Pfizer Presents Positive Phase 2 Data in Alopecia Areata During Late-Breaker Session at the 27th European Academy of Dermatology and Venereology (EADV) Congress

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Pfizer Inc. (NYSE:PFE) today announced results from its Phase 2a study of PF-06651600, an oral Janus kinase (JAK) 3 inhibitor, and PF-06700841, a tyrosine kinase (TYK) 2/JAK1 inhibitor, compared to placebo, in patients with moderate to severe alopecia areata (AA), an autoimmune disease characterized by hair loss and often associated with profound psychological consequences. Both JAK inhibitors met the primary efficacy endpoint in improving hair regrowth on the scalp relative to baseline at week 24 (33.6 points and 49.5 points for JAK3 and TYK2/JAK1, respectively) as measured by the Severity of Alopecia Tool (SALT) score (100 point scale). The findings were presented during a Late-Breaking News session at the 27th European Academy of Dermatology and Venereology (EADV) Congress in Paris, France.

“We are pleased with these results and excited by the potential of kinase inhibition as a new therapeutic target for patients living with alopecia areata. This is the first well-controlled study of oral JAK inhibitors in alopecia areata, helping enhance our understanding of this disease with significant unmet need and advance the science of kinase inhibition,” said Michael Vincent, M.D, Ph.D., Senior Vice President and Chief Scientific Officer, Pfizer Inflammation and Immunology.

Based on the totality of the data and the emerging clinical profiles, the investigational JAK3 inhibitor, which was recently granted Breakthrough Therapy designation from FDA

for alopecia areata, is advancing to the next phase of development for moderate to severe AA and will continue to be evaluated for rheumatoid arthritis (RA), Crohn's disease (CD) and ulcerative colitis (UC). PF-06700841 will continue to be evaluated for psoriasis (PsO), CD and UC.

"People living with alopecia areata face a difficult journey as there are currently no approved treatments," said study investigator Rodney Sinclair, MD, Sinclair Dermatology, Melbourne, Victoria, Australia. "The results seen with these JAK inhibitors are very encouraging for me as a clinician as they signal a potential new way to think about the treatment of alopecia, which may bring hope for patients with this distressing condition."

About the Study

This Phase 2a, randomized, double-blind, multicenter study evaluates the efficacy, safety, and tolerability of PF-06651600 and PF-06700841 compared to placebo in patients with moderate to severe AA. Patients were randomized 1:1:1 to receive: PF-06651600 (200 mg once daily [QD] for 4 weeks, followed by 50 mg QD for 20 weeks), or PF-06700841 (60 mg QD for 4 weeks, followed by 30 mg QD for 20 weeks), or placebo.

The study found that the placebo-adjusted mean (95% CI) in SALT change from baseline scores at Week 24 were 33.6 points (21.4, 45.7), ($P<0.0001$) for PF-06651600 and 49.5 points (37.1, 61.8), ($P<0.0001$) for PF-06700841, with statistically significant separation from placebo occurring as early as Week 6 and Week 4, respectively.

In addition to meeting the primary efficacy endpoint, the investigational candidates also met all secondary endpoints in this study.

Overall, adverse event (AE) rates were comparable between treatment groups. The most common adverse events seen in the study were in the infections, gastrointestinal and skin/subcutaneous tissue categories. There were no cases of herpes zoster reactivation.

About Alopecia Areata

Alopecia areata (AA) is an autoimmune disease, characterized by hair loss, often patchy, on the scalp, face, or body.1,2 People suffering from AA experience symptoms when immune cells attack healthy hair follicles, causing the hair to fall out, often starting with smooth, round patches.1,2 The mean age of onset is between 25 and 35, but it can also impact children and adolescents, and is seen in both sexes and all ethnicities.1,2 More than half of patients with AA experience poor health-related quality of life and, as a result, the condition may lead to serious psychological consequences, including high

levels of depression and anxiety.1

Pfizer’s Kinase Inhibitor Leadership

The JAK pathways are believed to play an important role in inflammatory processes as they are involved in signaling for over 50 cytokines and growth factors, many of which drive immune-mediated conditions.1 JAK inhibition offers the potential for new advanced treatment options for these conditions through unique and targeted selectivity.

Pfizer has established a leading kinase research capability with multiple unique kinase inhibitor therapies in development. As a pioneer in JAK science, the Company is continuing to advance several investigational programs for molecules with novel selectivity profiles, which, if approved, could potentially deliver transformative therapies for patients. Pfizer has the following kinase inhibitors in trials across multiple indications:

PF-06651600: A JAK 3 inhibitor for RA arthritis, CD and UC; PF-06651600 received Breakthrough Therapy designation from the FDA for the treatment of patients with AA PF-06700841: A TYK2/JAK1 inhibitor under investigation for the treatment of PsO, CD and UC PF-04965842: A selective JAK1 inhibitor in Phase 3 clinical trials for the treatment of atopic dermatitis(AD)2; PF-04965842 received Breakthrough Therapy designation from the FDA for the treatment of patients with moderate to severe AD PF-06650833: An interleukin-1 receptor associated kinase 4 (IRAK4) inhibitor under investigation for the treatment of RA PF-06826647: A TYK2 inhibitor under investigation for the treatment of PsO and inflammatory bowel disease
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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. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. 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, 2018. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about PF-06651600 and Pfizer's ongoing investigational programs in kinase inhibitor therapies, including their potential benefits, that involves 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 trial commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing data; risks associated with preliminary data; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in any jurisdictions for any potential indication for PF-06651600 or any other investigational kinase inhibitor therapies; whether and when any such applications may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted, and, if approved, whether PF-06651600 or any such other investigational kinase inhibitor therapies will be commercially successful; decisions by regulatory authorities regarding labeling, safety and other matters that could affect the availability or commercial potential of PF-06651600 or any other investigational kinase inhibitor therapies; 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, 2017 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 .

_____ 1 Banerjee, S, Biehl, A, Gadina, M, et al. JAK–STAT Signaling as a Target for Inflammatory and Autoimmune Diseases: Current and Future Prospects.

Drugs. 2017;77: 521. https://doi.org/10.1007/s40265-017 2 J Med Chem. 2018 Feb 8;61(3):1130-1152. doi: 10.1021/acs.jmedchem.7b01598. Epub 2018 Jan 23.

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