Efficacy and Safety of Ritlecitinib (PF-06651600) in Patients With Alopecia Areata and ≥50% Scalp Hair Loss: Results From the International ALLEGRO Phase 2b/3 Randomized, Double-Blind, Placebo-Controlled Study (NCT03732807)

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Disclosures

Brett King: advisory boards and/or consultant and/or clinical trial investigator for AbbVie, Aclaris Therapeutics Inc, AltruBio Inc, Almirall, Arena Pharmaceuticals, Bioniz Therapeutics, Bristol Meyers Squibb (BMS), Concert Pharmaceuticals Inc, Dermavant Sciences Inc, Eli Lilly and Company (Eli Lilly), Incyte Corp, LEO Pharma, Otsuka/Visterra Inc, Pfizer, Regeneron, Sanofi Genzyme, TWi Biotechnology Inc, and Viela Bio; speaker bureaus for Pfizer, Regeneron, and Sanofi Genzyme.

Xingqi Zhang: no conflicts of interest.

Walter Gubelin Harcha: scientific advisor and/or clinical study investigator for Beiersdorf/Eucerin, BioNOOX, Eucerin, Galderma, GSK, Janssen, Johnson & Johnson, Pfizer, Sanofi.

Jacek C. Szepietowski: scientific advisor/consultant for AbbVie, Leo Pharma, Novartis, Sandoz, Sanofi-Genzyme, Trevi, and Viator; speaker for AbbVie, Eli Lilly, Janssen-Cilag, Lep Pharma, and Sanofi-Genzyme; investigator for AbbVie, Amgen, BMS, Galderma, Galapagos, Incyte, InfraRX, Janssen-Cilag, Menlo Therapeutics, Merck, Novartis, Pfizer, Regeneron, Trevi, and UCB.

Jerry Shapiro: consultant and/or clinical study investigator for 30 Madison, Eirion, Eli Lilly, Pfizer, and Regenlab; stockholder of 30 Madison.

Charles Lynde: speaker and/or consultant for AbbVie, Altius, Amgen, Arazel, Arcutis, Bausch Health, Bayer, Boehringer Ingelheim BMS, Celgene, Cipher, Dermavant, Eli Lilly, Fresenius Kabi, GlaxoSmithKline (GSK), Innovaderm, Integra Skin, Janssen, Kyowa, La Roche Posay, LEO Pharma, L’Oreal, Medexus, Merck, P&G, Pediapharm, Regeneron, Roche, Sanofi Genzyme, Sentiex, TEVA, Tribute, UCB, Valeant, and Viatris; principal investigator for AbbVie, Amgen, Arazel, Arcutis, Bausch Health, Bayer, Boehringer Ingelheim, BMS, Celgene, Cipher, Dermavant, Eli Lilly, GSK, Innovaderm, Janssen, Kyowa, LEO Pharma, L'Oreal, Merck, Pediapharm, Regeneron, Roche, Sanofi Genzyme, Tribute, UCB, and Valeant.

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Rana Fayyad: employee of and owned stock in Pfizer at the time this study was conducted.
Introduction

- Alopecia areata (AA) is an autoimmune disease characterized by nonscarring hair loss ranging from small bald patches to complete scalp and body hair loss (Perera et al. 2015)
  - Immunobiology of AA involves T cell attack on hair follicles mediated by INF-γ and IL-15, which signal through the JAK/STAT pathways
- No treatments for AA are currently approved by the FDA or EMA
- In a phase 2a trial, the JAK3/TEC inhibitor ritlecitinib (PF-06651600), demonstrated efficacy in patients with AA with ≥50% of scalp hair loss (King et al. 2021)

The ALLEGRO Phase 2b/3 study evaluated the efficacy and safety of multiple dosing regimens of ritlecitinib compared to placebo in regrowing hair in adult and adolescent patients with AA

EMA=European Medicines Agency; FDA=US Food and Drug Administration; IL=interleukin; INF-γ=interferon gamma, JAK/STAT=Signal Transducer and Activator of Transcription
ALLEGRO 2b/3: study design

- ALLEGRO 2b/3 was an international, randomized, double-blind, placebo-controlled, combined dose-ranging and pivotal phase 2b/3 study

