Q4 2020 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
- Andrew Galer, Analyst
- Carter Gould, Analyst
- Colin Bristow, Analyst
- Dane Leone, Analyst
- Evan Seigerman, Analyst
- Geoff Meacham, Analyst
- Geoffrey Porges, Analyst
- Jay Olson, Analyst
- Kennen MacKay, Analyst
- Matthew Harrison, Analyst
- Michael Schmidt, 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 Erica, and I will be your conference facilitator today for Amgen's Fourth Quarter 2020 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, Erica. Good afternoon, everybody. Welcome to our call to review our Q4 and full-year financial results for 2020.

I would say the strong execution despite the pandemic and pipeline advancement are two themes that are pervasive so let's get after it. We will stick to an efficient format of limited prepared comments or one question rule as Erica pointed out and the overall duration of the call to one-hour. Slides have been posted. Just a quick reminder that we will use non-GAAP financial measures in our presentation and some of the statements will be forward-looking. Our 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 our Chairman and CEO, Bob Bradway. Bob?

Robert A. Bradway {BIO 1850760 <GO>}

Great. Thank you, Arvind, and thank all of you for joining our call. I'll start today by discussing Amgen's performance in 2020 and then provide some perspective on our priorities for 2021. By any measure, 2020 was a very successful year for us. Despite the disruption of COVID-19, we delivered strong sales and earnings driven by volume growth of 15% in our products. We advanced our innovative pipeline, most notably sotorasib and tezepelumab, both of which have received Breakthrough Therapy Designation from the FDA.

We successfully integrated Otezla, strengthening our decades-long leadership and inflammation with a $2 billion-plus product that we believe has a runway for further global growth. We grew our sales outside the US to more than $6 billion, delivering on long-term goals by expanding our presence in China and Japan with successful transactions in both markets. And we did all this while staying focused on the health and safety of our 24,000 employees around the world, and to all of them, I want to say thank you for a job well done.

As we look to 2021, we're embracing three realities. First, COVID-19 is leading to some lasting changes in how we do business, for example, we expect to continue leveraging digital capabilities to call on customers and run clinical trials around the world with improved speed, efficiency and effectiveness. Second, we expect ongoing pressure on drug prices across the industry. We are fortunate to have products like Repatha, Prolia and

Aimovig, that meet the needs of millions of patients and then grow through increased penetration of the appropriate patient populations. Our industry-leading portfolio of biosimilars is also well-positioned for the future.

Third is capital continues to flow into our sector. We've entered a time of intense competition where the speed of execution is paramount. We've built a track record featuring quality and speed, shown that with innovative first-in-class medicines like Repatha, the first approved PCSK9 inhibitor, and Aimovig, the first approved CGRP inhibitor. We shown it also with biosimilars like MVASI and Kanjinti, the first approved biosimilars to Avastin and Herceptin here in the US. And we're doing it right now sotorasib, the first KRAS G12C inhibitor to be filed for approval just 28 months after we dosed our first patient. And we expect to do it again later in the year with tezepelumab as the first TSLP inhibitor.

We're excited about our pipeline and plan on increasing our R&D investment in 2021. Dave will speak in a moment about some of our promising mid-stage pipeline candidates, but since this is the time of year when I'd like to address our long-term investments, I want to focus for a moment, on a couple of areas central to our early research strategy. These are areas where we are building differentiated capabilities.

First, in human genetics, where we have industry-leading capabilities, we are adding to our database approximately 1 million subjects from the US and the UK for whom we will have extensive phenotypic and genotypic information. This will augment the data we already have on in excess of 1.5 million individuals. In addition, we are pioneering the use of large-scale proteomics to measure the relative levels of some 5,000 different proteins in the blood. We are excited about the insights we're generating from this genomic proteomic work and expect to benefit in the selection of new drug targets and clinical trial design.

There is growing interest in our industry in the area of targeted protein degradation. We believe the opportunity is broader than that and our efforts are not just limited to degrading proteins. We're looking at integrating other biologic molecules as well. We're designing molecules to have multi-specific activity through a principle we call induced proximity. The idea is to use this platform to dramatically expand the universe of druggable targets. It's still early days in the field, but I wanted to flag it as an area where we want to immerse through time as an industry leader.

All of our work is taking place at a time when more is expected of companies than ever before. Amgen is advancing an ambitious ESG agenda that includes providing medicines at no cost to low-income patients and funding world-class STEM education programs. With respect to the environment, we're committed to achieving carbon neutrality by 2027, along with a 40% reduction in water-use and 75% reduction in waste.

In summary, our success in 2020 gives me great confidence in our ability to deliver in 2021 and beyond. The world needs more innovation, not less, and we've proven ourselves ready, willing and able to provide it.

I look forward to your questions a little later on in the call. And right now, let me turn over to Dave Reese, our Head of R&D.

David M. Reese {BIO 19782623 <GO>}

Thanks, Bob, and good afternoon, everyone.

I'll begin today with sotorasib, our first-in-class KRAS G12C inhibitor. To date, more than 700 patients have been treated across five continents and we are accelerating this groundbreaking program into new indications and earlier lines of therapy. A few days ago, we presented the first pivotal data for our KRAS G12C inhibitor at the World Conference on Lung Cancer, where we reported on 126 patients with second-line plus non-small cell lung cancer. Sotorasib drove rapid, deep and durable responses across a broad range of mutational profiles and subgroups with poor prognosis. And a centrally adjudicated intent to treat analysis, the objective response rate was 37% including three complete remissions, progression-free survival was 6.8 months and duration of response was 10 months.

Importantly, sotorasib demonstrated a very tolerable and differentiated clinical profile, and based on these data, we completed regulatory submissions in the United States and EU in December. More recently, we submitted files in Canada, UK, Brazil and Australia with additional global submissions anticipated in the coming weeks and months, and launch preparations are well advanced.

The Phase 3 non-small cell lung cancer monotherapy study versus docetaxel continues to advance nicely as to our 10 combination cohorts and Phase 2 colorectal study, with data expected from these latter two beginning in the first half of this year. We will initiate a Phase 2 study in first-line non-small cell lung cancer in the second quarter, where we will investigate sotorasib monotherapy in patients most likely to benefit based on tumor profiling, for example, those tumors harboring STK11 mutations. Finally, we recently cleared the safety hurdle at the full sotorasib dose in our MEK inhibitor combination study, and have completed enrollment in an expansion cohort.

In inflammation, along with our partner AstraZeneca, we look forward to presenting the results from the Phase 3 NAVIGATOR study at the American Academy of Allergy, Asthma and Immunology Virtual Annual Meeting, also known as AAAAI, at the end of February. You may have seen the abstract posting yesterday with results from the primary and key secondary endpoints, data that in our view, provide a compelling rationale for the potential utility of tezepelumab in a broad population of patients with severe uncontrolled asthma, including those with low eosinophil counts where we have Breakthrough Therapy designation in the United States. We are working closely with AstraZeneca on our US and EU filing packages, which we expect to submit in the first half.

