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PRESENTATION

Salveen Richter - Goldman Sachs Group, Inc. - Analyst

Good morning, everyone. Thank you for joining us, and welcome to day two of the Goldman Sachs Healthcare Conference. We're really pleased to have the Regeneron team with us. We have Chris Fenimore, CFO; and Ryan Crowe, Head of IR.

QUESTIONS AND ANSWERS

Salveen Richter - Goldman Sachs Group, Inc. - Analyst

With that, Chris, to start here, could you walk us through how Regeneron approaches capital allocation, specifically, how you're thinking about allocation across internal R&D, share buybacks, noting the new \$3 billion share repurchase program authorized in April as well as M&A and partnerships?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Vice President of Investor Relations

Maybe before we get to that, Salveen, just let me read this forward-looking statement. Thanks for having us. We really enjoy this conference every year. Nice to be in Miami this year, too.

So I'd like to remind you that remarks made today may include forward-looking statements about Regeneron, and each forward-looking statement is subject to risks and uncertainties that could cause actual results and events to differ materially from those projected in such statements. The description of material risks and uncertainties can be found in Regeneron's SEC filings. Regeneron does not undertake any obligation to update any forward-looking statements whether as a result of new information, future events, or otherwise.

Chris?

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Senior Vice President - Finance

Thanks, Salveen. So our capital allocation strategy is essentially three pillars. First and foremost is investment in our own internal R&D capabilities, and we'll talk a little bit more about the pipeline as we go through the talk today. But George Yancopoulos and his team have an enormous number of shots on goal, and that's where we think is the best place to put our capital in terms of long-term value for shareholders.

In addition to R&D, we also invest in our manufacturing capabilities. Most recently, we've invested in a fill packaging labeling facility up in Rensselaer, New York. Looking beyond internal projects that we're financing, we also we have a business development team that's out there looking at complementary technologies that might enhance the way we look at different therapeutic areas where maybe antibodies might not be the best way to approach those.

So you've seen us do deals in siRNA, gene editing, cell therapies, and we'll continue to do collaborative type arrangements like that. And our business development team is evaluating things on a regular basis. Most recently, we've done a few small acquisitions. We did Checkmate Pharmaceuticals. We did Decibel Therapeutics. Most recently, we acquired the preclinical programs from 2seventy. So that's the second pillar of our platform.

And the third is returning capital to shareholders. We've been buying back our shares over the past couple of years. It has been about a little more than \$12 billion since we started buying back our shares. We finished the first quarter with about a billion -- just over \$1 billion that was authorized under an existing program. And as you mentioned, we also added to that and our Board authorized an additional \$3 billion of capacity for our share buybacks. We are active buyers of our shares, and we continue to buy back stock.

Salveen Richter - Goldman Sachs Group, Inc. - Analyst

You've also framed the pay down of the Sanofi development balance potentially fully reimbursed by the end of 2026. Maybe help us understand what this will allow Regeneron to do on the forward post that.

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Senior Vice President - Finance

Sure. So the balance as of the first quarter was \$2.2 billion. And for those of you that are not familiar with this concept of the development balance, our arrangement with Sanofi is effectively, for the most part, a 50-50 type of profit split arrangement. However, Sanofi actually paid more than 50% of the development expenses at the outset, and we are obligated to reimburse to them that excess they paid above that 50%. So that balance, as I said, is about \$2.2 billion. We, for the first time, are going to continue to update our investors on what that balance looks like quarterly, and you'll see that in our 10-Q, so you can track how that balance is being paid down.

We also stated for the first time that we expect that balance to be paid down by the end of 2026, and that's obviously baked in. There's assumptions as to how well Dupixent does from a sales perspective and a profitability perspective, but that's our current working assumption.

So what that means to Regeneron in terms of profitability? We have publicly talked about it. That's an inflection point of close to \$600 million to \$800 million of additional profitability for us as it relates to the alliance. And at that point, that's incremental earnings and cash flow that would come to us at Regeneron.

