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# **EDITED TRANSCRIPT**

PFE.N - Q4 2020 Pfizer Inc Earnings Call

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### **OVERVIEW:**

Co. reported 2020 adjusted diluted EPS of \$2.22. Expects 2021 revenue of \$59.4-61.4b. Expects 2021 adjusted diluted EPS of \$3.10-3.20 and adjusted diluted EPS, excluding certain items, of \$2.50-2.60.



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### **PRESENTATION**

#### Operator

Good day, everyone, and welcome to Pfizer's Fourth Quarter 2020 Earnings Conference Call. Today's call is being recorded. At this time, I would like to turn the call over to Mr. Chuck Triano, Senior Vice President of Investor Relations. Please go ahead, sir.

### Charles E. Triano - Pfizer Inc. - SVP of IR

Thank you, operator. Good morning, everyone, and thanks for joining us today to review Pfizer's fourth quarter and full year 2020 financial results, our 2021 financial guidance as well as other relevant business topics. I'm joined today as usual by our Chairman and CEO, Dr. Albert Bourla; Frank D'Amelio, our CFO; Mikael Dolsten, President of Worldwide Research Development and Medical; Angela Hwang, Group President, Biopharmaceuticals Group; John Young, our Chief Business Officer; and Doug Lankler, General Counsel.

The slides that will be presented on this call were posted to our website earlier this morning and are available at pfizer.com/investors.



You'll see here on Slide 3 our disclaimer regarding forward-looking statements we will make during this call regarding, among other topics, our anticipated future operating and financial performance, business plans and prospects and expectations for our product pipeline and in-line products, which, of course, are subject to risks and uncertainties. In addition, we'll be using non-GAAP financial information.

Additional information regarding forward-looking statements and our non-GAAP financial measures is available in our earnings release, including under the disclosure Notice section and under Risk Factors in our SEC Forms 10-K and 10-Q. The forward-looking statements on this call speak only as of the original date of this call, and we undertake no obligation to update or revise any of the statements.

Albert and Frank will now make prepared remarks, and then we will move to a question-and-answer session.

With that, I'll now turn the call over to Albert Bourla. Albert?

#### Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you, Chuck, and good morning, everyone. 2020 was a year like none other in Pfizer's history. With the separation of Upjohn complete, we saw the combination of Pfizer's decade-long conversion into a pure-play science innovation-focused company.

Through our collaboration with BioNTech, we delivered the world's first breakthrough COVID-19 vaccine in less than a year. And by harnessing the power of the variety of digital capabilities, we made sure that despite the lockdowns and travel restrictions, we continue to serve patients around the world who rely on our medicines and vaccines.

Despite this challenging environment and the incredibly -- incredible amount of resources we devoted to develop a safe and effective COVID-19 vaccine, we generated 8% operational revenue growth for the year from our core biopharmaceutical product portfolio, excluding the revenue impact from Consumer Healthcare and excluding \$154 million in sales of the Pfizer-BioNTech COVID-19 vaccine that were recorded in the first quarter. Keep in mind that this 8% operation growth includes a negative 2% impact due to the slowdown in macroeconomic and health care activity resulting from the pandemic.

This operational growth was driven primarily by continued strong performances from Vyndaqel/Vyndamax, Eliquis, oncology biosimilars, IBRANCE, Prevnar 13 outside the U.S., Inlyta, Xeljanz and XTANDI. So basically, all the growth drivers contribute significantly.

Full year adjusted diluted EPS was \$2.22, up 20% operationally from 2019. I would like to point out that revenues and expenses associated with the Upjohn business have been recategorized as discontinued operations and excluded from our Adjusted results.

So overall, we had a strong year, which positions us well as we begin to operate as one global focused biopharmaceutical company, which I have envisioned for the past several years.

Let me start with a discussion of some of our key growth drivers. VYNDAQEL and VYNDAMAX generated revenues of \$1.3 billion in 2020, up 170% operationally. Our disease education efforts continued to support appropriate diagnosis, increasing diagnosis rate to move to 21% at the end of the fourth quarter as compared with approximately 2% before we launched, from 2% to 21%. As of December 31, more than 20,500 patients have been diagnosed, more than 40,500 patients have received prescription and more than 8,500 patients have received the drug, including patients who received the drug at no cost through our patient assistance programs.

We continue to see a recovery in new diagnoses since Q3 and the gradual rebound in new patient starts. With the current resurgence of COVID-19, however, we are seeing varying levels of regional lockdowns that could impact this recovery.

Eliquis delivered another strong performance in 2020, with revenues up 18% operationally to \$4.9 billion for the year. In the U.S., strong volume growth was partially offset by a lower net price due to an increased number of lives in the Medicare coverage gap and the expansion of that gap as well as unfavorable channel mix.



Revenues from our global biosimilars product portfolio grew 68% operationally and totaled approximately \$1.5 billion for the full year 2020, making them a meaningful contributor to our growth. This was driven primarily by our oncology biosimilars, which grew 203% operationally, generating revenue of \$866 million.

Global IBRANCE revenues increased 9% operationally to \$5.4 billion in 2020. IBRANCE continues to be a leader in the CDK4/6 inhibitor class for metastatic breast cancer. In fact, 8 out of 10, first-line HR+/HER2- metastatic breast cancer patients in the U.S. who are prescribed a CDK4/6 inhibitor received IBRANCE. This is a testament to the continued benefit IBRANCE delivers to patients with its compelling safety and efficacy profile.

Based on the continued strong prescribing patterns, IBRANCE compelling safety and efficacy profile and more than 5 years of using everyday clinical practice with continued positive patients and physician experiences, we remain confident in its future performance of the metastatic setting.

Global Prevnar 13 revenues were up 1% operationally to \$5.9 billion in 2020. Revenues outside the U.S. grew 13% operationally in 2020 driven primarily by increased adult uptake in certain international markets, resulting from greater vaccine awareness arising from the COVID-19 pandemic. Although I should note that Prevnar 13 is indicated for the prevention of pneumonia resulting from pneumococcal bacteria, not SARS-CoV-2. Strong pediatric uptake in China also contributed to this growth.

Inlyta had a strong 2020 performance, growing revenues 66% operationally. For the full year 2020, Global Xeljanz's revenue grew 9% operationally to \$2.4 billion. The underlying prescription demand in the U.S. grew 12% in 2020 compared with 2019, outpacing the advanced therapy market by 9%. We have invested in formulary access in the U.S., which played a vital role in enabling this volume growth.

Last week, we reported top line data from a post-marketing safety study, which did not meet the noninferiority criteria for the co-primary endpoint of MACE and malignancies, excluding non-melanoma skin cancer versus TNFi. We are continuing to analyze the secondary endpoints of the study and will discuss the full data set as well as the potential implications to labeling with the regulatory agents. At this point, it is premature to make an assessment as to what impact this data may have of Xeljanz, but of course, patient safety remains our priority.

For Xtandi, alliance revenues for the U.S. were up 22% for the year. And when combined with our royalty income from ex U.S. sales totaled \$1.4 billion. Xtandi new patient starts grew 12%, bolstered by the successful launch of the metastatic castration-sensitive indication, which is helping patients earlier in their disease who will benefit from a longer duration of therapy.

Of course, the biggest story of 2020 for Pfizer was our work with BioNTech to develop and deliver the world's first COVID-19 vaccine authorized for use in developed markets. It took us just 248 days to get from the day we announced our plans to collaborate with BioNTech to the day we submitted to the FDA for emergency use authorization. And I couldn't be more proud of how our colleagues stepped up when the world needed us the most.

Our ability to move at such extraordinary speed while always maintaining our focus on quality and safety was the first powerful display of what the new Pfizer is capable of. While we never imagined a pandemic of this magnitude, every action we have taken over the past several years has been to transform Pfizer into an agile scientific powerhouse capable of addressing the world's most devastating diseases like the one that happened now.