Turning to our BiTE platform, we are particularly excited about the rapid progress we are making with two solid tumor programs, AMG 160 targeting prostate-specific membrane antigen, or PSMA for castrate-resistant prostate cancer, and AMG 757 targeting DLL3 for small cell lung cancer. AMG 160 is currently in dose expansion, and we expect to advance

AMG 757 into dose expansion in the coming months. We are quite pleased with the clinical profiles we are seeing with both of these molecules.

And as you will see in our press release, we also continue to actively prioritize our oncology portfolio. In migraine, Aimovig continues to demonstrate important benefits for patients as our colleagues at Novartis announced positive Phase 4 results, showing superior efficacy and safety of Aimovig over topiramate in the migraine prevention setting. Finally, our biosimilars portfolio continues to advance, and we have completed enrollment in our Phase 3 study of ABP 959, our biosimilar Soliris.

In closing, I'd like to thank our staff for their ongoing efforts to deliver our portfolio for patients. Murdo?

Murdo Gordon {BIO 18450783 <GO>}

Thanks, Dave. 2020 product sales grew 9% year-over-year driven by 15% volume growth with roughly equal growth rates in the US and internationally. Starting with our innovative portfolio, Prolia grew year-over-year despite significant impacts from the pandemic, and EVENITY sales increased 85% year-over-year driven by strong volume growth. Repatha is now annualizing at over $1 billion in revenues, with 67% year-over-year volume growth. In the first full year since the acquisition, we've seamlessly integrated Otezla, growing total prescriptions by 13% year-over-year. And finally, our biosimilars portfolio totaled $1.7 billion in sales.

Moving to fourth quarter performance, product sales grew 8% year-over-year driven by 13% volume growth. In our bone franchise, we remain focused on ensuring patient continuity. By year-end, osteoporosis diagnosis reached approximately 80% of pre-COVID levels, leading to a positive trend in new patient starts entering 2021.

In Q4, Prolia's repeat patient numbers were lower than historical trends as a result of the echo effect of COVID disruption in Q2. EVENITY sales grew quarter-over-quarter. We believe, EVENITY's unique bone-building profile will continue to drive growth in our franchise as physicians appreciate its benefit-risk profile for treating their high-risk post-fracture patients.

In cardiovascular, Repatha remains the global PCSK9 leader. Net sales in Q4 were $253 million driven by sequential volume growth and stable US net price. As we enter 2021, we expect continued momentum for this brand globally, driven by growth from international markets, improved US PBM formulary position, and relatively stable net price in the US.

Moving on to Aimovig, which is the market leader in the highly competitive CGRP class, volumes grew 21% year-over-year in the fourth quarter but remained flat quarter-over-quarter as the pandemic negatively impacted new patient starts.

Next, Parsabiv, Q4 sales declined 8% quarter-over-quarter in the US as some customers decreased utilization while others built inventory in advance of the January reimbursement change. With Parsabiv's inclusion in the end-stage renal disease bundle,

we expect sales to decline by approximately 40% to 50% in 2021 as US dialysis centers update their treatment protocols to accommodate generic forms of cinacalcet. We also expect sales in Q1 to be the lowest of the year as customers deplete $40 million of inventory build in the second half of 2020. For patients on hemodialysis, Parsabiv is the only IV administered calcimimetic that lowers and maintains key secondary hyperparathyroidism lab values. Also, Parsabiv offers providers control over calcimimetic delivery and the opportunity to reduce patient bill pill burden.

Transitioning to our inflammation portfolio, Otezla sales were $617 million in Q4, driven by a 13% year-over-year increase in total US prescriptions. We see attractive future growth opportunities through global launches and our plan submission for the mild to moderate psoriasis indication in the US in the coming weeks. With Enbrel, fourth quarter sales declined 5% year-over-year. Volumes declined from gradual share loss coupled with slower growth in the rheumatology segment, which we attribute in part to the pandemic. For 2020, net price declined in the low-single digits, and we expect volume and net price trends to persist in 2021. Enbrel has an established record of safety and efficacy, and we will continue to invest in innovative solutions to enhance the patient experience.

Switching to biosimilars, Q4 sales were $541million driven by volume growth, which was partially offset by declines in net selling price. We are leading in biosimilar share in Europe for AMGEVITA and in the US for MVASI and KANJINTI, with respect to 48% and 41% average share in Q4. We recently launched our fifth biosimilar, RIABNI, a biosimilar to Rituxan. For 2021, we expect biosimilar volume growth to be partially offset by a decline in net selling prices due to increased competition.

In oncology, in the last, Onpro remains the preferred long-acting GCSF with 54% share of volume in the quarter. Onpro continues to demonstrate the value of innovation, allowing patients to treat -- to receive their GCSF treatment without having to return to their doctor's office or other sites of care for administration. Overall, Neulasta sales decreased 19% year-over-year driven by declines in volume and net selling price. And the most recent published average selling price for Neulasta in the US declined 28% year-over-year. Going forward, we expect the price and volume trends to persist as biosimilar competition increases.

Looking ahead, we are excited about new opportunities across our business. Internationally, we recently received a national reimbursement drug listing for Prolia, which will accelerate growth in China. In Japan, we are preparing for the launch of Aimovig, and we're planning for the launch of our biosimilar brands across multiple markets in 2021.

Finally, our team is ready to launch sotorasib upon approval, and we're excited to establish it as a foundational therapy for patients with advanced lung cancer. And we're also preparing for the launch of tezepelumab with our partner AstraZeneca, and are enthusiastic about the prospect of having a therapy that can help treat the 2.5 million people in the world living with severe uncontrolled asthma. Overall, I'm pleased with our Q4 and full-year performance, and look forward to Amgen serving more patients in 2021.

Now, I'll turn it over to Peter.

Peter Griffith {BIO 4299061 <GO>}

Thank you, Murdo. Good afternoon and good evening, everyone. We are pleased with our strong execution and performance in the fourth quarter and for the full year 2020. In Q4, we delivered 7% revenue and 5% non-GAAP EPS year-over-year growth. For the full year, we delivered 9% revenue and 12% non-GAAP EPS year-over-year growth. As Murdo mentioned, both Q4 and the full year benefited from volume-driven sales growth of 13% and 15%, respectively.

Non-GAAP operating expenses increased 9% year-over-year in the fourth quarter as spend accelerated to advance our innovative pipeline, drive volume growth for much of our portfolio around the globe and prepare for future launches, particularly for sotorasib and tezepelumab. Operating expense grew 7% for the full year, including a full year of Otezla related activities and expenses. Free cash flow for the fourth quarter and the full year was $2.0 billion and $9.9 billion, respectively.

