Safety and Efficacy of Mepolizumab in Hypereosinophilic Syndrome: An Open-Label Extension Study

Aims

HES is a heterogeneous disorder characterized by elevated eosinophil counts in peripheral blood and/or tissues, marked deposition of eosinophilic granules in tissues, and eosinophil-mediated organ damage.1,2 Treatment options for FIP1L1-PDGFRα-negative HES include OCS and cytotoxic and/or immunosuppressive agents, which can fail to achieve complete disease remission and can have significant dose limiting side effects.3,4 Mepolizumab, a humanized monoclonal anti-IL-5 antibody, has recently been approved for the treatment of patients with HES, based on the results of the Phase II 200622 study (NCT02836496). This study demonstrated that mepolizumab significantly reduced disease flares and blood eosinophil counts versus placebo, with a favorable safety profile in patients with HES.5

Methods

This OLE study aimed to further investigate the safety and efficacy of mepolizumab in patients who had previously completed the double-blind study 200622 study.

Results

The safety profile of mepolizumab was consistent with previous reports.

Patient demographics and characteristics (n=52)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mepolizumab (n=50)</th>
<th>Placebo (n=52)</th>
<th>Total (n=102)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>44 (24–68)</td>
<td>47 (20–68)</td>
<td>45.5 (20–68)</td>
</tr>
<tr>
<td>Sex (M/F)</td>
<td>30/20</td>
<td>22/30</td>
<td>52/52</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>25 (22–30)</td>
<td>25 (22–30)</td>
<td>25 (22–30)</td>
</tr>
</tbody>
</table>

The annualized rate of HES flares was reduced from baseline with mepolizumab treatment.

Conclusions

Label extension with mepolizumab 300 mg SC plus background therapy has a favorable safety profile, without the development of neutralizing antibodies in patients with HES, consistent with previous reports.6

Mepolizumab was associated with reductions in OCS use among the initial OLE study population.

These results provide further evidence of the clinical benefit of mepolizumab in patients with uncontrolled FIP1L1-PDGFRα-negative HES.