- The ritocilatinib 10 mg treatment group was assessed for dose-ranging only and was not tested for superiority to placebo

- Primary endpoint was proportion of patients with a SALT score ≤20 at Week 24

- Safety was monitored throughout the study

BL=baseline; F/U=follow-up; QD-once daily; SALT=Severity of Alopecia Tool
ALLEGRO 2b/3: inclusion criteria

- Patients aged ≥12 years with a diagnosis of AA with ≥50% scalp hair (including patients with alopecia totalis and alopecia universalis)
- No evidence of terminal hair regrowth within 6 months at both the screening and baseline visits
- Maximum duration of current episode of hair loss ≤10 years

AA=alopecia areata
SALT and PGI-C scores

SALT score:

- Assessment of the amount of scalp hair loss (Olsen et al. 2004)
- SALT score ranges from 0–100:
  - 0: no scalp hair loss
  - 100: total scalp hair loss

PGI-C score:

- Self-administered questionnaire (patient-reported outcome)
- Patients rate the improvement or worsening of AA compared with start of the study, using a scale of 7 responses ranging from “greatly improved” to “greatly worsened”

AA=alopecia areata; PGI-C=Patient Global Impression of Change; SALT=Severity of Alopecia Tool
## ALLEGRO 2b/3: endpoints

<table>
<thead>
<tr>
<th>Primary and Key Secondary Endpoints at Week 24 (vs Placebo)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary endpoint</strong></td>
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<tr>
<td>Proportion with absolute SALT score ≤20</td>
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<tr>
<td>Proportion with absolute SALT score ≤10</td>
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<tr>
<td>Proportion with absolute SALT score ≤20</td>
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<tr>
<td><strong>Key secondary endpoint</strong></td>
</tr>
<tr>
<td>Proportion with absolute SALT score ≤10</td>
</tr>
<tr>
<td>Proportion with PGI-C score of “moderately improved” or “greatly improved”</td>
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<tr>
<td>N/A</td>
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<tr>
<td><strong>Additional secondary endpoints</strong></td>
</tr>
<tr>
<td>Proportion with PGI-C score of “moderately improved” or “greatly improved” ≥2-grade improvement in eyelashes and eyebrows (4-point scale ranging from 0 [none] to 4 [normal])</td>
</tr>
<tr>
<td><strong>Overall alpha (α)</strong></td>
</tr>
<tr>
<td>0.05 (2-sided)</td>
</tr>
<tr>
<td>0.01 (2-sided)</td>
</tr>
<tr>
<td>0.00125 (2-sided)</td>
</tr>
</tbody>
</table>

EMA=European Medicine Agency; FDA=US Food and Drug Agency; N/A=not applicable; PGI-C=Patient Global Impressions of Change; PMDA=Pharmaceuticals and Medical Devices Agency; SALT=Severity of Alopecia Tool
• The hypothesis tested was that each ritlecitinib group was superior to placebo on the primary and key secondary endpoints, following a pre-specified algorithm controlling family-wise Type I error using a gatekeeping approach.

• For the primary analyses of the overall study, patients with missing SALT score at Week 24 due to reasons related to the COVID-19 pandemic were excluded from the analysis; patients with missing scores due to other reasons were counted as non-responders.

• The Miettinen and Nurminen (MN) method was used to calculate confidence intervals for comparison between proportions.
## Results: baseline characteristics

<table>
<thead>
<tr>
<th>N=718</th>
<th>Placeboa (n=131)</th>
<th>Ritlecitinib 10 mg QD (n=63)</th>
<th>Ritlecitinib 30 mg QD (n=132)</th>
<th>Ritlecitinib 50 mg QD (n=130)</th>
<th>Ritlecitinib 200/30 mg QD (n=130)</th>
<th>Ritlecitinib 200/50 mg QD (n=132)</th>
</tr>
</thead>
</table>

### Age
- **Mean (SD), y**
  - Placebo: 34.0 (15.0)
  - 10 mg QD: 34.3 (13.9)
  - 30 mg QD: 33.7 (14.8)
  - 50 mg QD: 32.4 (13.4)
  - 200/30 mg QD: 33.7 (13.8)
  - 200/50 mg QD: 34.5 (15.0)

