Pfizer Investor Day Features Significant Number of Pipeline Advances for COVID-19 Programs and Across Numerous Therapeutic Areas

Tuesday, September 15, 2020 - 01:45pm

.q4default .bwalignc { text-align: center; list-style-position: inside }.q4default .bwlistcircle { list-style-type: circle }.q4default .bwlistdisc { list-style-type: disc }

Company has 89 pipeline projects spread across 6 targeted therapeutic areas with 4 programs in registration and 23 in Phase 3 27 key programs highlighted, including assets that could potentially contribute revenue by 2025 and others in the 2026-2028 time frame Pipeline contributes to the Company’s expectation of at least 6% revenue CAGR over the next five years – and delivery of longer-term topline growth beyond that period Major revenue contributions through 2025 anticipated from Oncology, Vaccines, Rare Disease and Inflammation and Immunology New stability, immunogenicity, and tolerability data for COVID-19 vaccine candidate, BNT162b2, presented
NEW YORK--(BUSINESS WIRE)-- As part of a two-day virtual Investor Day, Pfizer Inc. (NYSE: PFE) provided an extensive overview of pipeline advances and shared updates on the Company’s efforts to battle the COVID-19 pandemic on multiple fronts, including new data on the BNT162b2 vaccine candidate being developed in collaboration with BioNTech SE. The pipeline updates contribute to the Company’s expectation of at least a 6% revenue CAGR over the next five years, as well as delivery of longer-term topline growth beyond that period.

Pfizer’s goal of delivering up to 25 breakthroughs to patients by the year 2025 has 38 such opportunities to draw from as of today, including the company’s 20-valent pneumococcal conjugate vaccine candidate (20vPnC). On a non-risk adjusted basis, these opportunities collectively represent more than $15 billion (excluding 20vPnC) in potential

incremental revenue for Pfizer from 2020 to 2025, as well as aggregate peak annual sales potential of $35 billion to $40 billion (including 20vPnC). If successful, the Company's COVID-19 programs would be incremental to these estimates.

"Pfizer's purpose – Breakthroughs that change patients' lives – has never been more relevant, and our R&D pipeline has never been more dynamic," said Dr. Albert Bourla, Pfizer Chairman and CEO. "I am proud of the truly transformational science that our research and clinical teams are bringing to the fight against disease, as well as the unprecedented speed with which we are advancing our clinical programs in the battle against COVID-19. In the coming months and years, I look forward to the new Pfizer continuing to demonstrate the agility and innovative spirit of a biotech combined with the scale of Big Pharma. With the depth and breadth of our current portfolio, the tremendous potential of our pipeline and scientific engine, and the power of our culture of innovation, we are poised to continue delivering meaningful value to patients by addressing some of the world's most difficult health challenges."

UPDATES ON COVID-19 DEVELOPMENT PROGRAMS

Pfizer announced several key advances in its efforts to protect humankind from the COVID-19 pandemic and prepare the pharmaceutical industry to better respond to future global health crises.

BNT162 mRNA-based Vaccine Program

Pfizer and BioNTech shared several updates from their BNT162 mRNA-based vaccine program against SARS-CoV-2, the virus that causes COVID-19 disease, including:

Additional information on the BNT162b2 vaccine candidate, including new stability data that supports the storage of vials at refrigerated (2-8 °C) conditions for up to 5 days at the administration point of use locations. Phase 1 immunogenicity data for the BNT162b2 candidate at two weeks post second dose (35 days) provide additional data that neutralizing geometric mean titers remain higher than that of a panel of human SARS-CoV-2 convalescent sera, building on data previously shared by the companies. Limited blinded tolerability data from the ongoing Phase 3 trial, confirming the mostly mild to moderate tolerability profile as was observed in Phase 1. In the blinded data presented, 50% of trial participants received placebo and 50% received BNT162b2. Submission of an amended protocol to the FDA for the Phase 3 pivotal trial to expand recruitment to approximately 44,000 participants that allows for the enrollment of new populations. Enrollment in the trial has been proceeding as planned with current enrollment at more than 29,000. Based on current infection rates, the companies continue to expect that a

conclusive readout on efficacy is likely by the end of October.

Protease Inhibitor Program

The company announced the initiation of its Phase 1b clinical trial to evaluate the safety of a novel investigational therapeutic for COVID-19, PF-07304814. Of note,

The Phase 1b study is a double-blind, placebo-controlled clinical trial evaluating the safety, tolerability and pharmacokinetics of PF-07304814, a phosphate prodrug that when administered intravenously is metabolized to the active compound PF-00835321, shown to be a very potent inhibitor of the SARS-Cov2 3CL protease in preclinical studies. The start of this clinical study is supported by preclinical data conducted in collaboration with leading academic collaborators and demonstrates the anti-viral activity of this potential first-in-class SARS-CoV-2 therapeutic designed specifically to address COVID-19. Two manuscripts describing the preliminary preclinical data are currently available on preprint servers at Link and Link; both manuscripts are concurrently undergoing scientific peer review for potential publication.