The manufacturing and distribution of our COVID-19 vaccine have gone very well as well. Not only did we achieve our commitment for 2020. But as of January 31, we had supplied 65 million doses globally, of which 29 million doses were supplied to the U.S. government. We are continuing to work closely with the U.S. government on our production, release and shipping schedules to help states ensure Americans receive their first and second doses of the vaccine on time. We have provided the government with a specific forward-looking schedule so they can plan accordingly.

We foresee no issues with delivering the commitments we have made and expect to deliver 200 million doses to the U.S. by end of May, 2 months earlier than our contractual obligation.

Because of the dire need to vaccinate more people, we have explored innovative plans to increase the number of doses we are able to produce globally by the end of 2021. As a result, we now believe that we can potentially deliver at least 2 billion doses in total by the end of 2021. This is



based on the updated 6-dose label, continuous progress improvements and expansion at our current facilities and contingent upon adding more suppliers as well as contract manufacturers.

We are now approaching a year since the beginning of the pandemic. Based on what we have seen so far, we believe it is increasingly like it but a durable COVID-19 vaccine revenue stream like is happening in flu is a potential outcome for a couple of reasons. First, there likely will be a need to boost regularly to maintain high levels of vaccine-elicited immune response. Second and maybe more important, we may need to boost to counter the threat of the emerging mutant strains we have seen with variations in the spike receptor-binding domain side.

Genetic mutations occur naturally during virus replication and spread. We recently announced results of in vitro studies that saw that sera from people who have received our COVID-19 vaccine effectively neutralized a pseudovirus bearing the SARS-CoV-2 U.K. variant spike and also neutralize engineered SARS-CoV-2's with key mutations from South Africa variant and U.K. variant spikes.

We are encouraged by this early in vitro study findings and will continue to monitor our vaccine's effectiveness in preventing COVID-19 caused by the virus strains in circulation. We are awaiting data on neutralization of an engineered SARS-CoV-2 with a full set of mutations from the spike of the South African variant.

That said, there is an increasingly probable scenario when it could become necessary within the next few years to boost COVID-19 vaccinated patients with a vaccine encoding the spike variant.

One of the reasons Pfizer and BioNTech chose to utilize an mRNA platform is because of the potential for the flexibility of the technology in comparison to traditional vaccine technologies. This flexibility includes the ability to alter the RNA sequence in the vaccine to potentially address new strains of the virus if one develop -- if one ever were to emerge that it is not covered by the current vaccine.

Of course, this requires additional development work and regulatory submissions and approvals. Pfizer and BioNTech are preparing for such a possible scenario by working closely with regulatory agencies as well as relevant scientific bodies to enable vaccine technical committees to review data and make appropriate updates to recommendation.

Regarding other applications of the mRNA platform, we are advancing plans to deploy this technology for flu vaccines and may explore other opportunities to work on other viral diseases and other therapeutic applications outside infectious diseases.

Turning now to our 2021 guidance. I want to share just a few thoughts as Frank will go into more detail. The midpoint of our 2020 revenue guidance range reflects 6% operational growth compared to 2020 if you exclude completely the impact of our COVID-19 vaccine. While there are signs that COVID-19 may be here for some time, which could result, as I said, in a more recurring revenue stream, we are carving out the COVID-19 vaccines revenue for now. Frank will provide some context on both our anticipated COVID-19 revenue and margins in his remarks.

While this COVID-19 vaccine has created a new cash flow stream, there is no change in our capital allocation priorities. We remain focused on growth initiatives and the growing dividend, though at a slower rate.

Now let's turn to the pipeline, which is the engine for the new Pfizer and continues to be one of our great strengths. As discussed during last September's Investor Day meetings, we still see unappreciated potential in our pipeline, particularly in our rare disease, vaccine and internal medicines R&D portfolios.

I would like to start with highlighting the incredible improvements we have driven in our clinical success rates and how they compare with industry benchmarks. Between 2015 and 2020, our Phase 2 success rates on a 5-year rolling average more than tripled from 15% to 52%, which is almost double the 2019 industry benchmark of 29%. Significantly, most of these successes are either first-in-class assets of innovations built on established mechanisms with novel scientific designs.



Our Phase 3 success rate on a 5-year rolling average improved from 70% to 85%, 13 points higher than the 2019 industry benchmark of 72%. And our end-to-end success rate more than quadrupled from 5% to 21%, almost triple the 2019 industry benchmark of 8%. I would also point out that while our Phase 1 success rates on a 3-year rolling average stayed flat at 48%. This is 8 points higher than the 2019 industry benchmark.

We believe these metrics demonstrate that through our science, we are selecting assets to move through the research and development process that have the best chance of benefiting patients. This did not happen by accident, but was a result of a purposeful R&D turnaround strategy that we began in 2011. We aim to sustain these success rates, which we believe clearly demonstrates the value of our pipeline.

In Rare Diseases, we achieved 2 Phase 3 study starts since our last earnings call. On November 23, we announced the third participant has been dosed in the Phase 3 BASIS study of marstacimab, an anti-tissue factor pathway inhibitor being evaluated for the treatment of people with severe hemophilia A or B.

On January 7, we announced we had closed -- we had dosed the first participant in our Phase 3 Duchenne muscular dystrophy gene therapy program. The CIFFREO trial is expected to enroll 99 ambulatory male patients, ages 4 through 7, across 55 clinical trial sites in 15 countries. Our DMD program is the first gene therapy to start the Phase 3 trial with a potential first and best-in-class profile.

In inflammation, our unique ritlecitinib, the JAK3/TEC selective oral small molecule, has reported positive top line results in 2 Phase 2 studies, 1 for vitiligo and 1 demonstrating strong clinical remission rates in ulcerative colitis. Data from both studies will be presented in scientific congresses later this year.

Last October, we announced FDA and EMA filing acceptance of our applications for abrocitinib in patients with moderate to severe atopic dermatitis with a priority review PDUFA date for the FDA in April. There is a large unmet medical need here. Many of the 60 million patients are not well controlled on current therapy or are simply untreated, and we see an attractive opportunity to capture many of these patients. In other words, we are not just looking to convert existing patients from other therapies.

In vaccines, the FDA had accepted for priority review the Biologic License Application for our investigational 20-valent pneumococcal conjugate vaccine for adults 18 years of age and older, with a PDUFA date expected in June. If approved, we believe the vaccine could provide the most comprehensive coverage against pneumococcal disease in adults compared with the standard of care and other pneumococcal conjugate vaccines in late-stage clinical development.

In internal medicine, we are progressing potentially novel treatments that address underlying causes of metabolic diseases and cardiovascular risk. We initiated a Phase 2b clinical trial to investigate -- to evaluate vupanorsen for the potential to reduce cardiovascular risk and treat severe hypertriglyceridemia.

Our Phase 2 diabetes trial for our oral GLP-1 is enrolling rapidly, and we expect to initiate a Phase 2 trial for obesity shortly. We expect a proof-of-concept readout in the third quarter of this year, which will inform the next step, the potential pivotal Phase 3 program.

In oncology, we recorded robust response rates for Braftovi in the Phase 2 ANCHOR first-line colorectal cancer study and have initiated a Phase 3 pivotal trial. We also achieved a positive readout for talazoparib in DDR+ metastatic castrate resistant prostate cancer in the Phase 2 TALAPRO-1 trial, which gives us increased confidence for a potential positive outcome of the pivotal Phase 3 TALAPRO-2 trial which has an expected readout for all-comers in 2021 and subsequently for the DDR+ subset of patients.

We are very excited about elranatamab, our investigation BCMA/CD3-targeted bispecific antibody for the treatment of multiple myeloma. In December, we presented encouraging data from our ongoing Phase 1 trial that demonstrated high response rates and manageable safety in patients with relapsed or refractory multiple myeloma, including a few patients who relapsed on or progressed after prior BCMA-targeted therapies.