- **12–17 y, n (%)**
  - Placebo: 19 (14.5)
  - 10 mg QD: 9 (14.3)
  - 30 mg QD: 20 (15.2)
  - 50 mg QD: 18 (13.8)
  - 200/30 mg QD: 19 (14.6)
  - 200/50 mg QD: 20 (15.2)

- **≥18 y, n (%)**
  - Placebo: 112 (85.5)
  - 10 mg QD: 54 (85.7)
  - 30 mg QD: 112 (84.8)
  - 50 mg QD: 112 (86.2)
  - 200/30 mg QD: 111 (85.4)
  - 200/50 mg QD: 112 (84.8)

### Female, n (%)
- Placebo: 86 (65.6)
- 10 mg QD: 43 (68.3)
- 30 mg QD: 80 (60.6)
- 50 mg QD: 71 (54.6)
- 200/30 mg QD: 85 (65.4)
- 200/50 mg QD: 81 (61.4)

### Race, n (%)
- **White**
  - Placebo: 94 (71.8)
  - 10 mg QD: 42 (66.7)
  - 30 mg QD: 91 (68.9)
  - 50 mg QD: 79 (60.8)
  - 200/30 mg QD: 90 (69.2)
  - 200/50 mg QD: 92 (69.7)

### Severity of AA, n (%)
- **AT/AU groupb**
  - Placebo: 60 (45.8)
  - 10 mg QD: 29 (46.0)
  - 30 mg QD: 61 (46.2)
  - 50 mg QD: 60 (46.2)
  - 200/30 mg QD: 60 (46.2)
  - 200/50 mg QD: 60 (45.5)

### Baseline SALT score, mean (SD)
- **All patients**
  - Placebo: 93.0 (11.5)
  - 10 mg QD: 88.3 (16.9)
  - 30 mg QD: 90.0 (15.1)
  - 50 mg QD: 90.3 (14.7)
  - 200/30 mg QD: 90.5 (14.3)
  - 200/50 mg QD: 90.3 (15.1)

- **Non-AT/AU groupb**
  - Placebo: 87.0 (12.9)
  - 10 mg QD: 78.3 (17.6)
  - 30 mg QD: 81.5 (16.27)
  - 50 mg QD: 82.0 (15.9)
  - 200/30 mg QD: 82.4 (15.4)
  - 200/50 mg QD: 82.2 (16.5)

### Duration of current AA episode, mean (SD), y
- Placebo: 3.2 (2.65)
- 10 mg QD: 3.3 (2.65)
- 30 mg QD: 3.6 (2.82)
- 50 mg QD: 3.2 (2.67)
- 200/30 mg QD: 3.4 (2.89)
- 200/50 mg QD: 3.4 (2.93)

---

a Groups F and G: placebo for 24 weeks (and later switched to ritlecitinib).

b Participants in the AT/AU category had a SALT score of 100% at baseline as assessed by the investigator (regardless of the category in the AA history case report form). AA=alopecia areata; AT=alopecia totalis; AU=alopecia universalis; QD=once daily; SD=standard deviation; y=years
Results: SALT score ≤20

- The primary endpoint of SALT score ≤20 at Week 24 was met for the 200/50 mg, 200/30 mg, 50 mg, and 30 mg ritlecitinib groups
- SALT score ≤20 responses continued to increase up until Week 48
- At Week 48, response rates for 200/50 mg and 50 mg were numerically higher vs 200/30 mg and 30 mg; response rates for 10 mg remained low

* Indicates statistical significance compared to placebo for overall study (P<0.05), EMA (P<0.01) and FDA (P<0.00125). QD=once daily; SALT=Severity of Alopecia Tool
Results: SALT score ≤10

- The key secondary endpoint of SALT score ≤10 at Week 24 was met for the 200/50 mg, 200/30 mg, 50 mg, and 30 mg ritlecitinib groups.
- SALT score ≤10 responses continued to increase up until Week 48.
- At Week 48, response rates for 200/50 mg and 50 mg were numerically higher vs 200/30 mg and 30 mg; response rates for 10 mg remained low.

* Indicates statistical significance compared to placebo for overall study (P<0.05), EMA (P<0.01) and FDA (P<0.00125).