Now, turning to the outlook for the business for 2021 on Page 37. We look forward to investing in innovation in 2021, and in launching new products, we will also continue to execute on our volume-driven growth strategy. Due to COVID, we also anticipate some uncertainty and quarter-to-quarter variability in revenue and earnings throughout 2021 with potential recovery later in the year contingent upon the speed and effectiveness of global vaccination.

Our 2021 revenue guidance is $25.8 billion to $26.6 billion, and our non-GAAP earnings per share guidance is $16 to $17 per share. GAAP earnings per share guidance is $12.12 per share to $13.17 per share.

Now, let me mention several key assumptions embedded in our guidance. First, our revenue range reflects volume growth from Prolia, Otezla, Repatha, EVENITY, Aimovig and our biosimilars portfolio, and importantly, our innovative oncology portfolio. At the same time, we expect continued competition against our filgrastim and ESA franchises, as well as accelerating erosion in US Parsabiv sales, as Murdo highlighted. We experienced a 6% decline in net selling prices globally in 2020. For 2021, we again expect mid-single-digit price declines.

A couple of points to recall when considering Q1 of 2021. Historically, the first quarter represents the lowest product sales quarter of the year with plan changes, insurance re-verifications, and higher co-pay expenses as US patients work through deductibles, especially for products including Enbrel, Otezla and Aimovig. Additionally, I want to remind everyone that in Q1 2020, Enbrel benefited from approximately $115 million [ph] of favorable changes to estimated sales deductions, and the entire portfolio saw roughly $100 million in inventory build due to COVID. So as a proportion of our full-year sales, we expect Q1 2021 to be a slightly lower percentage than the 24% it was in Q1 2020.

We expect other revenue to be in the range of approximately $1.4 billion to $1.5 billion for the full year 2021. This includes revenues from COVID-19 antibody manufacturing and profit share agreement with Lilly, under which we expect to begin shipping in the second quarter.

We expect 2021 total non-GAAP operating expenses to grow at a rate similar to the 7% 2020 non-GAAP operating expense growth, as we continue to invest in innovation, launches of new products and digitization efforts.

We have created an industry-leading cost structure and expect an operating margin of roughly 50% in 2021. Cost of sales as a percent of product sales will increase to a range of 16% to 17% due to an evolving product mix and higher royalties and profit share payments. Additionally, cost of sales will increase in connection with our manufacturing agreement with Lilly. As I mentioned previously, the revenues and profit share will be included in other revenue.

Research and development expenses will increase as our pipeline advances with year-over-year increases in early and late-stage investments, and SG&A will decline primarily due to changes in our commercial model, including an increased focus on digital efforts.

Now, let me take a moment to explain an update we are making to our non-GAAP policy. Effective January 2021, our non-GAAP results will no longer include fair value adjustments to equity investments. These adjustments to equity investments have historically been recorded in other income and expenses, and were positive in our 2020 non-GAAP results. This change will not apply to our strategic investment in BeiGene, which is included in our non-GAAP results and is accounted for under the equity method of accounting. The press release contains the pro forma 2020 results by a quarter under our updated policy.

We will also now use updated adjusted 2020 amounts that conform to this policy for comparison purposes going forward. Under our updated non-GAAP policy that I just explained, here is our guidance for other income and expense. We anticipate non-GAAP other income and expense in the range of $1.3 billion to $1.5 billion of expense. This 2021 guidance reflects incorporation of four quarters of BeiGene's results versus three quarters in 2020, which are recorded on a one-quarter lag. Recall that we only use the limited publicly available consensus estimates for BeiGene in connection with our guidance, and thus may experience additional variability depending on BeiGene's actual results. Our basis in BeiGene as of December 31, 2020, was approximately $2.9 billion, and this long-term investment is valued at approximately $6 billion today based upon the current US market price.

Our non-GAAP tax rate guidance is 13% to 14%, and we expect capital expenditures of approximately $900 million this year, including investments in additional manufacturing and other capacity to support our volume-driven growth strategy, as well as in environmental sustainability initiatives that will enable our global operations to achieve carbon neutrality by 2027, and also in our digitization efforts to continue to scale up and integrate data and analytics and everything we do at Amgen.

And finally, our capital allocation hierarchy remains unchanged. After both internal and external innovation and then investing in our capital expenditures, we remain committed to returning capital to shareholders in the form of growing dividends, including the 10% increase in the first quarter of 2021 to $1.76 per share. We anticipate opportunistic share repurchases in the range of $3 billion to $4 billion subject to our Board's authorization.

So in summary, we delivered for patients, every patient every time, and for our investors in a challenging year that included the greatest public health crisis in 100 years and the greatest economic disruption since the Great Depression. And we are confident in the outlook for Amgen's success in 2021 and beyond.

This concludes the financial update. I will now turn the call back over to Bob.

Robert A. Bradway {BIO 1850760 <GO>}

Okay. Thank you, Peter. And Erica, let me invite you to remind our callers of our process for Q&A, and let's begin the question session.

Questions And Answers

Operator

Yes. (Operator Instructions) Your first question in the queue is from Alethia Young with Cantor Fitzgerald.

Q - Alethia Young {BIO 17451976 <GO>}

Hey, guys, thanks for taking my question, and congrats on always solid guidance and a great quarter. I just wanted to maybe if you guys could talk a little bit about obviously, the KRAS program in the combinations, and maybe perhaps kind of -- I know, they're probably early Phase 1 studies, but what you're kind of looking to glean from some of these different combinations? I know you get asked a lot about this, but just kind of, as we're getting closer and closer, like how do you think about unpacking that with different indications? Thanks.

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

Hi, Alethia, and thanks for the question. Yeah, we do get this one quite a bit about the combinations. What I will say is there is no generic answer here. It's going to depend on line of therapy and indication, non-small cell lung cancer, of course, the colorectal cancer and then some of the other indications beyond that. And typically, you're looking for 15%, 20%, 30% increment on any given endpoint beyond a standard of care, but also looking at the totality of the data, I think in many of these settings, in particular, progression-free survival and ultimately, overall survival. So given the safety profile we've demonstrated to date, those are the sort of efficacy metrics that we'll probably take a look at.

Operator

Your next question is from Michael Yee with Jefferies.

Q - Michael Yee {BIO 15077976 <GO>}

Hi. Thanks. I bet you again get a lot of combo care ask questions, so I'm just going to ask as well. The MEK expansion cohort, David, I thought that's really exciting that you've actually completed enrollment, and then I guess that was mentioned at the conference as well, that could be potentially pivotal. Can you talk about whether you would actually be able to announce data on that at some point this year? It's pivotal. Do you want the whole thing to be done before you report out on it? Could you have piecemeal data? And then maybe make a comment on the SHIP2 combo as well. Thank you so much.