THERAPEUTIC AREAS OF FOCUS

Pfizer shared significant research advances across its various therapeutic areas including candidates with blockbuster potential expected to launch by 2025.

Vaccines

In addition to the COVID-19 vaccine program, Pfizer aims to deliver five innovative vaccines by 2025, subject to clinical success and regulatory approval. Updates on these late-stage clinical development programs include:

New data for 20vPNC from a pediatric Phase 2 proof-of-concept study starting at two months of age describing safety and immunogenicity in a four-dose series. 20vPnC showed a safety and tolerability profile that was similar to Prevnar 13® Pneumococcal 13-valent Conjugate Vaccine[Diphtheria CRM197 Protein]. Based on the acceptable safety profile and the favorable immune response data, including the 4th dose response data, Pfizer received Breakthrough Therapy Designation. Full results will be presented as part of ID Week’s virtual 2020 medical congress in October 2020, and a Phase 3 program for 20vPnC in infants is ongoing. A Phase 2 proof-of-concept study of Pfizer’s potential first-in-class pentavalent meningococcal vaccine candidate (Penta; MenABCWY). The results demonstrated that Penta immune responses were robust and noninferior to licensed meningococcal vaccines (MenB and MenACWY) in individuals 10-25 years of age, regardless of prior MenACWY exposure. Noninferiority of each Penta dose was demonstrated across serogroups one month after the second dose for Penta and MenB,

and one month after the first dose for Penta and MenACWY. Penta was well tolerated. Detailed results from this study will be presented as part of ID Week's virtual 2020 medical congress in October 2020, and a Phase 3 trial in adolescents and young adults is ongoing. An update on Pfizer's potential first-in-class maternal vaccine candidate for the prevention of respiratory syncytial virus (RSVpreF). Clinical Phase 1/2 study results demonstrated never before observed fold rises of RSV neutralizing antibodies; a fold rise of 15.2 for RSV A and 18.0 for RSV B in women of childbearing age one month post-immunization, compared with the fold rises of 2-3 seen with post-fusion or insufficiently stabilized forms. Using these data, the Company applied modelling to predict potential efficacy for RSVpreF; based on the model's output, the investigational vaccine RSVpreF has a high probability to demonstrate meaningful efficacy in newborns when administered to pregnant women. A Phase 3 trial is ongoing.

Rare Disease

Pfizer's Rare Disease late-stage pipeline currently includes three gene therapy programs that, if successful, are expected to gain regulatory approval by the end of 2023, with an additional pipeline of 10 preclinical initiatives that are at various stages of maturity. Key updates include:

Data from the Phase 1b DMD gene therapy program, including data from an additional nine boys, who were all administered the high dose of the investigational therapy. A total of 15 boys have now been treated with the high dose and 18 boys have been treated overall. No Serious Adverse Events (SAE) were observed among the nine additional boys who were treated using a modified immunomodulatory regimen and monitoring regimen. The prophylactic steroid treatment was also changed from 1 mg/kg to an intermediate dose of 2mg/kg. Three of the nine boys were dosed with gene therapy product that was manufactured using the commercial manufacturing process developed at Pfizer's facility in Sanford, North Carolina. Based on these data, the Company plans to initiate the pivotal study in the next several weeks, with the plan to perform an interim analysis of the clinical data in 2022. For the Hemophilia B gene therapy program, the Company shared data from the Phase 1/2 study of fidanocogene elaparvovec, which demonstrated sustained expression of Factor IX activity in the ~20% of normal range at the four-year time point when administered at a dose of 5E11 vg/kg. These data represent the longest period of durability observed to date by a gene therapy for hemophilia B patients. Importantly, the mean annualized bleed rates (ABR) and the annualized infusion rates remained significantly reduced in these treated patients. Given the encouraging safety and efficacy profile, the Company initiated a Phase 3 study in 2019 and the prospective lead-in study with 40 patients has now been fully enrolled. The Company currently plans

to perform an interim analysis with 20 patients and 12 months of ABR in 2021. Given the sustained functional factor levels and the ABR rates that have been observed over a four-year period in the Phase 1/2 study, the Company believes that fidanacogene elaparvovec has the potential to be a best-in-class therapy for hemophilia B patients. For the Hemophilia A gene therapy program, an additional four months of expression data were presented for giroctocogene fitelparvovec showing sustained FVIII activity levels reflecting a mean of approximately 71% between weeks 9 and 52 in patients treated with a dose of 3E13 vg/kg of the viral vector. Patients with data beyond 52 weeks show consistent FVIII levels. Importantly, there have been no bleeds with this treated cohort. Patients are currently being enrolled in a Phase 3 lead-in study with plans to dose the first patient later this year.