Salveen Richter - Goldman Sachs Group, Inc. - Analyst

Switching over to EYLEA. So you recently received a permanent J-code for the high-dose asset. Could you speak to any trends that you've observed since that period with regard to physician use, entrance of new prescribers, and how that trajectory is progressing?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Vice President of Investor Relations

Yeah. Thanks, Salveen. And EYLEA obviously has been a great product for Regeneron. And EYLEA HD, we think, represents a meaningful advance on the best-in-class medicine. We were approved in August of 2023 for EYLEA HD, and were operating under a temporary J-code for the first, I guess, around eight months of the launch. And a temporary J-code is fine for reimbursement, but it's not guaranteed. It often takes a lot longer time.

As of April 1, the permanent J-code was assigned by CMS, and that really streamlines the reimbursement process for physicians and practices and guarantees that they'll get paid for utilizing EYLEA HD. What we've seen since the J-code has been a deepening of prescribing among those early adopters that were fine with using the temporary J-code, but we've also seen a broadening of the prescriber base as more and more physicians have confidence in reimbursement. And I think as more and more try the drug, they're finding that the benefits that were observed in the clinical studies are manifesting in the real world especially around the dosing interval.

So we're seeing expansion of the time between intravitreal injections for patients while seeing vision improvements. And that's really important for patients' quality of life and for physicians to help with their capacity constraints that their offices have. So the permanent J-code has really added some additional momentum. But I'd say it's steady. It has been a steady incremental improvement since the permanent J-code in early April, and we're excited about the momentum that we're building with the launch.

Salveen Richter - Goldman Sachs Group, Inc. - Analyst

You've also spoken to efforts to accelerate the conversion of patients from other agents to high-dose EYLEA. Could you just discuss the different factors that are playing out here?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Vice President of Investor Relations

Yes. So around 90% of scripts in this category come from repeat customers or in other industry speak, would be same-store sales. And so the primary opportunity for EYLEA HD is patient switches. And because EYLEA is the market leader, the majority of EYLEA HD patients are switches from EYLEA.

That's great, and we're seeing patients be able to, as I mentioned, extend their dosing interval from EYLEA. But the second largest source of business for EYLEA HD has been faricimab, where we're seeing around 20% of patients on EYLEA HD being switches from faricimab. And then, of course, there's other products in the category that are switching to EYLEA HD as well as a growing amount of naive patients that are getting EYLEA HD as a first-line treatment.

So we continue to implement the launch strategies that we have for EYLEA HD and really underscoring the clinical benefits with physicians. We launched the DTC promotional campaign in March just ahead of the permanent J-code that's really activated patients and brought them to retinal specialists and have asked about EYLEA HD. And we've seen some good uptake from that activity.

So we are, like I said, continue to be encouraged by the progress we've made in the launch. I think we're now around 10 months in and have over 80% of lives covered. So all things are going as planned, and we'll see what the future holds for HD. I think it really is going to become the new standard of care in this category.

Salveen Richter - Goldman Sachs Group, Inc. - Analyst

And the judge in the West Virginia court where the aflibercept litigation is taking place has extended the deadline for the judgment. Could you just speak to us about what's playing out in the courts but also your base case strategy around protection of the 2 mg IP?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Vice President of Investor Relations

Sure. And Salveen, we could spend a good amount of time talking about all the legal puts and takes that have gone in for this case. But to summarize, in December of 2023, the Northern District of West Virginia, the court decided in favor of Regeneron on a formulation patent known as the 865 patent. And this was a trial that was run in June and decided in December against Mylan. We have since filed litigation against other biosimilar applicants including Samsung, Celltrion, Formycon as well as Amgen. And we are currently seeking a permanent injunction preventing the launch of Biocon or Mylan's biosimilar version of aflibercept as well as preliminary injunctions against all of the other companies that I mentioned.

We are currently -- The judge issued a temporary restraining order when the regulatory exclusivity for EYLEA expired on May 17. And he subsequently, on May 31, extended the temporary restraining order for another two weeks. So the current order would expire this Friday on June 14. We're hopeful that the judge will agree with our position that these companies should be enjoined from launching until their trials are either held or the appeal for Mylan has been heard and decided.