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

Yeah. Thanks, Mike. Yeah. Now, we are very pleased with rapidity of enrollment in the MEK safety cohort. As we noted, we've moved beyond that to the expansion cohort. It's quite possible we'll have data from that over the course of this year. It will depend on just as the data come in and as we see those results. And again it's too early to speculate on whether this could be pivotal or not. As I've mentioned in the master protocol from which these data are derived is essentially designed so that any given arm can be blown up into a pretty rigorous Phase 2 trial, and depending on indication in line of therapy, of course, we would make any sort of decisions regarding regulatory intent in that context. So yeah, more to come as those data unfold, but we're quite happy with what we're seeing in terms of enrollment.

Q - Michael Yee {BIO 15077976 <GO>}

And SHIP2?

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

On SHIP2, it's moving along. I think biologically that is a very interesting combination, and again, potentially more to come over the course of the year on that combination as well.

Q - Michael Yee {BIO 15077976 <GO>}

Thank you.

Operator

Your next question is from Terence Flynn with Goldman Sachs.

Q - Terence Flynn {BIO 15030404 <GO>}

Hi. Thanks for taking the questions. Maybe just a two-part for me. Maybe for Peter. I was just wondering as you look out the sustainability of that 50% operating margin, how you think about some of the puts and takes? And then any visibility into your biosimilar franchise, the margins there? I know that's a question we get frequently.

And then again a higher level, and maybe for Bob, and you mentioned protein degradation is an interesting platform on the forward that you guys are spending a lot of time building out. Do you expect to do that all internally? Or is that an area where you could also look externally for opportunities? Thank you very much.

A - Peter Griffith {BIO 4299061 <GO>}

Terence, thank you. Great question on the operating margin. As you know, we don't go out on a long-term basis on that. But you also know that we intend to continue to be a top-performing biopharma firm when you look at any number of financial metrics and importantly operating margin. I do want to make sure that I mentioned and confirmed, we will remain flexible and adaptable as attractive internal and to our external investment opportunities arise. We have the underlying objective to grow our volumes and after-tax cash flows, so that's really important to us. We are committed to lean on our permanent productivity commitment. As I mentioned, we're investing in and working our digitization and automation. So we'll continue to exercise all that muscle to make sure that we do remain the top-performing biopharma firm in operating margin.

On the biosimilars, it's a fair question. We continue to see biosimilars as an extremely strong allocation of capital for us. The margins continue to be very competitive and we're very confident in terms of allocating capital to that category, and we'll continue to do that. And we think we've got some strong expertise there. I like to quote Murdo who says that we've played a lot of defense in biosimilars and now as we're on offense, we're able to have a high quality of execution level.

So good questions in that. And I'll flip it over to -- I think to Bob.

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

Terence, thanks for your question. As I said in my remarks, rather than calling it targeted protein degradation, we're describing it as our induced proximity platform. And intention there, as I said, it's just to be clear that we think it's the technology that we're building can be used, not just to degrade proteins, but other molecules as well.

So we're excited about it. This is -- as I said again in my remarks, long-term research strategy. And Dave and his team and I spent a lot of time with each other, trying to think about how to position for the long term. And in this area, we'll be both internal and external. I'd remind you that we acquired Nuevolution now two years ago for the purpose of helping to build out the set of capabilities. And I would imagine, we'll continue to look, as I said, both internally and externally.

Dave, feel free to jump in and add your thoughts.

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

Yeah. I think that covers it pretty well, Bob. I would say that we view this multi-specificity and drugs as part of the future. Many of you know that 80% to 85% of the currently desirable targets are currently undruggable. We think this is going to be a very important technology and making many of those targets tractable. And as Bob mentioned, we are

investing for the long-haul, we expect that to be a combination of both internal and external innovation.

Operator

Your next question is from Matthew Harrison with Morgan Stanley.

Q - Matthew Harrison {BIO 17603148 <GO>}

Great. Good afternoon. Thanks for taking the question. Dave, I was wondering if you could just comment a little bit more on the BiTE programs, and some of the, I guess, safety issues that have happened? And just what's your confidence in those programs, especially as it seems to relate to some of these extended to half-life programs? Thanks.

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

Yeah. Thanks, Matt, and thank you for this question. Yeah. I would say overall, I feel very bullish on the BiTE program. As we mentioned, AMG 160 and AMG 757 are advancing quite rapidly. Cytokine release syndrome is clearly the single challenge that sits before the entire field, and we're making adjustments in the AMG 701 program to handle that. And I'm quite confident that we can come up with a clinically important profile for that molecule. There are many BCMA molecules in development, and of course, we'll shape our investments according to whether we can really fulfill an unmet medical need.

I would say in closing that I'm quite optimistic about the half-life extended BiTE platform. The -- a few of the positives such as AMG 673 for acute myelogenous leukemia were done on purpose because we selected the first generation molecule which we are investigating in a minimal residual disease setting, where that technology is well suited. This was done in close concert with our investigators. Many of these choices were part of our strategy. We anticipated making these choices as part of a prudent shaping of our portfolio going forward. So overall, I feel quite good about where we are and how that platform is evolving.

Operator

Your next question is from Yaron Werber with Cowen.

Q - Yaron Werber {BIO 19486720 <GO>}

Hi, team, good afternoon. David, I have a question for you if you don't mind and a quick follow-up on sotorasib. Can you give us a sense, obviously, it's encouraging that the MEK combo, you're able to get the full dose of sotorasib? Any comments on KEYTRUDA shipped to Erbitux? And then on tezepelumab, the (inaudible) looks really good. The data on the steroid-refractory was surprising, and I'm not sure if it's potentially trial design differences from the other biologics just given how robust the responses otherwise. Would you consider repeating that study with a more similar trial design to the other ones? Thank you.

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

Yeah. Thanks for the questions. In regards to the combinations, the ones you mentioned are all actively in dose escalation, looking at either different doses or in some cases, even scheduling depending on the agents. This is standard Phase 1b oncology drug development. I feel good about how quickly we're moving. And we'll provide guidance as we expect those data to emerge.

With tezepelumab, as you mentioned, the abstract is out now. We feel the data are very strong. We feel we are competitive with the best in the high eosinophil population, and in many ways, stand-alone in the low eosinophil population. The steroid-sparing study, as you alluded, we think there were potentially trial design issues, and we're going through that with our investigators and anticipate presenting those data a little later this spring. And we're discussing with our partners, whether a differently designed follow-on study would be appropriate.

