NOW ENROLLING IN ALOPECIA AREATA

For adults and adolescents with alopecia areata

Ritlecinitib (PF-06651603) is an investigational oral JAK3/TEC inhibitor with FDA Breakthrough Therapy designation for alopecia areata. The kinase activity of JAK3 and TEC family of non-receptor tyrosine kinases may play a role in the pathophysiology of several autoimmune diseases. This is a phase 3, open-label, multicenter, long-term study to evaluate the safety and efficacy of ritlecinitib in subjects aged 12 years and older with alopecia areata.

Planned countries for recruitment include Argentina, Australia, Canada, Colombia, Japan, Mexico, Russia, South Korea, Taiwan, and the United States.

*Breakthrough designation is defined as a drug under investigation with preliminary clinical evidence indicating that the drug may demonstrate substantial improvement over existing therapies on at least one clinically significant endpoint.

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**STUDY DESIGN**

- New subjects
- Subjects from prior study of ritlecinitib (NCT02974666 and NCT03732807)

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**CLINICAL ENDPOINTS**

- Treatment period (24 months)
- Ritlecinitib 200 mg for 1 month, 50 mg QD for 23 months
- Ritlecinitib 50 mg QD

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**ELIGIBILITY CRITERIA**

FDA=US Food and Drug Administration; JAK=Janus kinase; QD=once daily; TEC=tyrosine kinase expressed in hepatocellular carcinoma.

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Questions about a trial? Contact a Pfizer Clinical Trial Contact Center Representative:

https://www.pfizer.com/science/find-a-trial
Call center: 1-800-718-1021
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Efficacy and safety of these compounds, for the uses identified within, have not been established and are currently under investigation. Regulatory approval of any of these compounds or uses is dependent on the completion of the study programs and review and approval by regulatory authorities.

This is not a complete representation of all Pfizer pipeline compounds. This information is current as of April 28, 2020.
The clinical trial information is available at www.clinicaltrials.gov.
# NOW ENROLLING IN ALOPECIA AREATA

For adults and adolescents with alopecia areata¹

Ritlecitinib (PF-06651600) is an investigational oral JAK3/TEC inhibitor with FDA Breakthrough Therapy® designation for alopecia areata.²³

The kinase activity of JAK3 and TEC family of non-receptor tyrosine kinases may play a role in the pathophysiology of several autoimmune diseases.²¹²

This is a phase 3, open-label, multicenter, long-term study to evaluate the safety and efficacy of ritlecitinib in subjects aged 12 years and older with alopecia areata.¹

Planned countries for recruitment include Argentina, Australia, Canada, Colombia, Japan, Mexico, Russia, South Korea, Taiwan, and the United States.²

*Breakthrough designation is defined as a drug under investigation with preliminary clinical evidence indicating that the drug may demonstrate substantial improvement over existing therapies on ≥1 clinically significant endpoints.²

## STUDY DESIGN

### Primary endpoints¹

- Number of subjects reporting treatment-emergent adverse events (AEs), serious AEs, and AEs
- Number of subjects with clinically significant abnormalities in vital signs
- Number of subjects with clinically significant abnormalities in clinical laboratory values

## CLINICAL ENDPOINTS

### Key selected secondary endpoints¹

- Percentage of subjects achieving an absolute Severity of Alopecia Tool (SALT) Score ≤10
- Percentage of subjects achieving a 50%, 75%, and 90% improvement in SALT score from baseline
- Absolute SALT scores
- Percentage of subjects achieving a ≥2 grade improvement or a score of 3 in Eyebrow Assessment (EBA) score and Eyelash Assessment (ELA) score
- Change from baseline in Alopecia Areata Patient Priority Outcomes (AAPPO) scale scores
- Change from baseline in the depression scale and anxiety scale of the Hospital Anxiety and Depression Scale (HADS)
- Change from baseline in 36 Item Short Form Health Survey version 2 Acute (SF-36v2 Acute)

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¹FDA-US Food and Drug Administration; JAK=Janus kinase; TEC=tyrosine kinase expressed in hepatocellular carcinoma.

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**Efficacy and safety of these compounds, for the use identified within, have not been established and are currently under investigation. Regulatory approval of any of these compounds or uses is dependent on the completion of the study programs and review and approval by regulatory authorities.**

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NOW ENROLLING IN ALOPECIA AREATA

For adults and adolescents with alopecia areata

Riltecevimab (PF-06651600) is an investigational oral JAK3/TEC inhibitor with FDA Breakthrough Therapy designation for alopecia areata. The kinase activity of JAK3 and TEC family of non-receptor tyrosine kinases may play a role in the pathophysiology of several autoimmune diseases. This is a phase 3, open-label, multicenter, long-term study to evaluate the safety and efficacy of riltecevimab in subjects aged 12 years and older with alopecia areata.

Planned countries for recruitment include Argentina, Australia, Canada, Colombia, Japan, Mexico, Russia, South Korea, Taiwan, and the United States.

*Breakthrough designation is defined as a drug under investigation with preliminary clinical evidence indicating that the drug may demonstrate substantial improvement over existing therapies on ≥1 clinically significant endpoints.

STUDY DESIGN

- Key selected inclusion criteria:
  - ≥12 years of age or older
  - Eligible subjects originating from study NCT03732807 with ≥30 days between the first visit of this study and the last dose of study NCT03732807
  - For new subjects and those from prior studies of riltecevimab (NCT02974868 and NCT03732807) with ≥50 days between the last dose in the prior study and the first visit in the current study:
    - Clinical diagnosis of alopecia areata with no other cause of hair loss; androgenetic alopecia consistent with alopecia areata is allowed
    - ≥25% hair loss of the scalp due to alopecia areata, including alopecia totalis and alopecia universalis
    - No evidence of terminal hair regrowth within 6 months
    - Current episode of hair loss ≥30 years

CLINICAL ENDPOINTS

- Key selected exclusion criteria:
  - For new subjects and those from prior studies of riltecevimab (NCT02974868 and NCT03732807) with ≥30 days between the last dose in the prior study and the first visit in the current study:
    - Other types of diseases that can cause hair loss or that could interfere with assessment of hair loss/regrowth
    - Subjects with shared heads must not enter the study until hair has grown back and is considered stable by the investigator
  - If subjects previously received JAK inhibitors other than riltecevimab, they must have received the last dose ≥12 weeks prior to the screening visit

FDA=US Food and Drug Administration; JAK=Janus kinase; TEC=tyrosine kinase expressed in hepatocellular carcinoma.

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