But we firmly believe that the 865 patent is valid and would be infringed by these companies, and they shouldn't be allowed to launch until the expiry of that intellectual property, which is in June of 2027. So we'll continue to assert and vigorously defend this patent and prevent these biosimilars from coming to market until that IP expires.

Salveen Richter - Goldman Sachs Group, Inc. - Analyst

Moving over to Dupixent here, the FDA extended the PDUFA date for the drug in COPD given requested additional analysis. Could you just frame the nature of these required analyses and whether there was a specific subpopulation that was in focus?

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Senior Vice President - Finance

So we're not going to get into the specifics of the types of subgroups that the FDA requested. It was just a broad request across a variety of different subgroups. We, with our collaborators at Sanofi, we've looked at the data. We see consistently across these various subgroups, a reduction in exacerbations in COPD. So we are confident in the approvability of Dupixent in eosinophilic COPD.

It's at the discretion of the FDA. When we had conversations with them, they basically said we've requested this information from you and Sanofi. And when we get that data back, we may deem that to be a major amendment. It was in their full discretion. They got the data, and they basically said that they deem that a major amendment. As a result, they pushed back the PDUFA date by three months. But we are, as well as with our collaborator, Sanofi, confident in the approvability of the product and look forward for the launch of COPD for patients in this unmet medical need.

Salveen Richter - Goldman Sachs Group, Inc. - Analyst

Maybe just delving further. Sorry, another question on IP here, but how are you thinking about lifecycle management of Dupixent and biobetters on the forward and even just your IP?

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Senior Vice President - Finance

So we -- if you look at the patent portfolio for Dupixent, it's a fairly comprehensive and robust patent estate. It goes beyond the composition of matter patent, and I won't get into details. But we're very confident in the breadth and the depth of the patent portfolio. Beyond that, we've got a lot of activity on the preclinical front of looking at different ways of going after type 2 inflammatory diseases. It's a little too early to talk about what some of those things might be.

But in addition to that, we're also looking at what we can do with Dupixent itself in terms of extending the treatment duration for Dupixent, among other things. But again, it's a little bit too early to talk about that.

Salveen Richter - Goldman Sachs Group, Inc. - Analyst

You have a slew of pipeline data that's going to start reading out midyear onwards. Perhaps it's just helpful to frame that dataset for us, and we can delve further into questions around them.

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Senior Vice President - Finance

Sure. I think if you look at what's happening on the pipeline front, and Ryan, if I miss anything, please chime in, the -- What's coming up most recently, not necessarily on the data front, but it's the PDUFA for linvoseltamab which is our CD3 BCMA bispecific that's coming up in August. We should see for Libtayo adjuvant CSCC data by the end of this year in the second half.

We expect to see for fianlimab which is our LAG-3 antibody program Phase 2 type data by the end of this year. Next year, in 2025, we expect to see Phase 3 data in our melanoma program. Most recently at ASCO, we presented early data, but encouraging data on our co-stim, our CD28 by EGFR co-stim, again, early but very encouraging data. So that all looks very good.

On additional things beyond oncology, we expect to start seeing data from our obesity program. The trials are enrolling now. But in 2025, we should see data from our two antibodies, which is a myostatin antibody as well as an activin A antibody where we're using those antibodies, either alone or in combination on top of the incretin-based based therapies. We've got data that we should expect to see coming out on our C5 program.

So we're looking at C5 in both PNH, MG, and then basically in geographic atrophy, where it's a program combining both our antibody as well as cemdisiran. So also very encouraging. And then we have our Factor XI antibodies that we should expect to see some data coming out at some point in the not-too-distant future.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Vice President of Investor Relations

I'll just drop in two more. We have, related to Dupixent, some early data from the allergy program we'd expect by the end of this year and into '25. And then Study C in the biologic naive population for chronic spontaneous urticaria, which we hope will resolve the CRL we received last year and enable us to resubmit and then get approved for that indication.