I would point out that that trial is not necessary for filing, and we are moving ahead with all deliberate speed as we announced with global submissions of tezepelumab based on the current data.

Operator

Your next question is from Geoff Meacham with Bank of America.

Q - Geoff Meacham {BIO 21252662 <GO>}

Afternoon, guys, and thanks so much for the question. Peter, I may have missed this. But looking to 2021 revenue guidance, can you speak at a higher level, what contribution, if any, you assume from sotorasib and tezepelumab for this year? And are there any COVID headwinds still factored in when you look at product sales? Or do you assume 2021 as a more normalized demand curve all year? Thank you.

A - Peter Griffith {BIO 4299061 <GO>}

Yeah. Thanks for the question, Geoff. And I'll invite Murdo here just a moment to jump in on soto and teze. And -- look, we expect continued COVID impacts throughout 2021, and revenue potential recovery in the latter part of the year, contingent on the vaccination rollout, as I mentioned. So we'll be closely monitoring that, as you can imagine.

And with respect to soto and teze, let me turn that over to Murdo. And look, it's a very exciting time for us and we've invested a lot of money, getting preparing the launches for those so forth. So Murdo?

A - Murdo Gordon {BIO 18450783 <GO>}

Thanks, Peter. And thanks for the question, Geoff. And obviously, we're quite excited about sotorasib. And I want to compliment Dave and his team on how fast they've moved in developing this product, and also just the number of regulatory submissions they've been able to effect in a very compressed timeframe.

So we are optimistic and hopeful that we'll get a fairly quick review in multiple markets around the world, and so we would expect sotorasib to contribute to revenue. We don't give product-specific guidance, but this is a very large population of high unmet medical need. There is not a lot of choice for these advanced non-small cell lung cancer patients, so we do anticipate that there'll be a potential market with a high need there.

The one caution that I put out is just the actual percentage of advanced non-small cell lung cancer patients that have a KRAS G12C status result in their file in their medical record. Right now we ascertain that to be at about 50%. So we've got work to do to grow that number. And obviously, we've seen with other targeted therapies, when you have an actionable mutation, the testing rate rises fairly rapidly, so we would expect upon approval to be able to do that. But nonetheless, we think sotorasib will be a meaningful contribution to, at least, revenue in the US.

And then teze, we will see what the regulatory authorities do with the filing. Obviously, given that we had Breakthrough Designation, and obviously, given the PAN eosinophilic results that we've seen, and now you guys you can see the breakdown in that and the abstract, we think this is an important medicine to get the market very quickly.

The last question you asked, about COVID, in fact, Geoff, it was just -- I think we actually anticipate COVID will have a fairly significant impact on the market through the better part of the year -- beyond the midpoint of the year. I hope we're wrong and I hope that vaccination programs will improve. But right now we think that COVID will be with us for the majority of 2021.

Q - Geoff Meacham {BIO 21252662 <GO>}

Okay. Thanks, guys.

Operator

Your next question is from Evan Seigerman with Credit Suisse.

Q - Evan Seigerman {BIO 18922817 <GO>}

Hey, guys, thank you so much for taking the question. So I want to ask one on business development and capital allocation priorities. So it seems that there is a growing need for more mid-stage assets noting several pipeline pauses as reported in this quarter. With 80% of free cash flow is going to dividends and repurchases, how do you think about bringing in larger-scale assets? And would you lever up beyond your current leverage levels if there was an attractive opportunity?

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

Evan, I think we've been pretty consistent in saying that our focus is on investing in the business. So as we said in our prepared remarks, we're planning to increase our investment in R&D this year, so committing internally to continue to allocate capital to R&D opportunities. We'll continue to look externally. We'll look at small and larger opportunities like licensing and business development. And we're very active in the areas

where we have demonstrated expertise therapeutically, and that's what our focus is very likely to entail opportunities that sit well with the areas that have demonstrated expertise in.

In terms of the balance sheet, rather than engage in hypothetical, we maintain a strong balance sheet so that we have strategic flexibility, and we will consider individual opportunities as they arise.

Q - Evan Seigerman {BIO 18922817 <GO>}

All right. Thank you for the color. I appreciate it.

Operator

Your next question is from Dane Leone with Raymond James.

Q - Dane Leone {BIO 15203956 <GO>}

Hi. Thank you for taking the questions. Congratulations on the update and outlook for 2021. So the question for me it focuses a bit on tezepelumab but is a little bit different than what's been discussed previously. Allergy and asthma specifically, in this case, will be a new vertical for Amgen. How are you thinking about building out that vertical around expected commercial launch of tezepelumab, but also thinking about other indications or assets behind that internally or externally that you could point to, to make it more of a broader vertical going forward?

In that same vein, maybe touch a little bit more on oncology. Obviously, in the solid tumor space, it hasn't been an area that you've been heavily invested in historically, but obviously, with sotorasib, approval coming in the first half this year. You're kind of resting on the BiTE program behind that. Are there other assets outside the BiTE program that you could highlight internally that might expand your presence there, and/or should we be thinking about something more differentiated that you might do externally around the solid tumor space? Thank you.

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

There is a lot there, Dane, in your question. Murdo and I'll just double team. But very quickly, let me remind you what we pointed out when we entered into a partnership with AstraZeneca, in particular, around the respiratory opportunity, which was that this -- as you pointed out is a new area for us. We felt that we could deliver more for our shareholders and more for patients by collaborating with a group that had demonstrated expertise in respiratory medicine. And so we chose to partner with AstraZeneca, and we're pleased with that collaboration and look forward to taking the molecule to market with them.

And I would just point out that we came to this through our commitment to anti-inflammation and have decades of experience in the biology of inflammation that we've been able to capitalize on this program and hopefully, others over time. But Murdo, jump in and in particular, share your thoughts also on the solid tumor question.

A - Murdo Gordon {BIO 18450783 <GO>}

Yeah, sure. We -- thanks, Bob. We are building out our teams as we speak, and Amgen will help commercialize tezepelumab in the Americas region. So US and Canada, we will be focused on allergists, while AstraZeneca will play a broader role beyond just allergists, including with the respiratory specialty. So this is, as you mentioned, it's a new area, but it's not that different from what we've done, as Bob mentioned in other inflammatory disease processes.

The other thing that's worth mentioning is we will be taking a leading role in establishing access for tezepelumab with payers. And again, our extensive biologics contracting experience in Part D and the government programs will help us secure broad access for tezepelumab for a broad range of patients. As you saw, we have a nice product profile here that will benefit a lot of patients regardless of their eosinophil status. And then Dave Reese's team is obviously, building out medical capabilities for the same customer-facing group.