In late January, elranatamab received Fast-Track Designation for treatment of patients with multiple myeloma who are refractory to at least 1 proteasome inhibitor, 1 immunomodulatory drug and 1 anti-CD38 antibodies. We recently initiated the potential registration-enabling Phase 2



trial of elranatamab monotherapy in triple class refractory multiple myeloma, and we anticipate the first patient to be dosed this month. As you can see, tremendous, tremendous activity.

Before I close, I want to say a few words about affordability. As we have said, our breakthrough medicines and vaccines won't do anyone any good if people can't affordably access them. We believe the industry has generated a great deal of goodwill with Congress and public opinion through our COVID-19 treatment and vaccine efforts. And we hope we can build on this goodwill by working together on a solution, including making a contribution as an industry through legislation or executive action that results in lower out-of-pocket costs to patients.

The status quo simply won't cut it, and we look forward to working with the Biden administration and members of Congress from both sides of the aisle to help ensure our breakthroughs are accessible to all.

In summary, 2020 was a transformational and very successful year for our company, and we look forward to sustaining this momentum in 2021 and beyond. We remain focused on being nimble and investing in our R&D organization, so we can build on the strong improvement in key metrics we have seen over the past 5 years. We continue to expect a revenue CAGR of at least 6% on a risk-adjusted basis through the end of 2025 and double-digit growth on the bottom line.

I would note that these projections do not include any potential impact from our COVID-19 vaccine. We remain very confident in our ability to achieve this growth rate because of the strength of both our current product portfolio and our R&D pipeline. At the same time, we will continue to pursue business development opportunities with the potential to enhance our long-term growth prospects post-2025.

We will focus mainly on smaller deals that fit within our current therapeutic areas. And as always, we are focused on value generation for Pfizer shareholders, not those of potential acquisition targets.

Now I will turn it over to Frank to provide details on the quarter and our outlook for the remainder of 2021. Frank?

### Frank A. D'Amelio - Pfizer Inc. - CFO & Executive VP of Global Supply

Thanks, Albert. Good day, everyone. I know you've seen our release, so let me provide a few highlights regarding the financials. We again saw a very solid revenue growth for the business in the quarter and the year, which continues to support our projected 6%-plus revenue CAGR through the end of 2025. As a reminder, this growth projection excludes any contribution from the COVID vaccine.

In terms of the price and volume mix for the year, if I go off of the 8% operational growth we posted, excluding Consumer Healthcare and the COVID vaccine, our underlying biopharmaceuticals portfolio generated 10% volume growth offset by a negative 2% price impact. So continued very strong volume overall.

Foreign exchange had a slightly positive impact on revenue in the quarter with a 1% benefit for the full year, while for the full year we saw an overall negative impact of 1%. So 1% positive for the quarter, 1% negative for the full year.

Now moving down the income statement. Adjusted gross margins were lower in the quarter, mainly due to the negative impact of foreign exchange, product mix and unfavorable year-over-year impact of cash flow hedging on inventory and COVID-related expenses. However, it's important to note that on an annual basis, adjusted gross margin for 2020 was within 90 basis points of 2019 at around 80%. Adjusted SI&A expenses in the quarter were lower by 2% on an operational basis and lower by 10% on an annual basis.

There remain 2 main factors that drive the decrease for the year: the exclusion of Consumer Health and lower selling expenses due to COVID and, to a lesser extent, the early implementation of a planned reduction in spending associated with our corporate-enabling functions.

Adjusted R&D expenses grew 24% in the quarter and 15% for the year on an operational basis. This growth was primarily driven by our investment in developing the COVID-19 vaccine.



Reported diluted EPS for the quarter was up significantly compared to the prior year quarter, mainly driven by lower asset impairment charges compared to the year ago quarter. For the year, reported earnings were lower mainly due to the nonrecurrence of the gain on the Consumer joint venture formation in 2019. And Adjusted diluted EPS grew 17% for the quarter and 20% for the year on an operational basis.

I'd add that our full year Adjusted diluted EPS was \$2.22, which is below the range of \$2.28 to \$2.38 we had given in terms of new Pfizer financials on a full year basis. Just want to remind you that we had indicated on last quarter's earnings call that our actual reported numbers would be lower than the guidance because the guidance assumed full year of operating without Upjohn as well as assuming a full year benefit of transitional service agreement recoveries and lower interest expenses from the deployment of the \$12 billion in proceeds to pay down debt. So with the deal not closing until November, we only had a small benefit from these factors in our reported 2020 financials.

Now let's move to our 2021 guidance. We provided total company guidance, which includes the COVID vaccine, and then we provided some additional sub-ledger detail on our assumptions regarding the projected COVID vaccine contribution, so you can also get a read on the business.

In terms of revenue, we are projecting a range of \$59.4 billion to \$61.4 billion, which includes a foreign exchange benefit of approximately \$1.4 billion, and at the guidance range midpoint represents operational growth of 41% from 2020.

For Adjusted cost of goods, the range is 32% to 33% as a percentage of revenue, which incorporates the COVID vaccine, gross profit share payment to BioNTech as well as some other related items I will speak to in a moment.

On SI&A, what we see is the impact of increased sales and marketing expense behind key growth brands as well as for expected product launches, offset by our enabling function cost savings. In addition, we see growth in R&D, which follows along with our pipeline development cadence. And I note, given our clinical trial success metrics Albert referenced, we're confident about making sound R&D investments.

Adjusted other income and deductions is projected at just over \$2 billion of income. In addition to the usual items included here, I remind you for modeling purpose that 3 larger items in terms of income are our GSK Consumer Healthcare joint venture equity income, ViiV dividend income and transition service agreement recoveries, primarily related to Viatris, working this through with our projected 15% tax rate yields and Adjusted diluted EPS range of \$3.10 to \$3.20, a 38% operational growth at the midpoint. This range is a bit higher than what we discussed 3 weeks ago and was driven mainly by an increase in our COVID vaccine sales projections since then.

Let me offer some assumptions and context on the projected COVID vaccine financial contribution and our collaboration agreement. The Pfizer-BioNTech vaccine collaboration construct is a 50-50 gross profit split. Pfizer will book the vast majority of the global collaboration revenue, except for Germany and Turkey, and we do not participate in China. We continue to expect that we can manufacture up to 2 billion doses in 2021. However, given it's still early in the year, we are not projecting that we will sell all those doses.

Ultimately, we may contract for all the doses. But for the purposes for our initial guidance, we primarily included doses that are covered by strong supply agreements with various governments. Based on this, we currently forecast approximately \$15 billion in COVID vaccine revenue, which is what you see here. Given we remain in negotiations for additional contracts, we are not providing the number of doses behind the revenue estimate.

Our cost of sales for the COVID vaccine revenue will include manufacturing and distribution costs, a royalty payment allowance as well as the payment to BioNTech, representing the 50% gross profit split. All in, this yields an anticipated income before tax from COVID vaccine in the high 20% range. Let me add that if we contract for additional -- if we contract for the delivery of additional doses during the year, we will provide a guidance update in our subsequent earnings releases.

If we remove the projected COVID vaccine contribution and related impacts on revenue, that results in our business having 2021 projected annual revenue between \$44.4 billion and \$46.6 billion. So 6% operational revenue growth at the midpoint and about 8% if we include the current favorable impact of foreign exchange compared to last year.



In terms of adjusted cost of goods, net of the COVID vaccine, we see a range between 21% and 22% as a percentage of revenues. For Adjusted diluted EPS, we see a range of \$2.50 to \$2.60, which represents 11% operational growth at the midpoint. These growth rates are all consistent with how we've been publicly positioning the business subsequent to the Upjohn separation.

In terms of reporting our quarterly earnings, we are not going to report 2 sets of financials, one with COVID and one without. But I think the context in terms of the vaccine margins will be helpful in calculating a good estimate of the Adjusted diluted EPS impact based on the COVID vaccine revenue, we will report in future earnings releases.