Salveen Richter - Goldman Sachs Group, Inc. - Analyst

Maybe starting with obesity here, could you frame the key learnings from the Phase 1 data in healthy volunteers evaluating this drug as well as the construct and how you think it differentiates itself from the competitors going after that same approach to target body composition?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Vice President of Investor Relations

Sure. I think Regeneron looks at obesity a little differently than a lot of the other companies out there. We believe that the solution to obesity is not starvation or food aversion but rather muscle and metabolism. And we have two antibodies that we think can help preserve muscle during the weight loss phase of patients taking these GLP-1s and GIP agonists or antagonists. And by preserving muscle over time, your metabolic rate will be conserved, and therefore, you should be able to hopefully maintain the weight that you do lose from preserving the muscle and your metabolic rate.

So what we presented last month was a single ascending dose study of both trevogrumab, our GDF8 or myostatin antibody; and garetosmab, our activin A antibody, and we were very encouraged by that data, limited read through since it's a single dose, but we did see muscle growth from these patients in terms of thigh muscle volume. And we also saw a reduction in fat. So both of those things are exactly what we would want to see from these antibodies.

And we also saw very good tolerability, particularly for trevogrumab, which we dosed in over 400 patients and has a very benign profile, which, of course, is very important in a broad population that we would hope to serve for obesity.

So everything is going right along on schedule. I think we'll have multiple dose data in the near future at an upcoming conference. And we've begun Part B of our Phase 2 study. This is going to be in obese patients, where we should be dosing patients this month, initial patients this month. So we will hopefully be able to read out that data sometime in 2025, at least in the weight reduction phase of that, the first 26 weeks, which would be the primary endpoint, where we'll look at overall weight loss as well as percentage of fat loss.

So we're very excited about the opportunity here. We have other irons in the fire, I suppose you could call it, where we're looking at our leptin agonist in combination with tirzepatide. And leptin, we think, is an important and maybe not totally understood hormone that's produced by fat. And when you lose a ton of weight and a lot of fat, your body starts to become deficient in leptin, and want to put that back on. You don't have

enough fat stores, your body's biologic natural response is to build more. By agonizing leptin, you kind of tell your body, you're actually okay at this level of fat.

So it's an interesting concept to perhaps break through the plateau we see in a lot of these products once you lose that initial weight and potentially also maintain the weight loss post discontinuation of the incretin. So that's another one to watch where we should have data in collaboration with Eli Lilly by the end of next year.

And then we also have a genetic discovery from the Regeneron Genetics Center for GPR75. And this is a very different approach from all the others that I've mentioned in that it's a very rare gene that people have that are super skinny, and they have a lot of activity. And it really looks like it's kind of the anti-laziness gene, is sort of the way that George has framed it. So we're excited to try, and we're working on targeting that in a variety of ways with siRNA with Alnylam, with a small molecule approach, with AstraZeneca, and we, ourselves, are looking at ways to target it with an antibody.

So we hope to be able to advance those programs to the clinic in the coming years. We don't have anything identified at this point, but it's an important discovery, and we hope to bring that to patients.

Salveen Richter - Goldman Sachs Group, Inc. - Analyst

And how are you thinking about read-through from other activin and myostatin pathway targeted approaches?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Vice President of Investor Relations

Yes. So bimagrumab is probably the one in the lead here, and that's a product that Lilly acquired from a company called Versanis, and I believe they're approaching the end of their study at this point. Bimagrumab blocks the activin type 2 receptor. And there's around three dozen different growth factors and BMPs that bind to this receptor, including myostatin and activin A. So they've kind of gone at the approach of block the receptors so nothing binds to it.

We've decided on a different approach, where we're only going to selectively target GDF8 and activin A, two different antibodies. So we're able to separate and parse out what we think the true negative regulators of muscle growth are. And by doing that, we believe we'll be able to potentially have a better side effect profile since we know exactly what we're blocking and what its downstream effects on the body are. And as I've mentioned, we have a lot of data on trevogrumab's tolerability and safety profile that looks very, very clean.

