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Pfizer Announces Positive Top-Line Results from Phase 2b/3 Trial of Ritlecitinib in Alopecia Areata

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– ALLEGRO 2b/3 trial met primary efficacy endpoint of improving scalp hair regrowth –

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced positive top-line results from the Phase 2b/3 ALLEGRO trial evaluating oral once-daily ritlecitinib in patients with alopecia areata, an autoimmune disease driven by an immune attack on the hair follicles that causes hair loss on the scalp and can also affect the face and body.[1,2] Ritlecitinib 50 mg and 30 mg achieved the primary efficacy endpoint of the study, namely the proportion of patients with less than or equal to 20 percent scalp hair loss after six months of treatment versus placebo.

“We are pleased by these positive results for ritlecitinib in patients with alopecia areata, a devastating and complex autoimmune disease for which there are currently no U.S. Food and Drug Administration (FDA) or European Medicines Agency approved treatments,” said Michael Corbo, PhD, Chief Development Officer, Inflammation & Immunology, Pfizer Global Product Development. “We look forward to bringing this potential new treatment option to patients living with alopecia areata as soon as possible.”

The Phase 2b/3 ALLEGRO trial met the primary efficacy endpoint of improving scalp hair regrowth. All participants entered the study with at least 50 percent scalp hair loss due to alopecia areata, as measured by the Severity of Alopecia Tool (SALT) score. A statistically significantly greater proportion of patients who took ritlecitinib 30 mg or 50 mg once-daily, with or without a four-week initial treatment of 200 mg once-daily, had 20 percent or less scalp hair loss (an absolute SALT score ?20) after 24 weeks of treatment compared with placebo. This was followed by a 24-week extension period, during which all participants initially randomized to receive ritlecitinib continued on the same regimen, while participants who received placebo during the initial 24 weeks advanced to one of two regimens: 200 mg for four weeks followed by 50 mg for 20 weeks, or 50 mg for 24 weeks. The study also included a 10 mg dosing arm, which was assessed for dose-ranging and was not tested for statistically significant efficacy compared to placebo.

The safety profile seen with ritlecitinib was consistent with previous studies. Overall, the percentage of patients with adverse events (AEs), serious AEs and discontinuing due to AEs was similar across all treatment groups. The most common AEs seen in the study were nasopharyngitis, headache and upper respiratory tract infection. There were no major adverse cardiac events (MACE), deaths or opportunistic infections in the trial. Eight patients who were treated with ritlecitinib developed mild to moderate herpes zoster (shingles). There was one case of pulmonary embolism in the ritlecitinib 50 mg group, which was reported to have occurred on Day 169. There were two malignancies (both breast cancers) reported in the ritlecitinib 50 mg group, which were reported to have occurred on Day 68 and Day 195. Both participants were discontinued from the study.

Full results from this study will be submitted for future scientific publication and presentation. These data, together with data that will become available from ALLEGRO-LT, will form the basis for planned future

regulatory filings.

Ritlecitinib is the first in a new investigational class of covalent kinase inhibitors that have high selectivity for Janus kinase 3 (JAK3) and members of the tyrosine kinase expressed in hepatocellular carcinoma (TEC) kinase family. In laboratory studies, ritlecitinib has been shown to block the activity of signaling molecules and immune cells believed to contribute to loss of hair in people with alopecia areata.[3]

Ritlecitinib, which was granted Breakthrough Therapy designation from the U.S. FDA for the treatment of alopecia areata in September 2018, is also being evaluated for vitiligo, rheumatoid arthritis, Crohn's disease and ulcerative colitis.

About the Phase 2b/3 ALLEGRO Trial

This randomized, placebo-controlled, double-blind study investigated ritlecitinib in patients 12 years of age and older with alopecia areata (n=718). Patients included in the study had 50 percent or more hair loss of the scalp, including patients with alopecia totalis (complete scalp hair loss) and alopecia universalis (complete scalp, face and body hair loss), and were experiencing a current episode of alopecia areata that had lasted between six months and ten years. Patients were randomized to receive ritlecitinib 50 mg or 30 mg (with or without one month of initial treatment with once-daily ritlecitinib 200 mg), ritlecitinib 10 mg or placebo.

The primary endpoint was the proportion of patients with scalp hair regrowth in response to ritlecitinib treatment, based on an absolute SALT Score ?20 at Week 24. SALT is a tool that measures the amount of scalp hair loss. The tool divides the scalp into standard regions, and each region contributes to the total SALT score, which ranges from 0 to 100. A SALT score of 0 corresponds to no scalp hair loss, while a SALT score of 100 corresponds to a total lack of hair on the scalp.[4]

More information about the Phase 2b/3 ALLEGRO trial can be found at https://www.clinicaltrials.gov under the identifier NCT03732807.

About Alopecia Areata

Alopecia areata is an autoimmune disease characterized by patchy hair loss, almost always involving the scalp, but sometimes also involving the face (eyebrows, eyelashes, beard), the whole scalp or the whole body.[1,2] People suffering from alopecia areata experience symptoms when immune cells attack healthy hair follicles, causing the hair to fall out.[1,2] The mean age of onset is between 25 and 35 years, but it can also impact older adults, children and adolescents, and is seen in both sexes and all ethnicities.[1,2] Alopecia areata is associated with poor health-related quality of life for many patients, who may suffer from serious psychological consequences, including depression and anxiety.[1]

About Pfizer Inflammation & Immunology

At Pfizer Inflammation & Immunology, we strive to deliver breakthroughs that enable freedom from day-to-day suffering for people living with autoimmune and chronic inflammatory diseases, which can be debilitating, disfiguring and distressing, dramatically affecting what they can do. With a focus on Rheumatology, Gastroenterology and Medical Dermatology, our current portfolio of approved medicines and investigational molecules spans multiple action and delivery mechanisms, from topicals to small molecules, biologics and biosimilars. Our differentiated R&D approach resulted in one of the broadest pipelines in the industry, where we purposefully match molecules to diseases where we believe they can make the biggest difference. Building on our decades-long commitment and pioneering science, we continue to advance the standard of care for patients with these debilitating diseases and are working hand-in-hand with patients, caregivers and the broader

healthcare community on healthcare solutions for the many challenges of managing chronic inflammatory diseases, allowing patients to live their best lives.

To learn more, visit www.pfizer.com/science/immunology-inflammation.

Pfizer Disclosure Notice

The information contained in this release is as of August 4, 2021. 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 a product candidate, ritlecitinib, including 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 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; 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 drug applications may be filed in any jurisdictions for any potential indication for ritlecitinib; whether and when any applications that may be pending or filed for ritlecitinib 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 ritlecitinib 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 ritlecitinib; uncertainties regarding the regulatory or commercial impact of or the results of clinical trials, including A3921133, or any potential actions by regulatory authorities based on analysis of such data; uncertainties regarding the impact of COVID-19 on our 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, 2020 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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