Oncology

Pfizer’s Oncology pipeline has the potential to deliver up to 14 approvals expected by the end of 2025 and the potential for 24 new molecular entities in the clinic by the end of 2021. Key updates included, for the first time, early-stage opportunities obtained from the 2019 acquisition of Array BioPharma:

Two novel programs from the former Array BioPharma labs in Boulder, Colorado, have begun enrollment of first-in-human trials: a novel selective AXL/MERTK inhibitor as well as a brain-penetrant V600X BRAF inhibitor. Pre-clinical data for AXL/MERTK support durable anti-tumor immunity, both as a single agent and in combination with checkpoint inhibition. For the brain penetrant BRAF inhibitor, pre-clinical studies have shown that the molecule matches the anti-tumor activity of encorafenib in treating systemic disease and demonstrates superior activity in eradicating intracranial tumor implants. This molecule, in combination with binimetinib, has the potential, if successful, to represent a significant advancement over standard of care regimens in melanoma and other BRAF-driven cancers. Two additional next-generation targeted oncology programs from the Boulder labs take aim at HER2-Exon 20 and cMET-Exon 14; both programs are expected to enter the clinic in 2021. Encouraging activity was presented from a Phase 2 single-arm study of encorafenib, binimetinib plus cetuximab in previously untreated BRAFV6000E-mutant metastatic colorectal cancer (CRC). The majority of patients benefited from this combination with a high response rate of 50% and a disease control rate of 85 percent. These data provided a proof-of-concept to initiate a 3-arm Phase 3 clinical study BREAKWATER that is planned to start later this year. Pfizer also underscored several potential first-in-class or best-in-class programs, such as selective CDK2 and CDK4 inhibitors, as well as data for a BCMA-targeted bispecific antibody for the treatment of multiple myeloma, a HER2-Antibody Drug Conjugate for the treatment of breast cancer

and other HER2-expressing cancers. In a Phase 1 trial, more than 50 patients have now been treated with BCMA, with encouraging responses so far, including stringent complete responses, and responses in several patients who had previously experienced other BCMA-targeting agents. Pfizer's BCMA is administered subcutaneously, which has significantly reduced the incidence and grade of cytokine release syndrome and is more convenient for patients and physicians. Clinical testing with the HER2-ADC began in 2017, and to date a very impressive response rate in HER2+ breast and gastrointestinal cancers has been observed in a Phase 1 trial, including in many patients who had previously been treated with T-DM1. Pfizer’s HER2-ADC is highly differentiated from other HER2-ADCs with a very stable site-specifically conjugated cell-permeable auristatin payload that yields a molecule with the potential for an improved safety and potency profile.

Inflammation and Immunology

The Inflammation & Immunology pipeline is focused on patients with autoimmune and chronic inflammatory diseases across rheumatology, gastroenterology and dermatology, with five distinct immuno-kinases, in oral and topical formulations, studied for potential treatment of 10 diseases, and three additional novel biologics in Phase 2 studies. Key updates included:

Phase 2 data were presented from a proof-of-concept study for topical brepocitinib (dual TYK2/JAK1 inhibitor) in patients with mild-to-moderate atopic dermatitis. A Phase 2a randomized, placebo-controlled study to evaluate efficacy and safety of topical brepocitinib in 292 patients with mild-to-moderate atopic dermatitis showed strong dose-dependent efficacy with 42% of those treated with the 3% once-daily brepocitinib topical achieving at least a 90% or greater change from baseline in their Eczema Area and Severity Index (EASI-90) score by week six. The most frequent treatment-emergent adverse events were nasopharyngitis and atopic dermatitis. Safety and efficacy data from the JADE COMPARE study for abrocitinib and dupilumab compared to placebo in adults on background topical therapy. Abrocitinib 200 mg demonstrated statistically superior improvement in severity of pruritus (itch) compared to dupilumab at week two, a key secondary endpoint. After two weeks of therapy, 15% of patients on abrocitinib 200 mg had resolution of itch (PRNS Score 0 or 1). Safety was consistent with published data. These results, together with results from JADE MONO-1 and JADE MONO-2, support the regulatory filing for abrocitinib submitted in August 2020, with potential for U.S. approval in 2021.