QD=once daily; SALT=Severity of Alopecia Tool
Results: PGI-C response

- For the EMA, the key secondary endpoint of PGI-C score of “moderately improved” or “greatly improved” at Week 24 was met for the 200/50 mg, 200/30 mg, 50 mg, and 30 mg ritlecitinib groups.
- At Week 48, response rates for 200/50 mg, 50 mg, 200/30 mg, and 30 mg were numerically higher vs 10 mg, which remained low.

* Indicates statistical significance compared to placebo for overall study (P<0.05), EMA (P<0.01) and FDA (P<0.00125).

EMA=European Medicine Agency; PGI-C=Patient Global Impression of Change; QD=once daily; SALT=Severity of Alopecia Tool
Results: eyebrows and eyelashes regrowth

• Proportions of patients with ≥2-grade improvement in eyebrows and eyelashes continued to increase up to Week 40

• At Week 48, response rates for ritlecitinib 200/50 mg and 50 mg were numerically higher compared with 200/30 mg and 30 mg; response rates for 10 mg remained low

a Among participants without normal eyebrows/eyelashes at baseline.
QD=once daily
Results: Photos at baseline and Week 24

Participant received Ritlecitinib 50 mg QD.
Results: efficacy summary

- At overall study level ($\alpha=0.05$), the primary endpoint of SALT score $\leq 20$ at Week 24 and key secondary endpoint of SALT score $\leq 10$ at Week 24 were met by the ritlecitinib 200/50 mg, 200/30 mg, 50 mg, and 30 mg treatment groups.
- For the EMA ($\alpha=0.01$), the primary endpoint of SALT score $\leq 10$ vs placebo at Week 24 and the key secondary endpoint of PGI-C score of “moderately improved” or “greatly improved” vs. placebo at Week 24 were met by the same 4 treatment groups.
- For the FDA ($\alpha=0.00125$), the primary endpoint of SALT score $\leq 20$ at Week 24 was met by the same 4 treatment groups.
- Eyebrow and eyelash hair regrowth was observed throughout the study, with numerically higher responses for higher doses of ritlecitinib.

EMA=European Medicines Agency; FDA=US Food and Drug Administration; PGI-C=Patient Global Impression of Change; SALT=Severity of Alopecia Tool
## Results: safety up to Week 24

<table>
<thead>
<tr>
<th></th>
<th>Placebo (n=131)</th>
<th>Ritlecitinib 10 mg QD (n=63)</th>
<th>Ritlecitinib 30 mg QD (n=132)</th>
<th>Ritlecitinib 50 mg QD (n=130)</th>
<th>Ritlecitinib 200/30 mg QD (n=130)</th>
<th>Ritlecitinib 200/50 mg QD (n=132)</th>
<th>All Patients (N=718)</th>
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<tbody>
<tr>
<td><strong>Permanent discontinuations</strong></td>
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<tr>
<td></td>
<td>2 (1.5)</td>
<td>2 (3.2)</td>
<td>7 (5.3)</td>
<td>3 (2.3)</td>
<td>4 (3.1)</td>
<td>3 (2.3)</td>
<td>21 (2.9)</td>
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<td>0</td>
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<td>1 (0.8)</td>
<td>0</td>
<td>1 (0.8)</td>
<td>4 (0.6)</td>
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<td>132</td>
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<td>129</td>
<td>131</td>
<td>715</td>
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<td></td>
<td>93 (71.0)</td>
<td>43 (69.4)</td>
<td>96 (72.7)</td>
<td>98 (75.4)</td>
<td>91 (70.5)</td>
<td>96 (73.3)</td>
<td>517 (72.3)</td>
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<td>12 (9.2)</td>
<td>10 (7.8)</td>
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<tr>
<td>Nasopharyngitis</td>
<td>8 (6.1)</td>
<td>6 (9.7)</td>
<td>16 (12.1)</td>
<td>13 (10.0)</td>
<td>18 (14.0)</td>
<td>15 (11.5)</td>
<td>76 (10.6)</td>
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<tr>
<td>Upper respiratory tract infection</td>
<td>10 (7.6)</td>
<td>2 (3.2)</td>
<td>11 (8.3)</td>
<td>8 (6.2)</td>
<td>10 (7.8)</td>
<td>16 (12.2)</td>
<td>57 (7.9)</td>
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<td><strong>Participants with SAEs</strong></td>
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<td>1 (0.8)</td>
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<td>4 (3.1)</td>
<td>10 (1.4)</td>
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</table>

All data are n (%) unless stated otherwise.