So we're excited about it. It's a focused effort. The beauty of focusing on allergists as they're very productive prescribers, but they are relatively small audience size. So we will be quite focused in addressing that. And when it comes to kind of how we're looking at our oncology portfolio, we've got a very strong base right now in oncology between our hematology business, our solid tumor therapeutics. So we have now our overall biosimilar portfolio and our supportive care. Basically, one in five oncology patients today receives an Amgen therapy. And so bringing sotorasib into that mix and then the potential of AMG 160 and AMG 757 and AMG 701, I think is a fairly action-packed next few years in oncology that we can build on the current strength that we have, and we're excited about that. And I'm always asking Dave Reese to deliver more, and I know his team have a lot of other earlier assets to put into the clinic.

I'll turn it over to Dave for additional comment.

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

Exactly. Yeah, we've got a couple of gastric cancer patients, of course, [ph] also solid tumor indication, and we've got some other molecules in late preclinical or just entering the clinic that will target solid tumor indications more on those as we're ready to speak about them going along. So I think it's going to be quite a broad portfolio.

A - Arvind Sood {BIO 4246286 <GO>}

We still have quite a few people in the line, so just a request, if you can please limit yourself to one question. Erica, let's go with the next question.

Operator

Your next question is from Robyn Karnauskas with Truist Securities.

A - Arvind Sood {BIO 4246286 <GO>}

Erica, are you there?

Q - Robyn Karnauskas {BIO 15238701 <GO>}

Hello? Hi. Thanks for taking my question. So the question for Murdo. I was just looking at the MVASI strength and KANJINTIdecline, and the Neulasta price decline was significant. Putting all these trends together, can you just help us think now what you think of how to model the tail for biosimilars? And if there's differences between some of your oncology drugs like the strength in MVASI is really impressive versus the decline in Neulasta, just get a sense of how we should think about that and help us model that? Thank you.

A - Murdo Gordon {BIO 18450783 <GO>}

Thanks for the question, Robyn. And as we look at 2021, I would say that the majority of our growth will come from additional international launches of our biosimilar portfolio, and obviously, some additional revenue from AVSOLA and RIABNI to relatively recent biosimilar launches in the US. And specifically, if you think about MVASI and KANJINTI, they are a little bit different. And the differences are twofold and there is more than that ballistic to the two major ones. Bevacizumab as a molecule is actually growing whereas trastuzumab, as a molecule, is flat to declining. So one thing that we're seeing in MVASI is actually the number of cycles of bevacizumab overall is growing. And so even holding a share in that molecule actually, holds up quite well. We also have less competition, that's the other factor. So there is less competition for now in the bevacizumab molecule, whereas with trastuzumab, we have more competitors. And so I think going forward, you would see competitive dynamics shaping those two brands a little bit differently.

Operator

Your next question is from Mohit Bansal with Citigroup.

Q - Mohit Bansal {BIO 18070890 <GO>}

Great. Thanks for taking my question, and congrats on the progress. Maybe one question on EVENITY. It seems like you have been able to grow this product, not just US, globally as well. And this has been a difficult market historically, so could you please help us track this growth in terms of whether you are taking share from existing anabolics, or you're expanding the market? And then do you expect any challenge when the batch (Technical Difficulty) comes to market for this product? Thank you.

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

Yeah. I was picking up a little bit of static. So I think the question is on EVENITY. And the first part of the question I understood was, how are we sourcing our EVENITY growth? Is it from existing anabolic patients, or are we expanding and treating new patients? I didn't catch the second part of the question, but let me address the first part.

Overall, we're pleased with how EVENITY has evolved, and we've got nice evolution in our Japan business. And in Japan, as obviously, as we've been in the market a little bit longer, so one thing that we're seeing with EVENITY is patients are on the product for a 12-month duration of treatment, and so you have to replenish those new patients. You do

have to source those new patients. And so I think the team in Japan is quite experienced now at sourcing new patients and not necessarily where we got our early growth was -- from which was switching from other anabolics. And there are -- unfortunately, there are a lot of aging patients in these markets where osteoporosis goes unchecked and patients suffer fractures, and these high-risk patients need a solid bond builder like EVENITY to be able to improve their clinical outcomes.

So I think in Japan, we're sourcing more de novo growth than we were perhaps six to 12 months ago. Whereas in the US, it's much more of a mix of de novo and switch. The other thing that's helping us in the US is, of course, having both Prolia and EVENITY for the customer, a lot of the time when a patient will come in and have a fracture despite their Prolia treatment, they're a really good candidate for EVENITY. So we're often getting patients on both treatments, and sometimes after the 12 months of EVENITY treatment up, they'll roll back on to Prolia.

So it's a nice franchise to have and have both an (inaudible) bone-building agent for our customers. So I think the future growth looks very good. Obviously, our partners at UCB are just getting going in Europe as they established reimbursement for the product. But I'm quite excited about what EVENITY could become for these -- for -- bone-building for these very high-risk post-fracture patients.

Operator

Your next question is from Umer Raffat with Evercore ISI.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi. Thanks for taking my question. I'll stick to one. Murdo, you recently mentioned 25,000 as a target population for KRAS, and that's sounded rather high to me, at least for US. So I was curious, A, whether that was for US only or worldwide? And B, if you are assuming a -- around 14% prevalence rate for G12C, and whether you're doing this analysis on non-squamous only for this math? Thank you so much.

A - Murdo Gordon {BIO 18450783 <GO>}

Yeah. Thanks for the question, Umer. The 25,000 was a US number. We actually estimate the non-small cell lung cancer incidence globally at 120,000 patients. Now obviously, there is some reduction from first line to second line in lung cancer because unfortunately, we lose patients in the front line. The second line and beyond is obviously our target population at launch, and we assume a 13% incidents of KRAS G12C in the broad non-small cell lung cancer patient population.

Q - Umer Raffat {BIO 16743519 <GO>}

Right. So Murdo, if we just go down that track, 13% of 120K, I was just confused with the 25K?

A - Murdo Gordon {BIO 18450783 <GO>}

Yeah. So that's the US only number for incidents of non-small cell lung cancer that will progress into second-line and beyond.

Q - Umer Raffat {BIO 16743519 <GO>}

Okay. Thank you very much.

A - Murdo Gordon {BIO 18450783 <GO>}

Thanks.

Operator

Your next question is from Kennen MacKay with RBC Capital Markets.

Q - Kennen MacKay {BIO 18821382 <GO>}

Hi. Thanks for taking the question. And it's wonderful to speak with everyone so soon after the Friday night conference call. Thanks for doing this. Maybe for Dave. Maybe it's the BiTEs that you spoke to previously, but I always love asking this question. Within the early stage Phase 1 or Stage 2 pipeline, what are you most excited about in 2021? What's going to be the next sotorasib? Thank you.