Internal Medicine

The Internal Medicine pipeline addresses the increasing global burden of cardiometabolic disease, with nine investigational medicines in active clinical studies and additional therapies in the pre-clinical pipeline. Key updates included:

Phase 2a data for the potential first-in-class combination of clesacostat (PF-05221304), an investigational acetyl-CoA carboxylase inhibitor (ACCi), and ervogastat (PF-06865571), an investigational diacylglycerol acyltransferase 2 inhibitor (DGAT2i), for the treatment of non-alcoholic steatohepatitis (NASH). The six-week study found that the co-administration of clesacostat/ervogastat demonstrated a statistically significant reduction from baseline in liver fat (-40.13%) compared to placebo (8.14%) in participants with nonalcoholic fatty liver disease (NAFLD) and was safe and well-tolerated. These results were presented in August at the Digital International Liver Congress 2020. Pfizer has progressed both ervogastat monotherapy and the clesacostat/ervogastat combination into a Phase 2b liver biopsy study, and the results of this study will guide which candidate or combination is progressed to Phase 3. Clinical data and development plans for vupanorsen, an investigational antisense oligonucleotide to reduce ANGPTL3, a genetically-validated target for lipid and cardiovascular risk reduction. The team shared results from a Phase 2a study that was conducted by Akcea Therapeutics/Ionis Pharmaceuticals and previously disclosed at the recent European Society of Cardiology Congress 2020. The study met its primary endpoint, with vupanorsen demonstrating significant triglyceride lowering from baseline of -33.2%, -63.1%, -53.8% and -50.4% at doses of 10, 20, 40 and 60 mg, respectively, compared to a placebo reduction of -11.4% in participants with hypertriglyceridemia, type 2 diabetes and NAFLD. Vupanorsen also demonstrated a favorable safety and tolerability profile in this study. Pfizer is leading further development of vupanorsen, with a focus on cardiovascular risk reduction, and plans to initiate a Phase 2b dose-ranging study in the coming weeks. Phase 1 data and development plans for danuglipron (PF-06882961), which has the potential to be the first-ever small molecule oral GLP-1RA for treating obesity and type 2 diabetes. In the four-week Phase 1 study, which was previously presented at the American Diabetes Association Scientific Sessions in June 2020, danuglipron demonstrated robust reductions in fasting plasma glucose of -66.6, -80.6 and -89.7 mg/dL at doses of 15, 70 and 120 mg respectively, compared to a -24.8 mg/dL reduction for placebo. Danuglipron also reduced HbA1c by -0.9, -1.2 and -1.2% at doses of 15, 70 and 120 mg respectively, compared to a -0.4% reduction for placebo treated subjects. The higher doses of danuglipron reduced body weight by -4.0 kg (70 mg) and -7.9 kg (120 mg) relative to a -1.9 kg change in the placebo arm. Danuglipron was well tolerated in this study with an adverse event profile consistent with the GLP-1 class. Pfizer has initiated a Phase 2 study for danuglipron in type 2 diabetes and plans to initiate a second Phase 2 study in obesity in the fourth quarter of 2020.

To access a replay of the webcast, including audio, video and presentation slides, visit our web site at www.pfizer.com/investors.

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Disclosure Notice: The information contained in this release is as of September 15, 2020. Pfizer assumes no obligation to update forward-looking statements contained in this release or the webcast as the result of new information or future events or developments.

This release and the webcast contain forward-looking information about Pfizer's anticipated operating and financial performance, business plans and prospects, Pfizer's pipeline portfolio (including anticipated regulatory submissions, data read-outs, study starts, approvals, revenue contributions and market opportunities), and our efforts to respond to COVID-19, including our investigational vaccine candidate against SARS-CoV-2 and our investigational protease inhibitor, including their potential benefits, among other things, that are subject to substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; risks associated with interim and preliminary data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when any

drug applications, biologics license applications and/or emergency use authorization applications may be filed in any jurisdictions for any potential indication for Pfizer’s product candidates; whether and when any such applications that may be filed for any of Pfizer’s product candidates may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether any such product candidates will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of Pfizer’s product candidates, including development of products or therapies by other companies; manufacturing capabilities or capacity; uncertainties regarding the ability to obtain recommendations from vaccine technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; uncertainties regarding the impact of COVID-19 on Pfizer’s business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer’s Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned “Risk Factors” and “Forward-Looking Information and Factors That May Affect Future Results”, as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

View source version on businesswire.com: https://www.businesswire.com/news/home/20200915006138/en/

Media Relations: Amy Rose +1 (646) 592-3157 Amy.Rose@Pfizer.com

Investor Relations: Chuck Triano +1 (212) 733-3901 charles.triano@pfizer.com

Source: Pfizer Inc.