Let me speak for a moment about our dividend going forward and how it will initially be linked to the Viatris dividend once it is declared. To make it simple, let's start with Pfizer's current annualized dividend rate of \$1.56 per share. A Pfizer shareholder owning 100 shares just prior to the spin-off would now still own their 100 shares of Pfizer and also 12 shares of Viatris, assuming they have continued to hold the Viatris shares. The 100 shares of Pfizer would generate \$156 in annual dividend income. And currently, the 12 shares of Viatris do not generate any dividend income. This \$156 in annual dividend income is what we will preserve.

Once Viatris declares its dividend, we will calculate the annual income generated by the 12 shares of Viatris and then adjust the Pfizer dividend, so the combined annual income generated from the 100 shares of Pfizer and 12 shares of Viatris totals at least that \$156 in 2021.

For the foreseeable future, we expect our Board to continue to support annual dividend increases at approximately this year's level. Obviously, we have no say as to what Viatris does with its future dividend. I hope this example is helpful.

In summary, we had a strong 2020. The separation of Upjohn is behind us. The business is on track for solid top and bottom line growth. And we are highly focused on advancing our pipeline, supporting end market brands and looking to deploy capital responsibly with a focus on initiatives that can solidify our long-term revenue and earnings growth.

With that, I'll turn it back to Chuck.

Charles E. Triano - Pfizer Inc. - SVP of IR

Great. Thank you, Frank and Albert, for the prepared remarks. Operator, at this point, can we please poll for questions? Thank you.

### **QUESTIONS AND ANSWERS**

### Operator

(Operator Instructions) Your first question comes from the line of David Risinger from Morgan Stanley.

**David Reed Risinger** - Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst

So first of all, congrats on the phenomenal vaccine progress and the benefits that Pfizer is driving for society. That's much appreciated by everyone on this call and beyond. My 2 questions relate to vaccine prospects and Xeljanz. So first, could you speak to how you are projecting vaccine sales per (inaudible)

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

David, unfortunately, you are cutting off, and I couldn't hear you. Can you repeat the question of the vaccine from the beginning?



David Reed Risinger - Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst

Sorry. The question is with respect to the vaccine (inaudible)

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Unfortunately, the line is not good, David. We can't hear you.

#### Operator

Your next question comes from the line of Steve Scala from Cowen.

Stephen Michael Scala - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

I have 2 questions. In what scenarios would you not sell all 2 billion doses of COVID vaccine Pfizer can manufacture in 2021? Some competitors haven't exactly exceeded expectations and only a small fraction of global demand has been satisfied to date. So it seems as though you'll sell every dose you make and that the current guidance is going to be way low.

Second question is on the Xeljanz CV study, should we assume DVT tracked similarly to MACE? And given that Pfizer has other JAKs in development, what do you believe are the long-term implications for JAK class -- for the JAK class overall given this recent Xeljanz CV study?

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you, Steve. Let me take the COVID one, and then I will ask Mikael to comment on the Xeljanz first part and then Angela on the implications from commercial.

Steve, we try not to give a low expectation. We try to give a responsible expectation. If you are asking is there is a scenario that we will sell everything, yes, there is. Also, I would tell you that if that was an open market, which means that the physicians and citizens, they have the ability to choose which vaccine they would receive, I would feel very comfortable that we will have the lion market's share because we are first and we are best, as you have clearly indicated, and we have great operations in basically every country in the world.

But this is not an open market, at least for this year. This year, it is a market that it is controlled by governments appropriately because I think we are in a crisis, as you know. And also, it is a market that creates a lot of political pressure. So not always the decisions are sound, solid and avoiding panic.

So with that in mind, we have a formula that we try to implement in a responsible way but takes into consideration the contracts that we have, the potential for future contracts, but also takes into consideration the strength of the contracts, takes into consideration the potential for other vaccines to present data.

And in fact, the reason why we changed our revenue projections, which resulted in (inaudible) which resulted in \$0.10 improvement in our bottom line, it is because we did have more news from the AstraZeneca registration and the way that it is perceived in Europe. We had the news from the J&J that reported data. We have much better visibility now in the last 2 weeks on their manufacturing capabilities. All of that resulted in us increasing our projections.

Clearly, there are a lot -- this is a multidimensional, let's say, challenge to have accurate projections. And clearly, we are having dynamic changes, which we will follow, and we will update our estimates as time comes. But in all honesty, I couldn't responsibly just say right now, we are going to sell everything we can make, the 2 billion, when we have all this dynamic situation that it is evolving.



Now why don't we move to Mikael to talk a little bit about the MACE on Xeljanz and then Angela on the revenues expectations.

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

Yes. Thank you, Albert and Steve, for the question. As you know, the 1133 study for Xeljanz was rather a unique population with increased CV risk. Now Xeljanz has been studied in numerous clinical trials and in the market where a large population have used it in a more general RA population or in ulcerative colitis. And in those populations, it has had a very robust efficacy to safety profile. I think RA by itself has more CV liabilities standard for a patient, and this was a very specific subset.

Now going to other JAK inhibitors, the next-generation of JAK inhibitors such as abrocitinib in registration for atopic dermatitis or, as Albert reported, ritlecitinib, which is a unique JAK3-TEC inhibitor, each JAK inhibitor differ by itself. And we think both of these 2 that I mentioned have very encouraging benefit-to-risk profile. And while regulatory agencies have, in some instances, inferred a general class label across JAKs, I think the experience will tell that abrocitinib for atopic dermatitis has a very compelling efficacy and risk profile and ritlecitinib for alopecia that's reading out later this year or for vitiligo and ulcerative colitis, where we have very encouraging Phase 2 data, again, has a unique profile.

So I don't think that we should extend 1133 to other JAKs. And I think we'll also need to look at Xeljanz having a very robust profile in population that was not a smaller version of the 1133 study.

### Angela Hwang - Pfizer Inc. - Group President of Biopharmaceuticals Group

Thanks, Mikael. And then just building off of what Mikael has said, as you know, we have a very robust data set that has been built around Xeljanz for over 7 years, 50 different clinical trials, 260,000 patients that are currently on Xeljanz and, of course, a very robust real-world data set that goes along with these 260,000 patients.

So I think based on all of this and together with the fact that we are still so early on in our understanding of the 1133 data as it pertains to Xeljanz that we feel confident that Xeljanz will remain an important part of the treatment paradigm for RA patients and for patients with PsA and UC as well and that it has an appropriate and favorable benefit/risk profile for this sort of patient population type.

And so of course, we will share the data with you as we continue to learn more about the study. But for now, that's how we see it.

And then I think you had one more question in terms of how do we think about in terms of impact on our other JAKs. And as Mikael said, scientifically, each one of these molecules are very different. And they're all being designed with a different benefit/risk profile to match the different disease condition as well as the different patient types. And so I think as a result, we continue to be very confident about our JAK portfolio and the investments that we're making in each one of these. And we think that what we will be able to deliver are differentiated profiles that will be appropriate and fit-for-purpose for that condition and for that patient type.

### Operator

Your next guestion comes from the line of Gregg Gilbert from Truist Securities.

### Gregory B. Gilbert - Truist Securities, Inc., Research Division - Analyst

Albert, it seems pretty clear that Pfizer, the stock anyway, is not getting a whole lot of credit for the COVID-19 vaccine. And whether or not you agree that that's fair, I'm curious how you expect to leverage the expertise you've built in this area into areas that investors might view as contributing more to long-term franchise value, regardless of what happens to the COVID-19 part of the story.



And then a second vaccine-related question perhaps for Angela. There's been a lot of focus on your vaccine and others about logistics and supply and coverage of variants. But it seems to me that at some point, a key metric, if not the most important metric, will be how many people want to get a vaccine. So curious what your work tells you on that front and whether you plan to get involved as a company in helping drive awareness and demand at some point or is that not really Pfizer's role to play.

#### Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Gregg, thank you very much. I fully agree with you that I don't think we're receiving a lot of credit not for the vaccines right now when you see the stock price, but mainly for our basic business and pipeline. This is a business that is growing 6% and double digit the bottom line, excluding any COVID, and clearly deserves much, much higher multiple in this industry.

The same comes even more when you speak about the COVID-19 vaccine that I think, clearly, people should see much more into that. So to your question, how do we plan to use strategically this platform? I believe that the RNA technology has been proven in a glorious way that will have an impact in treating diseases, in preventing diseases in multiple applications. And I believe Pfizer has accumulated expertise and knowledge of a decade into 1 year. And also Pfizer has completed infrastructure investments that would take 5 years again into 1 year. So clearly, we plan to use this expertise so that we will be able to benefit more and more patients.

I made some comments that within the COVID vaccine, I believe that COVID is -- the dynamics in the COVID more and more indicate a potential that we will have a clearly repeated business. The reasons for that are multiple. Let me start by saying, in the beginning, we were waiting to see if the immunity will be durable. Now we still don't have data about the immunity of our vaccine because it is early. But we do see that the people that have the disease, more and more publications indicate that after several months, the immune response goes down. So there is a need to boost.

Also, there are a lot of papers that have been published that indicate even for the new variants that if you have very high level of immune responses, you are protected against those virus in much higher level than if you have lower levels of these antibodies. So that indicates that the need to boost or that you maintain much higher levels, it's there.

And last but not least, it is clear that the scenario that the variants will develop in such a way that they may be escaping very effective protection from the current vaccine, which is not the case right now for us, then it will clearly preparing ourselves so that we will produce in a very speedy time. I made publicly a statement that, that needs to be done end to end in less than 100 days to provide new booster vaccines that will protect against the new variant.

So in scenarios like that and even in scenarios that the COVID will move from a pandemic into more of a normal type of vaccination business, it is very clear that Pfizer will have a key advantage not only because of the strength of the data, but also because we have developed significant brand equity and trust with the people when it comes to their choice, we have infrastructure and expertise that will help us.

RNA is not going to provide only COVID-19 vaccines. We are accelerating our work for flu right now, and we are clearly investigating multiple other applications in other vaccines for this RNA technology or therapeutic areas. So I believe that our business, excluding COVID, is very robust with robust pipeline. But I think COVID has a very good chance that could completely transform the revenue and earnings trajectory of this business starting from now.

And with that, I will ask Angela to comment on the question about, again, the COVID vaccine. Angela?

#### **Angela Hwang** - Pfizer Inc. - Group President of Biopharmaceuticals Group

Thanks for the question. And I think what you're talking about is vaccine confidence, which clearly has been a big topic since the vaccine was introduced. And I'm actually really encouraged by data that we're receiving on a routine basis that is demonstrating that vaccine confidence is indeed building. And that compared to where we were even a month ago, we've had a significant rise in interest and willingness of the public to



get vaccinated. And I think a lot of this is driven, obviously, by real-world experience, by many people who are now getting the vaccine and having good experiences with them. So I think that this will continue.

To your question about what is it that we're doing to drive awareness and demand, I think, first of all, we have to understand that right now, we are in a period where we are operating under an EUA, the emergency approval. So there's guardrails as it pertains to that and what it is that we can do.

For sure, we have worked very diligently with many, many medical and public health societies and institutions to ensure that we are supporting education in -- across the entire country. There recently was even a public service announcement that was launched where it had our support, in conjunction with a number of patient advocacy groups, to really educate and to create confidence for the public around this vaccine.

In addition to that, at a more specific level, Pfizer uniquely has really supported the health care professional community in its vaccination by providing a lot of training, a lot of support to ensure that confidence is gained at the vaccinated site.

And actually, just to share that over 30,000 HCPs have been trained by Pfizer alone in the recent month or so to be able to confidently vaccinate these -- vaccinate people. And I think that that's also helping to create confidence. But of course, where we can get most involved and we'll be able to do even more is once we receive our BLA. And so we're working towards that, and we will build on the education initiatives that we already have in place, that we'll be able to amplify that even more once we have a full label.

Charles E. Triano - Pfizer Inc. - SVP of IR

Thanks, Angela. And good point on the BLA opening up more opportunities.

### Operator

Your next question comes from the line of Terence Flynn with Goldman Sachs.

### Terence C. Flynn - Goldman Sachs Group, Inc., Research Division - MD

Thank you for all the work you're doing again on the COVID vaccine. I was just wondering, is there an integrated system that's being set up by either the government -- or governments or Pfizer to monitor instances of vaccine breakthroughs and conduct sequencing? And then what factors and who will ultimately dictate when a change in the -- the potential the vaccine is needed to cover an emerging variant? How does the consensus emerge on that question?

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Yes. Mikael, would you like to take this question, please?

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

Yes. There are different, organized at the government levels, efforts in the U.S. the position of sequences both to track new strains like the South Africa and Brazil as well among unvaccinated and vaccinated are deposited in certain databases. So there's one initiative in U.K. And then, of course, Pfizer has a unique collaboration in real-world evidence with the Israeli minister of health, which will allow us to track first real-world evidence for our vaccine in the population.

And as you may know, we are the #1 to have such data that shows 92% to 95% in real-world evidence vaccine efficacy, primarily seen initially in older population. That's harder normally to get this stunning data. And it also showed a very low 0.25 about for both -- 24 and 26 for first and second



injection of adverse events. So really well-performing in a large population of millions of individuals. And of course, they will also track if there are breakthrough infections.

Now in general, I think it has been claimed that South African and Brazil variants are more difficult to treat, and vaccines that have lower antibody levels will have much more breakthroughs. Given that the mRNA vaccines have a high antibody levels, and that was, I think, implied in Albert's answer, we expect them to be much more resistant to breakthroughs for a longer time.

And I think data from several lab shows that if you maintain with mRNA vaccines high antibody levels, you will actually protect very well even against those variants. And that suggests -- and we are just embarking on such studies that you could boost with the current vaccine a further time and avoid some of these breakthrough infections that were reported recently in some vaccine studies. That would be our aspiration to demonstrate that by keeping individuals with very high titers, you can really impact. And that can be recorded, as you asked in various systems that are now in place in many countries. And that could be a very important way to transit into a more sustained protection, sustained business models where the [mono] allow you to plan when the next boost should happen.

#### Operator

Your next question comes from the line of Louise Chen from Cantor.

### Louise Alesandra Chen - Cantor Fitzgerald & Co., Research Division - Senior Research Analyst & MD

So my first question is, if the COVID vaccine becomes routine, how do you think governments and physicians will choose amongst these different vaccines that have received emergency use authorization? And then how do you think about that 95% efficacy rate in light of mutations? And the last question is on your PCV20, if it's approved, what do you expect the ACIP recommendation to be your -- what would you ideally like it to be? And do you think there will be any upgrade for those 65-plus due to the additional serotypes?

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you. Why don't we start with PCV20, Angela, and then we can come back to COVID. Angela?

### Angela Hwang - Pfizer Inc. - Group President of Biopharmaceuticals Group

Sure. So in terms of PCV20, I mean, what we believe our value there is the additional serotype. And that in the adult, these additional serotypes are meaningful because it will give us 33% more protection against strains causing IPD in adult and 42% more protection against strains causing IPD for pediatrics. So we feel that this is very value-creating and provides us the opportunity to really bring an important option into the market that is an upgrade compared to what it is that we have today.

And then to your question about ACIP. Of course, we're working closely with the FDA for approval and with the CDC at the right moments in time to get the right recommendation. We believe that the recommendation will be positive as it pertains to PCV20, and we look forward to working with them to achieve that.

#### Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you. Now as regards the -- how people could choose or physicians could choose if that is a routine, I believe that if this is a routine, the decision will come as with all other vaccines and medicines, the strength of the data. I think that this is why I made before the comments that given that we are first could mean that we are vaccinating a lot of people right now with the first doses. Given that we have such a strong safety and efficacy and database in an open choice situation, we will get the vast majority of the share of choices.



But I think will come a reality likely after in 2022, when the governments do their whole vaccination scheme. And also in that year, there will be ample, I believe, capacity. So volume will not be a case. Even if everyone wants to get 1 vaccine, I think, will be enough to make this 1 vaccine.

What about the 95% efficacy in terms of variants. I think we answered that. But Mikael, maybe you want to reiterate once more why the higher the efficacy, the better it is not only for the current, but also for the variants.

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

Yes. Very brief, it's clear from convalescent plasma studies that now the last couple of weeks been out and also from plasma from vaccine recipient, higher antibody level seems to protect from variants in the preclinical studies from patients. So I think it will project into the vaccines with high antibody levels and T-cell immunity, which are an additional protection mechanism, will do very well against variant and keep boosting them will keep the variants off the population for a longer time before there is any need to shift to a variant selective.

So I think the data we have with mRNA vaccine put them really in a unique category, having the strong immune response, the ability to boost and the ability to, if needed, reconfigure.

### Operator

Your next question comes from the line of Umer Raffat from Evercore.

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

I want to hit up on 2 different topics. One, as we think about possible new vaccine for the new variants, do you guys have plans in place? Are you working on it right now? Should we anticipate some sort of Phase 1 data by -- at some point in this early summer? And has there been a consideration to allocate some of this 2 billion in doses capacity to a new version of the vaccine?

And separately, going back to the Phase 3 you reported, it's been a few weeks. And one of the questions I've had is, of the patients that tested positive on the vaccine post-dose 2, what did we learn about what mutations those patients had on deep sequencing? What did we learn about their NAV titers and T cells? And I wonder if there's anything we can draw on correlated protection.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Umer, very, very good, excellent questions. Mikael, do you want to take the last one and also the first one, and then I can speak then later on the manufacturing piece.

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

Yes. With variants, we are embarking on a study, which will give a boost after 6 months. And possibly also compared with a 12-month dose, we'll compare the wild type, the current vaccine with a variant vaccine, likely based on the 484 amino acid from Brazil and South Africa. I think that given the data are so strong with our vaccine, as we alluded to, it may very well be that a third boost at a proper time point is sufficient. And you'd continue to monitor variant. But we will be prepared if needed, with data, as you said, around early summer.

Quality protection is something we're working with a lot of scientists, not just looking at data in our trial, but in public consortium with INH, looking at data across many trials. And we will see the outcome. I expect, again, high antibody levels plus T cell immunity will provide the best durability. And that makes us very optimistic about the unique profile of mRNA vaccine.



#### Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you, Mikael. And the 2 billion doses that we are speaking about, it is clearly for this current vaccine. And clearly, also, we are working to see if we can improve that even further. But right now, we are at our commitment of 2 billion doses.

But the reason why we had selected mRNA in the first place was because it simplifies tremendously this type of process. Our ability with this technology to build a new construct of the same vaccine by just changing the RNA -- the messenger RNA within this vaccine, it is really at a very, very simple process in terms of manufacturing and in terms of actually developing it.

Now nothing is simple in biology when you speak about high complicated processes. But relatively to any other technology, this is very simple. So I wouldn't say that I would anticipate a major -- if we have to go to a new vaccine, that we will have a major shake up in our manufacturing capacity. I think overall 2 billion doses could be, and maybe a little bit less if we start producing new vaccine, replace altogether the new variants, altogether, cumulatively new and the old, if there is a need to do a new.

#### Operator

Your next question comes from the line of Geoffrey Porges from SVB Leerink.

**Geoffrey Craig Porges** - SVB Leerink LLC, Research Division - Director of Therapeutics Research & Diversified Biopharma and Senior Research Analyst

And unfortunately, we'll continue a little bit on this thing. Mikael, could you give us a sense of whether you think the so-called South African and Brazilian variants that have similar mutations represent terminal or near terminal adaptations of the virus? Or do you think that we will see sort of almost recurring and infinite adaptations that we may have to contemplate adapting the vaccines, too?

And then secondly, have you contemplated giving a single dose of vaccine to those who've previously been infected given what's probably 20% to 25% antibody positivity in the U.S. population? And lastly, could your next-gen variant vaccine be refrigerator-stable?

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Mikael?

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

Yes. Thank you. Yes, the first strains, like the U.K. strain, was mainly selected for transmissibility, to spread quickly. As to where -- in the previously infected people in South Africa and Brazil, the new strains have been selected for immune escape, which is the 484 amino acid, it's the most important.

High antibody titers, as alluded to before, from our vaccine seems still to be able to react quite nicely with that strain, although at somewhat more moderate reduction. And we think keeping high titer up in patients will be a very good to report approach until there is a need for strain change.

Now with that concept, keep up high antibody titer, you should immunize whether you have had infection or not twice. That gives you maximum titer and allow you to fight off variant strains for as long time as possible before you may need to boost or after some time that there may be any reason to a variant vaccine, as Albert alluded to. And we are currently initiating study to understand when a third immunization would be helpful for participants, and we will be studying 6 to 12 months as initial assumption.

And of course, we'll continue to make efforts to make refrigerator-based vaccines that includes lyophilization or possible liquid with a stabilized product. And we think end of this year or early next year, we'll have such a product.



#### Operator

Your next question is from Vamil Divan from Mizuho.

#### Vamil Kishore Divan - Mizuho Securities USA LLC, Research Division - MD

Maybe I'll just shift gears a little bit off the vaccine, I guess somewhat tied to the vaccine but in a little different angle here. In terms of capital allocation, Albert, you had mentioned that no change to your strategy. But the vaccine obviously is going to give you a boost to your sales and cash flow, at least in the near-term here. So I'm just wondering, should we expect Pfizer to be maybe more active and complete more transactions in the coming months, just trying to boost your pipeline than you otherwise might have been? Or if not, I guess, just if you could give sort comment on your kind of thoughts around this added cash flow and what you might look to do there.

And then my second question is on VYNDAMAX, where it looks like you are having pretty good traction there, maybe better than we thought given the pandemic. And I'm just wondering if you can maybe comment to where this product is now relative to where maybe you would have expected a year ago, sort of pre-pandemic. I'm trying to get a sense, there are real sort of bolus of patients or you could maybe make more traction with that as the pandemic eases? Or are you already doing quite well in terms of gaining penetration into those patients now, so we should sort of expect the same sort of state of uptake going forward? So any thoughts would be helpful.

#### Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you, Vamil, and thank you also for asking something outside COVID. That is -- it makes it very interesting. So you're right, the capital allocation, it is the result of our strategy. And if anything, the COVID-19 is proven our strategy correct. It is, I think, a demonstration that we do have a reserves machine that has the resources of a big biopharma and the agility of a small biotech. I don't think that many people would bet that Pfizer will be the first one to complete something like that. But this is what we are building in the last few years, and this is the demonstration that we are there.

So our capital allocation, we never say never. But right now, the dividend will be maintained. Frank was very clear about it, a growing dividend. It is an important thing part of our investment thesis. And we will continue in very intensive rhythms to try to bring in Phase 2, Phase 3 predominantly, programs that through our R&D machine very quickly and very successfully can become medicines and vaccines that could generate revenues that will fill the gap, but -- from the 6%, so we can sustain the 6% beyond 2025.

Nothing changes also -- we do have higher flexibility in terms of cash, with COVID, clearly. But it is not that we were lacking cash before and we couldn't do basically things that we wanted to do. And now that makes it even more comfortable to do that.

