitive impacts of the entry of bempedoic acid and inclisiran in high cholesterol? Thanks so much and congrats again.

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

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Thanks, Kennen. So why don't I start with the Repatha question and then perhaps turn it to Dave Reese to talk about the development of other competitors in the cholesterol-lowering category. First off, thank you for recognizing the price -- sorry, the decision to remove the OLP from the market. I think this was something we signaled, but it's something we feel is important to do to ensure that other actors in the supply chain make the right decision and provide the low list price Repatha on their formularies and within their benefits, so that patients can lower their out-of-pocket costs. So this is one where we've worked very closely with payors and we've made sure that both the prescribing community and patients understand what we're trying to do here and that's to provide a very effective medicine for serious cardiovascular patient -- disease patients who can benefit from it.

Overall, I think the execution on the ground has been very, very strong. The field teams, both on the medical side and on the commercial side, that are calling on cardiology have been very good at explaining who the ideal high-risk cardiovascular patient candidate is for Repatha. And so we're running at approximately 70% share right now. We don't see that declining. We see it holding or modestly increasing. We'll continue to invest in Repatha to ensure that prescribers and patients alike receive the option of using Repatha to lower cholesterol and to reduce cardiovascular risk going forward. So we're feeling confident and we're feeling like we're finally making some inroads here in addressing these -- the risk reduction for these patients.

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

Yeah. And in terms of other LDL targeting molecules, bempedoic acid is an oral. We think it really is going to occupy a different niche in the clinical landscape. This will be used either on top of statins or in patients who are close to goal or in those who are not tolerant to statins. We don't -- it's got a modest LDL lowering effect. We really don't see it as a direct competitor to Repatha. Inclisiran, I think what we will pay attention to in the long-term are long-term safety and then, of course, are cardiovascular outcomes data which are still we think some years out. That's what we'll be looking for in that space. And I think now I'll turn it back over to Bob.

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

Okay, thank you. Let's wrap up. Let me just note that we're pleased with our performance through the first nine months of the year. We hope you share our enthusiasm for the long-term outlook at Amgen driven by our recently launched innovative products as well as our biosimilar medicines and our rapidly advancing pipeline opportunities.

We think we're in a strong position to deliver long-term performance for our shareholders and the patients who needs, we're seeking to address. And as previously announced, David Meline will be retiring next year, and though this is not his last call with investors, I wanted to take a moment, fresh from his announcement, to thank him publicly for his contributions. He's been an extraordinary leader for us as our CFO, and he will leave Amgen a strengthened enterprise.

At the same time, I'm delighted to welcome Peter Griffith to Amgen as David's successor, and Peter's extensive financial and operational experience will benefit Amgen as we

continue our efforts globally to serve more patients and drive long-term growth. I know the whole team joins me in welcoming Peter aboard, and we'll look forward to introducing him to all of you. Finally, I'd be remiss if I didn't also thank the Amgen staff around the world who continue to deliver on our mission to serve patients and to drive value for our shareholders.

Thanks for your interest in the Company, and we look forward to talking to you on the next call.

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

Great. Thanks to all of you for your participation. If you'd like to continue the dialog, feel free to call me and the IR team will be standing by for several hours. Thanks again.

**Operator**

Ladies and gentlemen, this does conclude today's conference. We thank you greatly for joining us for Amgen's third quarter 2019 financial results conference call. You may now disconnect.

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