AE=adverse event; QD=once daily; SAE=serious adverse event
## Results: safety up to Week 48

<table>
<thead>
<tr>
<th></th>
<th>Placebo/50 mg QD (n=66)</th>
<th>Placebo/200/50 mg QD (n=65)</th>
<th>Ritlecitinib 10 mg QD (n=63)</th>
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<th>Ritlecitinib 50 mg QD (n=130)</th>
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<td></td>
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<tr>
<td>Due to AEs</td>
<td>3 (4.5)</td>
<td>0</td>
<td>2 (3.2)</td>
<td>6 (4.5)</td>
<td>4 (3.1)</td>
<td>2 (1.5)</td>
<td>2 (2.3)</td>
<td>19 (2.6)</td>
</tr>
<tr>
<td><strong>Temporary dose interruptions due to AEs</strong></td>
<td>8 (12.1)</td>
<td>13 (20.0)</td>
<td>5 (8.1)</td>
<td>16 (12.1)</td>
<td>20 (15.4)</td>
<td>16 (12.4)</td>
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<td>Participants evaluable for AEs</td>
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<td>132</td>
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<td><strong>Participants with AEs, n</strong></td>
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<td></td>
<td>57 (86.4)</td>
<td>54 (83.1)</td>
<td>47 (75.8)</td>
<td>106 (80.3)</td>
<td>110 (84.6)</td>
<td>105 (81.4)</td>
<td>108 (82.4)</td>
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<tr>
<td><strong>Headache</strong></td>
<td>8 (12.1)</td>
<td>8 (12.3)</td>
<td>12 (19.4)</td>
<td>24 (18.2)</td>
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<tr>
<td><strong>Nasopharyngitis</strong></td>
<td>4 (6.1)</td>
<td>7 (10.8)</td>
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<tr>
<td><strong>Upper respiratory tract infection</strong></td>
<td>6 (9.1)</td>
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<tr>
<td><strong>Participants with SAEs</strong></td>
<td>3 (4.5)</td>
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<td>2 (1.6)</td>
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<td>14 (2.0)</td>
</tr>
</tbody>
</table>

All data are n (%) unless stated otherwise.

AE=adverse event; QD=once daily; SAE=serious adverse event
Results: adverse events

- No major adverse cardiovascular events, deaths, or opportunistic infections were reported

<table>
<thead>
<tr>
<th>AEs of Special Interest</th>
<th>Placebo/50 mg QD (n=66)</th>
<th>Placebo/200/50 mg QD (n=65)</th>
<th>Ritlecitinib 10 mg QD (n=62)</th>
<th>Ritlecitinib 30 mg QD (n=132)</th>
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<th>Ritlecitinib 200/30 mg QD (n=129)</th>
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<td>Herpes zoster</td>
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</tbody>
</table>

\(^a\) 1 patient experienced 2 events of serious infections (empyema and sepsis).

AE=adverse event; QD=once daily; SAE=serious adverse event
ALLEGRO 2b/3: conclusions

• The ALLEGRO 2b/3 study met the primary endpoint of SALT score ≤20 and key secondary endpoint of SALT score ≤10 at Week 24 for ritlecitinib 50 mg QD and 30 mg QD (with or without loading dose of 200 mg QD)

• Response rates for ritlecitinib 200/50 mg QD and 50 mg QD were numerically higher vs 200/30 mg QD and 30 mg QD

• Response rates continued to rise up to Week 48 for SALT score ≤20 and SALT score ≤10

• Response rates as measured by the patient-reported outcome of PGI-C also increased throughout the study

• Hair regrowth in eyebrows and eyelashes was observed

• The safety profile was consistent with that observed in previous studies in healthy volunteers and in patients with AA

In conclusion, ritlecitinib doses of 50 mg and 30 mg QD (with or without loading dose of 200 mg QD) were efficacious, and generally safe and well tolerated over 48 weeks in patients with AA

PGI-C=Patient Global Impression of Change; QD=once daily; SALT=Severity of Alopecia Tool
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