Still, I don't think because you have this comfort level, we will do things that do not respect the fact that these are shareholders' money. So we will invest them very prudently. We are not going to spend them. But we are clearly ready to take risks when needed and also clearly ready to pay a full price for things that we really want. And as I said before, we never say never.

So Angela, how do you see VYNDAMAX evolving? Was there a bolus? Is it something that you can see growing? What is your views on that?

#### Angela Hwang - Pfizer Inc. - Group President of Biopharmaceuticals Group

So we have been really pleased with what we've seen with Vyndaqel/Vyndamax and the patients that we have been able to diagnose. And I think this has gone better than we thought actually, even with the pandemic.

Currently, this last quarter, we were able to diagnose 21% of the population with ATTR-CM. And so this increase that we've seen quarter-over-quarter gives us a lot of confidence that our ability to diagnose and the imaging techniques that are being used, the noninvasive techniques are working really well.



I would say the bolus is gone. That was something that was maybe in the first half of -- from the -- first half of the year when we launched. And I think where we are now is in a pretty good cadence of using our suspect and detect techniques as well as the ability to refer to imaging centers to get the diagnosis. And I think that our success rate in diagnosis is evidence of this.

And so I think we'll continue to see cadence like this. But of course, there's still massive opportunity, 80% more patients still to be diagnosed. And so we're really focused now on using technologies and different techniques to heighten and to look and to screen more effectively for patients. Because once we know that once we can find them, they can get diagnosed. So that's where our focus is going to continue to be in 2021.

#### Operator

Your next question comes from Tim Anderson from Wolfe Research.

#### Timothy Minton Anderson - Wolfe Research, LLC - MD of Equity Research

A couple of questions. On the mRNA platform, you talked about leveraging that technology. And outside -- there is outside of a COVID vaccine. I think you mentioned something like seasonal flu. I'm guessing time lines for any of those types of opportunities would be more normal. And I'm hoping you can kind of give us some idea, just a rough time line on when Pfizer and BioNTech might launch a non-COVID mRNA vaccine product totally unrelated to COVID-19. I'm guessing that would be something like 5 years away at a minimum, but maybe you can shed some light on that.

And then second question, just on guidance for 2021 and the other income line, a big number, \$2.2 billion, very much above the normal run rate for that line item. You mentioned the Consumer JV and ViiV and Viatris all going into that. The only brand-new piece there is Viatris. So can you just give us more details why that number goes so high in 2021? And importantly, what's the run rate for that line item beyond 2021?

#### Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you very much, Tim. Obviously, Frank will answer the second one and Mikael the first one. Let me also just make an introductory comment before I ask Mikael to speak about flu.

I believe the COVID thing has created a new normal. I don't think I will -- we are aspiring here in Pfizer to go back in the old normal of development time lines, even if we were, as you saw before, at the top of the industry benchmarks, right?

So if COVID, why not with cancer? If COVID, why not with flu? And I think that, clearly, with COVID, there was the collaboration of regulators that made that also possible, but it was a lot of other things that we have tested and we did differently than before.

So our aspiration is that these learnings will be clearly applied to everything in our portfolio and in our pipeline.

Now with that, Mikael, tell us a little bit how you see the time lines, where are we with the flu?

### Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

Yes. Thank you, Albert. And I think you said it well that the type of light speed approaches with the mRNA platform should, of course, be projected into other areas as well as flu. So Tim, you mentioned 2025, I think that it would be more conservative and traditionally realistical, and we are looking at ways to bring it as a potential product for approval earlier than 2025. Of course, it depends on whether there are good flu seasons with the cases coming along or not. And I think as life continues with vaccinated folks, flu will take up new momentum. So our aim is ahead of 2025.



#### Frank A. D'Amelio - Pfizer Inc. - CFO & Executive VP of Global Supply

And Albert, I'll answer on the other income, which is -- so Tim, let me run the numbers first, and then I'll answer the question. So you talked about the absolute size of the number in 2021 guidance. Remember, in 2020, our other income was about \$1.5 billion in adjusted results. So it's going from about \$1.5 billion to the guidance we gave, which was about \$2.2 billion.

The major elements in the increase are really transition service agreement recoveries, and that's primarily now as a result of closing the Viatris transaction, higher joint venture income and then we had some pension expense benefits as well. Those are the pieces that really get us from the, call it, \$1.5 billion in 2020 to the \$2.2 billion of guidance in 2021.

And then you asked about beyond '21. I think the way to think about beyond '21 just in terms of the cadence and the rhythm of that number is — the watch item for us will be what happens with the Consumer joint venture relative to what GSK decides to do with their portion of that venture. We own 32% of that venture. So we'll have to see what GSK does. And obviously, depending on what they do, that could impact our other income number going forward beyond that. So that's kind of the, I'll call it, the watch item for us in that line item.

### Operator

Your next question comes from the line of Geoff Meacham from Bank of America.

#### Jason Eron Zemansky - BofA Merrill Lynch, Research Division - VP

This is Jason on for Geoff. Real quickly, sorry to move back to COVID. But Frank, if you could talk a little bit about the vaccine, at least at a high level, about how the marginal contributions will change over time as manufacturing scales. I just want to get a better sense of the intermediate to longer term if COVID does ultimately transition to more of an endemic versus the pandemic.

And then secondly, we wanted to ask about next steps for Xeljanz after the recent safety data. Is the assumption here that the label will include these new data?

#### Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you very much. Frank?

### Frank A. D'Amelio - Pfizer Inc. - CFO & Executive VP of Global Supply

So let me -- Jason, let me do it this way. Let me talk about kind of how the current margins work, and then I'll pivot to how they can work going forward. So in terms of the current margins, I always start with, we're in a pandemic pricing environment. So the one price that we published is the price with the U.S. of \$19.50 per dose. Obviously, that's not a normal price like we typically get for a vaccine, \$150, \$175 per dose. So pandemic pricing.

Then what are the takeaways from that? Obviously, there's the direct material, the labor, the factory overhead, shipping, distribution. Then obviously, royalty assumptions we've made and then the 50% gross profit payment that we pay to our partner, BioNTech. Then you layer in on top of that some marketing and sales expense, some medical expense, some R&D expense, and you come out with the high 20s in terms of that as a percentage of revenue, what we guided to. That's kind of the existing financials for the vaccine.

Now let's go beyond a pandemic-pricing environment, the environment we're currently in. Obviously, we're going to get more on price. And clearly, to your point, the more volume we put through our factories, the lower unit cost will become. So clearly, there's a significant opportunity for those margins to improve once we get beyond the pandemic environment that we're in.



Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you very much, Frank. And then Angela, would you like to take also the Xeljanz?

### Angela Hwang - Pfizer Inc. - Group President of Biopharmaceuticals Group

Sure. So as it pertains to the label for Xeljanz, this is something that we don't have any sense of yet. This is a big study. 1133 was a big study, 5 years, 4,500 people. We only have the co-primary endpoints that we've shared with you. We still have a lot of work to do in terms of secondary endpoints, subpopulations and bringing all of this together to discuss this with regulators. So I think we're still a ways off in terms of really understanding what impact it will be to our label. And certainly, we'll keep you posted.

#### Operator

Your next question comes from the line of Ronny Gal from Bernstein.

#### Aaron Gal - Sanford C. Bernstein & Co., LLC., Research Division - Senior Research Analyst

Congratulations on the very impressive progress on COVID. And I got 2 questions, and they're both of the things that you haven't done. The first one is development of JAKs for RA. Obviously, you've got a really versatile platform for developing JAKs. And especially with NI to the Xeljanz's (inaudible) issue, it seems interesting. It should be interesting for you to consider a second-generation JAK in that core largest I&I market. So any thoughts about development there? And if there is, what will be the requirements for you?

The second one is about PD-1 approaches. You are participating in that market somewhat congenitally, if I had to put it that way. We've seen a couple of the other large pharma companies like Lilly and Novartis bringing in PD-1 simply as a base platform for combinations or maybe as a low-cost alternative in the current market. Have you considered that approach? And where do you come out on this issue?

#### Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

I think Mikael and John could provide some insights here. So Mikael, why don't you start a little bit with more scientific information? And then, John, you can summarize our strategy for JAKs and the PD-1 as a low cost alternative.

#### Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

Yes. Thank you. Our ritlecitinib, which is a completely unique JAK3/TEC inhibitor actually in a Phase 2 did deliver a really interesting profile. We have a study ongoing with that Phase 2 ritlecitinib by itself and combined with a second molecule, IRAK4, to see if we can do a step-change improvement in RA. Please recall also that we just communicated that ritlecitinib had really strong data in ulcerative colitis. So that product could grow very strongly in IBD as an option, but will continue in RA.

I'll say just something on our own PD-1, and maybe John can add to additional things we do globally there. We have a very nice, kind of best-in-class PD-1 platform, sasanlimab, that was developed in Pfizer that is subcutaneous and have delivered very nice response rates across multiple solid tumors. And we're actually starting a Phase 3 with that one in bladder cancer combining with BCG in order to improve outcomes for those patients.



#### John D. Young - Pfizer Inc. - Group President & Chief Business Officer

Thank you very much for the question, Ronny. I think Mikael sort of touched on the key points. I think we'd really just sort of highlight and obviously we have our existing partnership on BAVENCIO or PD-L1. I think you saw in our release that we confirmed the recent approval in Europe for a really interesting indication that could be very valuable for patients.

And as Mikael just said, additionally to that, with our own internal program, which is a PD-1, not a PD-L1, it's a PD-1 sasanlimab. In December, in fact, we initiated the study that Mikael just mentioned. And I think the thing that we are very excited about in terms of its potential for sasanlimab is that it's a subcutaneous PD-1.

We think the marketplace for more convenient PD-1s is actually still to be developed. Plainly PD-1s, given their efficacy data across a whole range of tumors have enormous potential to be a backbone for the long term. So we think that as that market evolves, the opportunity for a PD-1 that has effectiveness, which has been proven across multiple other compounds, but also combined significant convenience enhancements is actually very significant. So we're very excited about sasanlimab, and we will keep you updated with progress as that program develops.

#### Operator

Your next question comes from the line of Navin Jacob from UBS.

Navin Cyriac Jacob - UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutic

A couple of questions for Frank and one for Mikael, if I may. Frank, just wondering if you -- if there was any change in inventory in the U.S. during -- between Q3, Q4 of 2021 and -- sorry, 2020 and how does that compare to the change in inventory in the U.S. between Q3 and Q4 in 2019.

And then separately, Frank, the high 20% margins for the COVID vaccine suggests, at 100% economics, closer to 50% to -- somewhere between 50% to 60% op margin. But wondering -- because I know, obviously, you're investing a ton into R&D. Moving forward into 2022, could we -- how much could we see that operating margin increase over time as R&D spend lowers?

And then for Mikael. Mikael, obviously, a key question that everyone has is durability of efficacy, which is, in part, affected by new variants. But how exactly is the agency measuring durability of efficacy or requiring manufacturers or developers to measure durability of efficacy? What specific trials and/or endpoints or how is that characterized, please? Any color would be helpful.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Frank?

### Frank A. D'Amelio - Pfizer Inc. - CFO & Executive VP of Global Supply

So thanks for the question, Navin. So on the inventory, it's approximately 3 weeks on hand and roughly the same as it was last year at the end of the year. And in terms of Q3 to Q4, no major change in the rhythm of the inventory. Roughly, it's approximately 3 weeks on hand.

And then in terms of the high 20s percentage, it's interesting how you framed the question. Because the way I think about it is the R&D spend isn't the big -- it's not the big driver of what's getting us to that high 20s, which is kind of how I heard the question. It's really the COGS. And it's like I said, because primarily, it's the pandemic pricing. And then the different layers of the COGS that I answered earlier on in the Q&A, that's really what's driving gross, the higher -- the lower IBT as a percentage of margin. So I think you mentioned 50%. Based on all the current financials, we're lower, significantly lower than 50% on the gross margin. And then when you layer in the expenses, you get into the high 20s.



Now to your question beyond that, once again, I think the big factor in it will be the pricing. We'll continue to take the unit cost down as volumes improve. The royalty is what the royalty is. The profit share is the profit share is. Obviously, we're spending R&D, but we'll continue to manage the R&D spend. To me, the big-ticket item there will be what we can do on pricing. And then obviously, the more volume we generate, the lower it will take the unit cost. And those items will clearly drop to the bottom line.

#### Operator

Your final question comes from the line of Chris Schott from JPMorgan.

#### Christopher Thomas Schott - JPMorgan Chase & Co, Research Division - Senior Analyst

Just 2 quick ones here. Maybe on the BCMA bispecific. Can you just talk a little bit about how you see these agents fitting in the treatment paradigm and, maybe as importantly, how you're seeing the competitive landscape shaping up? So basically what differentiation do you see with your program versus others?

And maybe just then a follow-up on capital allocation priorities post-Upjohn. Share repo has -- the company has been historically pretty active on that front. Should we think about less or -- less relevant role for share repo in the paradigm going forward as we think about maybe a little bit higher dividend payout ratio and then some of these priorities to bring in additional assets ahead of the 26 through 28 LOE cycles? Just would love to kind of hear how you see that fitting in the mix.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Sorry, I was muted. Mikael, would you like to take the first question?

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

Yes. BCMA, elranatamab, we're very excited about that, right. And this had at a high dose, 1,000 microgram per kilogram, 83% response rate in a heavy pretreated population. And it has shown a significant number of stringent or complete responses. And it's given subcut. It has a very nice tolerability profile.

So although it's filled with several entrants, I think we have an opportunity to aim for being absolutely in the first wave here and with a really nice best-in-class profile. We're moving with first opportunity we see for accelerated approval in triple refractory patients that either have seen no prior BCMA-based treatment or have seen prior BCMA treatments such as ADC or CAR-T.

So we are planning such cohorts to start soon with a potential for registration. And we're moving into second and third line, in combination with classical image and other combinations that are used in order to come to first and second-line opportunity, particularly within it.

### Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thanks. And Chris, as regards to the stock repurchases, we never say never to anything, right? We don't want to leave any weapons, but we will say we never use. But clearly, the share repurchases fall at the bottom of the priorities right now. The dividend is a clear commitment, that of course, we will honor.

And we believe there are tremendous opportunities right now to invest in the business. As Frank has said, we have already an authorization from the Board that we could exercise at any point to buy back shares. And we could ask for a renewal. But this is not the priority right now. The priority, it is to make sure that we keep investing for business development and for infrastructure. So for example, our COVID franchise will thrive over time, and our R&D machine will get many more programs from the external world that can run through it.



Charles E. Triano - Pfizer Inc. - SVP of IR

Thank you. Albert, did you have some closing remarks?

#### Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

So wow, time flies, 11:30. So thank you very much for joining us today and for your continued engagement with Pfizer. The new Pfizer is all about 2 things: science and patients. I think it's the combination of a bold, decade-long transformation from a diversified enterprise to a more focused and innovative biopharma company. By uniting transformational technology and cutting-edge science, we are pioneering biopharmaceutical innovations to do more than just treat difficult diseases. I think we are curing and preventing them. We believe our success in developing COVID-19 was just the beginning. Thanks to the incredible transformation we have executed over the last 10 years, Pfizer is now advancing one of the strongest pipelines in our company's history.

We have 95 potential new therapies or indications in 6 therapeutic areas with 9 programs in registration, 24 in Phase 3 clinical trials. This means 95 potential opportunities to change the lives of patients around the world. And when patients win, we all win. Have a great rest of your day.

#### Operator

Ladies and gentlemen, this does conclude Pfizer's Fourth Quarter 2020 Earnings Conference Call. You may now disconnect.

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