CAPTAIN: Effects of Cardiovascular Risk on Response to Triple Therapy in Patients With Inadequately Controlled Asthma on Inhaled Corticosteroids/Long-acting β₂-agonists (ICS/LABA)

Poster No. 179

Hannah N1, Davies J2, Chang D1, Fowler AE1, Lim M1, Mannino DM1, Millard MIV1, Spix CJ1, Weinheit N1, Nathan R1

Background
- Approximately 30-60% of patients with asthma remain uncontrolled, despite adherence to standardized long-acting, agent (GCS/LABA) therapy.1
- The addition of a long-acting inhaled β₂-agonist (LABA) to ICS/LABA therapy has been shown to improve lung function,2-3 asthma exacerbations,4-5 and mortality.5
- The CAPTAIN (Cardiovascular and Pulmonary Treatment and Asthma Response Network) study was a phase III randomized, controlled trial in patients with asthma inadequately controlled on medium-dose ICS/LABA.
- The objectives of the subgroup analysis of CAPTAIN was to investigate the effects of adding UMEC 62.5 mcg to FF at prespecified doses on long-term asthma exacerbations and asthma control according to gender, ethnicity, CV risk at screening.

Aims
- To investigate the effects of adding UMEC 62.5 mcg to FF at prespecified doses on long-term asthma exacerbations and asthma control according to gender, ethnicity, CV risk at screening.

Methods
- The CAPTAIN study was a double-blind, placebo-controlled, parallel-group study (2 study phases: 2017-2018, NCT03519498). The study design is shown in Figure 1.
- Patients were randomized to receive either placebo, FF/VI 200/25*, FF/UMEC/VI 100/50/16.25, or FF/UMEC/VI 50/25/16.25 mg once daily for 52 weeks.
- Data for both UMEC doses (31.25 and 62.5 mcg) are included.

Results
- At screening, medium dose defined as >250 to ≤500 mcg/day FP (or UMEC) for CV risk subgroups.
- At screening, medium dose defined as >250 to ≤500 mcg/day FP (or UMEC) for CV risk subgroups.

Table 1: Baseline demographics and clinical characteristics

<table>
<thead>
<tr>
<th>Demographic/clinical characteristic</th>
<th>Placebo</th>
<th>FF/VI 200/25*</th>
<th>FF/UMEC/VI 100/50/16.25</th>
<th>FF/UMEC/VI 50/25/16.25</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years, mean)</td>
<td>53.6 (14.2)</td>
<td>52.9 (13.7)</td>
<td>53.2 (13.1)</td>
<td>53.2 (13.1)</td>
</tr>
<tr>
<td>Male, n (%</td>
<td>652 (57.0)</td>
<td>650 (56.8)</td>
<td>648 (56.2)</td>
<td>646 (56.0)</td>
</tr>
<tr>
<td>BMI, mean (mg)</td>
<td>27.6 (5.9)</td>
<td>27.6 (5.9)</td>
<td>27.6 (5.9)</td>
<td>27.6 (5.9)</td>
</tr>
<tr>
<td>CV risk at screening: yes</td>
<td>100 (8.7)</td>
<td>97 (8.3)</td>
<td>98 (8.6)</td>
<td>98 (8.6)</td>
</tr>
<tr>
<td>CV risk at screening: no</td>
<td>113 (9.8)</td>
<td>114 (9.8)</td>
<td>114 (9.8)</td>
<td>114 (9.8)</td>
</tr>
</tbody>
</table>

Table 2: Safety outcomes by CV risk at screening

<table>
<thead>
<tr>
<th>Event</th>
<th>Placebo</th>
<th>FF/VI 200/25*</th>
<th>FF/UMEC/VI 100/50/16.25</th>
<th>FF/UMEC/VI 50/25/16.25</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total adverse events, n (%)</td>
<td>366 (31.8)</td>
<td>364 (31.7)</td>
<td>363 (31.6)</td>
<td>362 (31.5)</td>
</tr>
<tr>
<td>CV adverse events, n (%)</td>
<td>10 (0.9)</td>
<td>9 (0.8)</td>
<td>9 (0.8)</td>
<td>9 (0.8)</td>
</tr>
</tbody>
</table>

Conclusions
- The addition of UMEC to FF at prespecified doses improved lung function and asthma control compared to placebo, with no significant differences between the UMEC doses.
- CV risk at screening was associated with a higher risk of CV events, but this was not significantly different between the UMEC doses.

References