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Pfizer Initiates Phase 2b/3 Clinical Trial for PF-06651600, an Oral JAK3 Inhibitor, for the Treatment of Patients with Moderate to Severe Alopecia Areata

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NEW YORK--(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today the initiation of a Phase 2b/3 clinical trial for its oral JAK3 inhibitor, PF-06651600, for the treatment of patients with moderate to severe alopecia areata, a chronic autoimmune skin disease that causes hair loss on the scalp, face, or body, and currently has no approved therapies.[1,2]

“We are proud to start this global pivotal Phase 2b/3 trial for PF-06651600 in patients with alopecia areata. We hope this potential treatment will be able to help patients who currently have limited treatment options,” said Michael Corbo, Chief Development Officer, Inflammation & Immunology, Pfizer Global Product Development. “Including our JAK3 program, Pfizer has several selective kinase programs in the clinic with studies spanning across rheumatology, gastrointestinal disorders, and medical dermatology, where we aspire to deliver potentially transformative medicines to those living with chronic autoimmune and inflammatory conditions.”

Positive Phase 2a data for PF-06651600 was recently presented as a late-breaker at the 27th European Academy of Dermatology and Venerology (EADV). The study met the primary efficacy endpoint in improving hair regrowth on the scalp relative to baseline at week 24 as measured by the Severity of Alopecia Tool (SALT) score (100 point scale). In addition to meeting the primary efficacy endpoint, the investigational candidate also met all secondary endpoints in the study. Overall, adverse event (AE) rates were comparable between treatment groups. The most common AEs seen in the study were in the infections, gastrointestinal and skin/subcutaneous tissue categories. There were no cases of herpes zoster reactivation.

Based on the totality of the data and the emerging clinical profile, PF-06651600 was granted Breakthrough Therapy designation from U.S. FDA for the treatment of alopecia areata in September 2018. PF-06651600 will also continue to be evaluated for rheumatoid arthritis, Crohn’s disease and ulcerative colitis.

About the PF-06651600 Phase 2b/3 Program

The pivotal trial will enroll an estimated 660 patients and will be a double-blind, placebo-controlled, dose-ranging study to evaluate the safety and effectiveness of PF-06651600 in adults and adolescents (12 years and older) who have 50% or greater scalp hair loss. More on the study can be found on www.clinicaltrials.gov under the identifier NCT03732807.

About Alopecia Areata

Alopecia areata is an autoimmune disease, characterized by hair loss, often patchy, on the scalp, face, or body.[1,2] People suffering from alopecia areata 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 alopecia areata 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]

About PF-06651600 and 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.[3] JAK inhibition may offer patients with these conditions a potential new advanced treatment option.[4]

PF-06651600 is an oral JAK3 inhibitor that is also under investigation for the treatment of rheumatoid arthritis, Crohn's disease and ulcerative colitis.[4]

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. In addition to PF-06651600, Pfizer has a number of kinase inhibitors in clinical trials across multiple indications, including:

- PF-04965842: An investigational selective JAK1 inhibitor in Phase 3 clinical trials for the treatment of atopic dermatitis(AD)[5]; PF-04965842 received Breakthrough Therapy designation from the FDA for the treatment of patients with moderate-to-severe AD in February 2018
- PF-06700841: A tyrosine kinase 2(TYK2)/JAK1 inhibitor under investigation for the treatment of psoriasis, Crohn's disease, ulcerative colitis and alopecia areata
- PF-06650833: An interleukin-1 receptor associated kinase 4 (IRAK4) inhibitor under investigation for the treatment of rheumatoid arthritis
- PF-06826647: A TYK2 inhibitor under investigation for the treatment of psoriasis and inflammatory bowel disease (IBD)

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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 January 3, 2019. 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.

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