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

Yeah. Thanks. And I think we were able to just rejoin in time for that question. Again --

Q - Kennen MacKay {BIO 18821382 <GO>}

(Multiple Speakers)

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

-- I think in terms of the early pipeline, AMG 160 and AMG 757, as I highlighted in my prepared remarks are ones that we're really looking at. AMG 160 has advanced into the expansion cohort. And if we continue to generate data as we have recently through a larger number of patients, that's a program that we would probably be discussing potential registration as sooner rather than later. I think AMG 757 is just one step behind, and that's another one that we're keeping a very close eye on. And then in our inflammation portfolio, we've got the variety of Phase 2 assets in autoimmune indications, as we previously indicated, and those programs are ones that I'm quite interested in as we move forward. So thanks for the question.

Operator

Your next question is from Geoffrey Porges with SVB Leerink.

Q - Geoffrey Porges {BIO 3112036 <GO>}

Thank you very much. I appreciate the question. Murdo, a question about value commercial model. You mentioned in the prepared remarks a couple of times that you are shifting to more of a digital approach. And I'm just wondering, we've heard that there have been significant reductions in your commercial field organizations. Can you give us a sense of what the magnitude of the efficiency in headcount you're seeing on your average sales force by moving towards digital? And could you talk about how you think that might play out in a post-COVID world? Wouldn't you expect to have to ramp back up once we eliminate social distancing?

A - Murdo Gordon {BIO 18450783 <GO>}

Thanks, Geoffrey for the question. And there were a couple of factors that went into our -- recent reorganization of our field force. One is just portfolio evolution and creating capacity for the new product launches, and then reallocating from the older side of the portfolio. And depending on which region you're talking about in the world with Amgen, we are in very different stages of development.

So for example, we're placing large investments in field force in Japan and in China, even in Russia and some other markets that are emerging for us as being important growth drivers. And in the US, we're really paying close attention to the forces in the market beyond COVID. We are looking at potential negative net price effects and/or price reform, as Bob mentioned in his opening remarks as being a bit of a prevailing wind here. And so what we're doing is looking at our overall commercial model, and to your point, making it more productive and making it more efficient.

So we are largely on track with that plan. We were able to move very rapidly last year and build out our digital capabilities to an even greater extent than we had historically. We are seeing customers willing to engage in those channels. And we think some of those engagements will be persistent beyond COVID, quite frankly. And it's that persistency that we're betting on. What we haven't done is compromised the ability to have a competitive share of voice in our field facing interactions, both on the medical side, both on the commercial side in front of the customer. And so we think we will continue to be able to compete effectively in the categories we're in, as well as, augment that with highly efficient digital channels of communication.

Q - Geoffrey Porges {BIO 3112036 <GO>}

Thanks very much.

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

Erica, I know we're approaching the top of the hour, and some of our callers might need to drop off, but the management team is available. I know we still have several questions in the queue. So for those who have questions that they would like to ask, we'll go beyond the top of the hour. And I apologize to those of you who have other plans and need to drop off here in two minutes.

So, Erica, can you take us to the next caller?

Operator

Yeah. So our next question is from Carter Gould with Barclays.

Q - Carter Gould {BIO 21330584 <GO>}

Yeah. Thanks, guys, and congrats on the sotorasib data, the impressive execution. I guess Murdo and Bob, coming back to Otezla, at the time of the acquisition, things have oriented us that the majority of the growth will come from the US. And I guess your comments today seem to be teeing up really, I guess, the global nature of the growth going forward. I guess just -- your level of confidence around Otezla growth in the US through the mid-2025 timeframe, I guess, given the competition and what have you? Thank you.

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

Maybe I'll just take the sotorasib and then Murdo you can augment however you'd like. But Carter, what I'd say is that when we acquired it, we said we felt we could achieve double-digit growth through the first several years of ownership, and we continue to feel confident in that. And that's a function of both potential for increased label range in the US as well as the opportunity to launch in international markets. But Murdo, maybe you want to elaborate on the opportunity the mild to moderate -- severe opportunity?

A - Murdo Gordon {BIO 18450783 <GO>}

Yeah. Thanks, Bob. And we do see some of the international expansion maturing. Now we've got a good business for Otezla in Japan. We are pursuing registration in China, and we recently secured reimbursement in Australia. So we're evolving the global footprint of Otezla beyond where the legacy Celgene efforts had it. So that is one source of growth. But as Bob mentioned, we're also pursuing in the US mild to moderate approval on the basis of the positive data set we have there. And that will allow us to move Otezla into a patient population that really is still an unmet need. These are patients who have enough skin surface area that they might be seeking an alternative to messy and inconvenient topical agents. And I think Otezla can play a very important role there in helping treat those patients.

We are also in making investments in Otezla by expanding the promotional footprint of the product to include primary care promotion, something that Celgene had not done historically. So we're doing that, both for the moderate to severe patient, but as well for that mild to moderate indication in anticipation of that potential approval.

And then the only other thing I would say is, while we are seeing a little bit of softness in psoriasis and broader rheumatology for the category due to COVID, Otezla being an oral has held up quite well and the execution has been strong. I also think that the established safety and efficacy profile of Otezla is highly appreciated given recent news in the broader rheumatology category of other orals, where perhaps that risk-benefit equation is different than it is where it's very strong with Otezla. So we think we've got a good opportunity for growth. We also said when we gave that guidance. it assumed a successful competitive program from the take two asset and of course, that was confirmed today.

Operator

Your next question is from Jay Olson with Oppenheimer.

Q - Jay Olson {BIO 18027199 <GO>}

Hey, congrats on all the progress, and thank you for taking the question. Since you received Breakthrough Therapy Designation for sotorasib in China, can you comment on how fast you could submit a filing and gain regulatory approval? And what percent of Asian non-small cell lung cancer patients have to KRAS G12C mutation? And how large that commercial opportunity is for sotorasib in China? Thank you.

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

Thanks, Jay. Yeah, we are very pleased to get Breakthrough Therapy Designation in China. As our filing plans move forward with our colleagues at Beijing, we'll provide guidance about what those timelines might look like. That has little bit different implications in China than it does potentially in the United States. And then one thing that we're looking at quite carefully is the epidemiology of G12C mutations. There is a suggestion that it may be a little lower in prevalence in Asian populations, probably because they are mutually exclusive with mutations in EGFR, which are quite high in these populations, up to 40% in China and Japan, for example. So that will be an important question that we address. We've got active research collaborations now looking at just that.

And Murdo, I don't know if you want to add anything about the commercial side in China?

A - Murdo Gordon {BIO 18450783 <GO>}

Yeah. I think we're obviously very excited about what we can do with the product, a huge unmet medical need. We're seeing that China is an attractive market for specialty products, and the fact that sotorasib is an oral makes it very accessible. So we will pursue commercialization of sotorasib in China, and our affiliate is very excited about that.