And so we believe that will be sufficient to at least preserve body composition. And with activin A, at least in nonhuman primates, we were able to see some muscle growth and additional fat loss. So we're very encouraged. We hope the data from the nonhuman primates that we presented last year at ADA can translate to humans. That's what the Phase 2 study we're currently running is intending to do. And as I mentioned, we hope to have data sometime next year from at least the first 26 weeks of that study to read out.

Salveen Richter - Goldman Sachs Group, Inc. - Analyst

Pivoting over to allergy, we will see first data this year from the initial clinical study of the combination of livoseltamab and Dupixent in severe food allergy. Could you frame for us what we should be thinking about when we see this first data set?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Vice President of Investor Relations

Yes. So Salveen, it's a really exciting program and a totally novel approach to potentially curing severe allergies, which I think everyone here probably has either a relative or a friend who has been affected by it.

There's around 8% of children in the US, 6% of adults that are impacted by severe allergies, and there are over 30,000 emergency room visits due to anaphylaxis last year alone. So it's a very important intervention that we're hoping to bring forward.

What we're going to be looking at, and linvoseltamab will deplete plasma cells that harbor this IgE, which is what these allergies are mediated by, while Dupixent will prevent class switching for when these plasma cells reconstitute, and they will be prevented from becoming IgE immunoglobulin.

So the study will look at a transient period of linvoseltamab or BCMA by CD3 treatment. And once patients' IgE levels are nondetectable, linvoseltamab will be discontinued, and they'll go to a maintenance phase on Dupixent, which, as I mentioned, will prevent the IgEs from returning. And these patients will be monitoring their IgE levels, and we'll be intermittently testing for their allergens in the skin prick test. And I believe after 30 weeks post their final dose of linvoseltamab, there is an optional food challenge study where we would hope that patients would, of course, under medical supervision, be willing to try a food that perhaps they haven't had in a very, very long time.

So we're optimistic about this. I think we'll probably get initial data from our first patient by the end of this year, and we're enrolling a half dozen patients in this Phase 1 study. And depending on those results, we would look to expand the development program from there.

Salveen Richter - Goldman Sachs Group, Inc. - Analyst

Great. You also mentioned the oncology portfolio, and there's quite a bit of data that's going to play out over the year. Could you speak to what you're most excited about?

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Senior Vice President - Finance

So I think we touched on this a little bit. We view fianlimab as a program that's very exciting. So we'll start to see out of that program lung data by the end of this year. And then as we talked about on our last earnings call, there was a decision basically to forgo an earlier readout on the melanoma program because the study was progressing so well and enrolling so quickly, which is encouraging that it was going so well.

And as a result, we're going to have Phase 3 data sometime in 2025 on the melanoma program, which we find very, very exciting. We're also very encouraged with linvoseltamab, which not necessarily on the data front, but just the prospect of what that might look like in terms of the competitive profile for linvoseltamab. So we really truly think we've got an opportunity there to have a best-in-class type of molecule when you compare obviously cross-study comparisons versus the competition, but definitely opportunities to differentiate on efficacy, on safety, and on patient convenience, and on dosing and administration. So very exciting.

I don't know, Ryan, anything else you'd add on that?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Vice President of Investor Relations

No. I think that was a very good summary.

Salveen Richter - Goldman Sachs Group, Inc. - Analyst

There are numerous programs in development on the bispecific platform, both with different tumor antigens and numerous T cell side targets. Could you just talk about your strategy about how you're prioritizing these targets on the forward?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Vice President of Investor Relations

Sure. We at Regeneron rely very heavily on preclinical models, especially with our humanized mouse. So that's really how we identify the best tumor antigens to pair in our bispecific portfolio in which tumors to try and attack. Genetics also plays a role, but I think we're more dependent on

screening our antibodies and our bispecifics on these mouse models. And they've been highly predictive of the results with the PSMA by CD28 program, right at the dose levels where the animal models were suggesting we should see activity, we saw activity.

