ACIP Meningococcal Vaccine Working Group Suggests Waiting on Infant Vaccination

BY HEIDI SPLYTE

ATLANTA — The meningococcal vaccine working group of the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices believes “that the ACIP should consider not adding meningococcal conjugate vaccines to the routine infant vaccine schedule at this time,” said working group member Dr. Amanda Cohn.

At its fall meeting, the ACIP discussed safety and epidemiology data on meningococcal vaccines in development. The group concluded that “these products have not yet been licensed.”

The low burden of meningococcal disease in infants raises the question of whether every vaccine that is shown to be safe and effective should be recommended if the burden of disease is low, said Dr. H. Cody Messmer, chair of the working group.

ACIP made some recommendations for meningococcal vaccines were published in May 2005, and an update is planned for 2010, he noted.

**Table 1: Adverse Reactions (Regardless of Investigator Assessment Monotherapy and Add-On Combination Therapy**

<table>
<thead>
<tr>
<th>Condition</th>
<th>ONGLYZA: saxagliptin tablets</th>
<th>Placebo</th>
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<tbody>
<tr>
<td>Headache</td>
<td>5.0%</td>
<td>3.4%</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>0.7%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Platelets</td>
<td>46.6%</td>
<td>46.6%</td>
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</table>

In patients treated with ONGLYZA 2.5 mg, headache (3.5%) was the only adverse event reported in ≥5% of patients treated with ONGLYZA 2.5 mg and placebo, respectively.

In placebo-controlled trials that reported any gastrointestinal (GI) adverse events, ONGLYZA (2.5 mg) had an incidence of nausea (10.5%), vomiting (1.4%), and diarrhea (9.1%) versus placebo (5.5%, 1.5%, and 8.2%, respectively). No differences were observed in patients treated with ONGLYZA 5 mg versus placebo in any of these GI adverse events.

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In two placebo-controlled monotherapy trials of 24-weeks duration, patients were randomized to add-on therapy with ONGLYZA 2.5 mg daily, ONGLYZA 5 mg, or placebo. A 30% to 50% increase in platelet counts were observed in ≥5% of patients treated with ONGLYZA 5 mg, versus placebo.

In the add-on to TZD trial, the incidence of peripheral edema was higher for ONGLYZA 5 mg (3.5%) compared to placebo (2.0%). The most common adverse events (reported in at least 2% of patients) in the add-on to TZD trial were peripheral edema, joint pain, headache, and muscle spasms.

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