Q - Jay Olson {BIO 18027199 <GO>}

Great. Thank you.

Operator

Your next question is from Colin Bristow with UBS.

Q - Colin Bristow {BIO 17216671 <GO>}

Hey, thanks for taking the questions. And obviously, seeing the abstract data for trastuzumab for less than 150 group looks pretty impressive. I was just curious what your level of confidence is in getting a broad label in light of the fact that you didn't test the statistical significance? Is that something you've discussed with the FDA previously? And I'll keep it short. Thanks.

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

Yeah. Thank you, Colin. This is a question we get frequently. We demonstrated efficacy in the -- across a broad range of patients regardless of eosinophil count, I think that's where clinicians will pay attention to. We'll provide guidance as regulatory discussions are proceed. I think it's too early, of course, prior to submitting to debate what a potential label would look like. But our view is that overall, these are very, very strong data pointing to a differentiated project -- product. And I think this is just going to be a really important medicine for patients with severe uncontrolled asthma.

Q - Colin Bristow {BIO 17216671 <GO>}

Great. Thanks.

Operator

Your next question is from Ronny Gal with Bernstein.

Q - Ronny Gal {BIO 15022045 <GO>}

Thank you for squeezing me in here. Just about biosimilars, (inaudible) talking about increased competition pressure. Is the -- is the anticipation during 2021 the kind of -- the price decrease in oncology will exit that 10%, 15% decline rate? Is there any reason to expect that? Are the payers coming in and they can change it? Or is this just an issue of, you (inaudible) the market, it's going to be hard to get 100%?

A - Peter Griffith {BIO 4299061 <GO>}

Yeah. Ronny, I think we -- you definitely see a diminishing rate of return or gain in terms of volume share. You see that in the shape of our uptake curves for both our oncology biosimilars in the US. I think that the way, of course, these products are used, they're largely used in the community setting, about 80% of the usage of both bevacizumab and trastuzumab is community oncology setting. And those businesses tend to contract on the network by network basis. And by now, most of those contracts are set in motion. There is still some incremental opportunity to add to our overall revenue base. But yeah, I think the gains on volume will be incremental, and then price trends as I mentioned in my scripted remarks, we will continue to evolve the way we're seeing them.

Q - Ronny Gal {BIO 15022045 <GO>}

All right. Thank you.

Operator

Your next question is from Michael Schmidt with Guggenheim Securities.

Q - Michael Schmidt {BIO 3870043 <GO>}

Hey, guys, good afternoon. I thought it was interesting to hear about some of the early-stage R&D efforts, and the comments that were made around the induced proximity platform. Along those lines, I was wondering if you could provide a little bit more insight

into progress that may have been made within your human genetics initiative? And when or how this initiative may translate into new pipeline products? Thanks so much.

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

Yeah. Thanks, Michael. With -- in human genetics, as Bob mentioned and as we previously announced, we have collaborations with Intermountain Health and the UK Biobank that will add up to 1 million participants, so we think we'll have the largest database on earth as these projects move towards completion. And we have broadened our focus on human data to include other omeg [ph] technologies such as transcriptome mix and proteomics, really in the belief that in the long term, it will be human data such as these that are most important for drug discovery and development.

At the current time, a majority of our non-oncology portfolio, assets have genetic support that is either primary or secondary, and we expect over time that, that percentage will simply increase because there is now clear evidence that targets for which there is genetic validation in programs based on them have a higher rate of success. So more to come, but we firmly believe that the interim human data is upon us, and we believe our collection of capabilities is almost unique in the industry, and we intend to push that forward. Thanks.

Q - Michael Schmidt {BIO 3870043 <GO>}

Thank you.

Operator

Your next question is from Salim Syed with Mizuho Securities.

Q - Salim Syed {BIO 16887281 <GO>}

Great. Good evening, guys, and thanks for the question. Just one from me strategically, high-level here guys. When do you think about Amgen here, is it a correct interpretation to say that the interest in (inaudible) has gone significantly down, and the interest in solid tumors has gone significantly up? And just curious of KYPROLIS has anything to do with that, if that's the correct interpretation? Thank you.

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

I don't think it is, Salim, but I'd like Dave to --

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

Yeah. So Salim, yeah, KYPROLIS, I think has nothing to do with that. What you're seeing is the natural evolution of a portfolio based on emerging data, and we will expect that to be shaped going forward based on emerging data, of course. And some of the changes we announced today are strategic choices that we had teed up that we anticipated are making, and we think it's a prudent portfolio management to make those choices.

Let me call out the MCL-1 programs, in particular, where we have elected to move forward with the IV formulation. Again, we had anticipated we would choose among those molecules, and given our ability to more precisely control exposures and achieve a therapeutic window in collaboration with our investigators, we made that decision, and we're moving through dose escalation after re-initiation of that program. So no specific conscious choices based on hematology versus solid tumors, and more shaping to come as data emergence.

Q - Salim Syed {BIO 16887281 <GO>}

Okay, great. Thanks so much.

A - Murdo Gordon {BIO 18450783 <GO>}

Yeah. Salim, I would just jump in and say, we had a strong quarter on KYPROLIS in the fourth quarter given the approval of CANDOR in our first full quarter promoting it. And we expect to be able to do a nice job of making (inaudible) specialists around the world aware of those data in combination with daratumumab. So more growth to come on KYPROLIS, and it's a good story now.

Q - Salim Syed {BIO 16887281 <GO>}

Great. Thank you.

Operator

Your final question is from Tim Anderson with Wolfe Research.

Q - Andrew Galer

Hi. This is Andrew Galer [ph] on to Tim. Thanks for taking my question. Just thinking about sotorasib in Europe, given EMA typically have a higher threshold for approval for a single-arm study, could you describe your degree of confidence will be able to get approved on this 37% response rate in 10-month DOR? [ph]

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

Yes, sure. Let me take that question. We filed in the EU, obviously, we've got ongoing discussions. We'll provide guidance at the appropriate time. We don't speculate on likely timelines or probabilities in terms of regulatory approvals. But I think it is fair to say that regulators around the world do recognize the large unmet medical need in patients with G12C mutations after first-line therapy. And that's certainly will be the focus of the discussion going forward.

Q - Andrew Galer

Okay. Thank you.

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

Okay. Well, thank you again, and apologize for the fact that we went about 12 minutes over tonight, but we did want to get all of your questions. So thank you for your interest and your support of the Company. And we'll look forward to seeing you or being back together with you after the end of the first quarter. Thank you.

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

Thanks, everybody.

Operator

Ladies and gentlemen, this concludes Amgen's fourth quarter 2020 financial results conference call. You may now disconnect.