Now we also saw some adverse events with that program, and we're working on sort of retooling the approach there. But again, the animal models really are going to inform the programs that we're going to move into the clinic. And I think we have a very differentiated VelociSuite mouse program that allows us to make very informed decisions before moving into humans.

Salveen Richter - Goldman Sachs Group, Inc. - Analyst

And linvo is under FDA review at this point. Maybe frame for us how you think about this launch on the forward?

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Senior Vice President - Finance

So I briefly touched on that. If you look at the opportunity in terms of the profile of the drug, from an efficacy perspective, our ORR rates at 71% compares favorably to the competition. And again, the caveat with cross- study comparisons. Our CR rates at 46%, again, compare favorably to the competition. So we think we've got an opportunity there clearly for differentiation.

If you look at safety, our CRS rates are lower than what you see with the competing molecules at 46%, and the onset of CRS actually happens a lot quicker which is actually with our molecule which is easier to manage that for patients and physicians.

If you look at patient convenience in terms of differentiation, we really think there's an opportunity for lower days in the hospital. So if you look at where the competing molecules are, there's somewhere between three and six days of required hospitalization, we're at two or fewer days, and we're working on trying to lower that.

The other thing in terms of dosing is that we've actually studied the ability after 24 weeks, if the patients get a very good partial response or better, the ability to extend dosing to every four weeks, which is unique out there. So we think when you look at sort of that offering relative to what's out there, we're very optimistic about the potential for livoseltamab.

Salveen Richter - Goldman Sachs Group, Inc. - Analyst

The company always talks about this iceberg and what we see is just the tip of the iceberg. Is there any insight you want to provide about what's under the water and how you think about just this overall portfolio of R&D that you have behind what is in the clinic?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Vice President of Investor Relations

Yeah. I mean the iceberg is huge at Regeneron. There is no shortage of really innovative ideas there. Obviously, we're not going to be out here telling people what we're looking at and considering for next in clinic. But I can certainly say that we're very focused on oncology. We're very focused on genetic medicines, inflammation, immunology. We have some very interesting novel targets there that I think will hopefully advance the clinic in the next year or two.

And even in the cardiovascular metabolic realm, we have some interesting things (technical difficulty) antibody tethered ligand that we hope (technical difficulty) the unimolecular solution that would (technical difficulty) that I discussed earlier, providing a one-shot solution potentially on a longer dosing interval than what's currently available today.

So there's a ton of stuff happening behind the scenes in Tarrytown. There's no shortage of excitement going on in the labs, and I can't wait to share it all with you at the appropriate time.

Salveen Richter - Goldman Sachs Group, Inc. - Analyst

Great. One last question for you, Chris. We talked about capital allocation. I think one question that comes up is, given the cash generation, are you interested in larger-scale M&A or issuing a dividend? How do you think about that in the context of everything you're doing?

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Senior Vice President - Finance

Yes. So we finished the first quarter with about \$17.5 billion in cash, gives us a tremendous amount of flexibility. On the M&A front, as I talked about earlier, we've done some fairly modest transactions in terms of size. We're always looking at opportunities that are out there. We don't feel compelled to do any sort of a transaction just based on, as you heard from Ryan, the breadth and depth of what we have in our own internal R&D portfolio. But we have the flexibility to do something if the right transaction came about. But we, like I said, we have no compelling reason right now like we feel like we have to do something.

With respect to dividends, we evaluated that periodically. Most recently, last year, we looked at it exhaustively. We actually brought in some outside advisers to sort of help us in making sure that we're thinking about things properly.

The decision at that point was that it wasn't the right time then or right now as we're sitting here in 2024. But we're going to continue to evaluate it. We haven't necessarily ruled it out, and that might be something that we do in the future.

One thing that we've talked about is the potential of when we described the development balance earlier, that incremental cash flow, that might be a catalyst for where we might think about doing something like that. But again, still under evaluation and no commitment to actually paying a dividend at this point.

Salveen Richter - Goldman Sachs Group, Inc. - Analyst

Great. Well, with that, Chris and Ryan, thank you so much. I appreciate the time today.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Vice President of Investor Relations

Thank you.

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