LETTER

Immunogenicity and safety profile of the monovalent A/H1N1 MF59-adjuvanted vaccine in patients affected by cystic fibrosis

Viral respiratory tract infections may determine lung function deterioration in patients affected by cystic fibrosis (CF). Viruses may have a synergistic action with bacteria to damage the respiratory tract; they may also promote airway bacterial colonisation. Influenza virus infection has been described to increase the number of CF pulmonary exacerbations and the incidence of hospitalisation. For this reason, vaccination is strongly recommended annually. The immunogenic effect and safety of influenza vaccines in CF children are comparable with that of healthy individuals. The reported adverse events after vaccination are mild and not persisting. In 2009, a novel swine pandemic influenza A virus (A/H1N1) was identified. To date, the outcome of H1N1 infection has been described only in CF adults, and no data are available about the safety and immunogenicity of the A/H1N1 vaccine administered to CF patients. The aim of our study was to evaluate safety and immunogenicity of the monovalent A/H1N1 MF59-adjuvanted vaccine in affected by cystic fibrosis (CF). Viruses may not have the same efficacy. Future clinical outcomes.

**Table 1** Demographics, immunogenicity and safety data of the study group

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Nutritional status</th>
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<tr>
<td>Patients: enrolled: 48</td>
<td>Patients: 18 yrs (n = 32): mean HAP 25.1</td>
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<td>Mean age: 14.4 years (range 8 months–26 years)</td>
<td>Patient: mean WAP 41.8</td>
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<td>M/F: 20/28</td>
<td>Mean BMI 21.9</td>
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<td>Pseudomonas colonisation: 29/48 (60.4%)</td>
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<td>Mean FEV₁: 86.5% ± 25.1</td>
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**Safety**

**Local reactions:** 13/48 (27.1%)

- Pain: 12/48 (25%)
- Swelling/redness: 7/48 (14.6%)
- Fever: 5/48 (10.4%)
- Myalgia: 4/48 (8.3%)
- Headache: 3/48 (6.3%)
- Fatigue: 3/48 (6.3%)
- Chills: 1/48 (2.1%)

**Systemic reactions:** 12/48 (25%)

- Headache: 3/48 (6.3%)
- Myalgia: 4/48 (8.3%)
- Fatigue: 3/48 (6.3%)
- Chills: 1/48 (2.1%)

- Chills: 1/48 (2.1%)

**Immunogenicity**

- Patients: assessed 33
- Mean CD4 T cell/μl (%): 1163 (42.3)
- Geometric mean titre (95% CI): 83 (60–91)
- Geometric mean ratio of HI titre (95% CI): 1163 (42.3)
- % Seroconversion (95% CI): 1163 (42.3)

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**Ethics approval** This study was conducted with the approval of the Bambino Gesù Children’s Hospital Ethic Committee.

**Provenance and peer review** Not commissioned; not externally peer reviewed.

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**REFERENCES**

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References

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