High-dose spesolimab showed consistent efficacy in preventing GPP flares in patients, over 48 weeks, irrespective of IL36RN mutation status, the presence or absence of plaque PsO at baseline, or BMI category.

### INTRODUCTION

- **AIM**
  - To analyze the effect of high-dose spesolimab vs placebo on the prevention of GPP flares, over 48 weeks, in prespecified subgroups from the Effisayil 2 trial.

### METHODS

- **The primary endpoint:** Time to GPP flare, up to Week 48, and key secondary endpoint: proportion of patients with ≥1 GPP flare by Week 48, were analyzed for high-dose spesolimab (≥300 mg SC q12w) in the following prespecified subgroups:
  - IL36RN mutation status (yes/no)
  - Baseline comorbid plaque PsO status (yes/no)
  - BMI category (<25, 25 to <30, ≥30 kg/m²)

- **Patients** were classified as having a GPP flare if they had an increase in GPPGA total score ≥2 from a baseline score ≥2.

### RESULTS

#### Table 1. Primary endpoint: Time to GPP flare, up to Week 48, by prespecified subgroups

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Number of patients</th>
<th>Patients at risk</th>
<th>GPP flare within 48 weeks, %</th>
<th>HR (95% CI)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spesolimab high-dose</td>
<td>30</td>
<td>29</td>
<td>1/29</td>
<td>0.42 (0.15, 1.20)</td>
</tr>
<tr>
<td>Placebo</td>
<td>31</td>
<td>31</td>
<td>1/31</td>
<td>0.40 (0.15, 1.20)</td>
</tr>
</tbody>
</table>

*Adjusted risk difference (95% CI)*

#### Table 2. Key secondary endpoint: Proportion of patients with ≥1 GPP flare, by Week 48, by prespecified subgroups

<table>
<thead>
<tr>
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<th>Number of patients</th>
<th>GPP flare, %</th>
<th>HR (95% CI)*</th>
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### CONCLUSIONS

- **In Effisayil 2, high-dose spesolimab showed superiority vs placebo in preventing GPP flares over 48 weeks.**

- **In this subgroup analysis, spesolimab showed consistent efficacy in preventing GPP flares, over 48 weeks, regardless of IL36RN mutation status, the presence or absence of plaque PsO at baseline, or BMI category.**

- The main limitation of this analysis is the low patient number within each subgroup.

- The findings were generally consistent across all prespecified subgroups for the primary and key secondary endpoints.