

**Supplementary Table 2a. GMT and seroconversion rate comparisons for QIV versus TIV in subjects 6 months to < 36 months of age.**

|          |                              |            | QIV   |              | Comparator vaccine      |     |                  |                 |               |
|----------|------------------------------|------------|-------|--------------|-------------------------|-----|------------------|-----------------|---------------|
|          |                              |            |       |              |                         |     |                  | GMT ratio or    |               |
|          |                              |            | Value |              | Value                   |     |                  | seroconversion  | Comparison    |
| Endpoint | Comparison                   | Strain     | M     | (95% CI)     | Vaccine                 | M   | (95% CI)         | rate difference | criteria met? |
| GMT      |                              |            |       |              |                         |     |                  | ---GMT ratio--- |               |
|          | Non-inferiority <sup>a</sup> | A/H1N1     | 947   | 747          | Pooled TIV <sup>b</sup> | 467 | 714              | 1.05            | Yes           |
|          |                              |            |       | (680; 821)   |                         |     | (624; 816)       | (0.89; 1.23)    |               |
|          |                              | A/H3N2     | 944   | 526          | Pooled TIV              | 467 | 571              | 0.92            | Yes           |
|          |                              |            |       | (492; 562)   |                         |     | (517; 632)       | (0.82; 1.04)    |               |
|          |                              | B/Brisbane | 948   | 72.8         | Licensed TIV            | 225 | 54.7             | 1.33            | Yes           |
|          |                              |            |       | (67.3; 78.7) |                         |     | (47.2; 63.4)     | (1.12; 1.59)    |               |
|          |                              | B/Florida  | 948   | 36.2         | Investigational         | 245 | 32.9             | 1.10            | Yes           |
|          |                              |            |       | (33.7; 38.8) |                         |     | TIV              | (28.7; 37.6)    |               |
|          | Superiority <sup>c</sup>     | B/Brisbane | 948   | 72.8         | Investigational         | 245 | 12.0             | 6.09            | Yes           |
|          |                              |            |       | (67.3; 78.7) |                         |     | TIV <sup>d</sup> | (10.3; 13.9)    |               |

|           |     |              |                           |     |              |              |     |
|-----------|-----|--------------|---------------------------|-----|--------------|--------------|-----|
| B/Florida | 948 | 36.2         | Licensed TIV <sup>d</sup> | 225 | 8.56         | 4.22         | Yes |
|           |     | (33.7; 38.8) |                           |     | (7.68; 9.54) | (3.62; 4.93) |     |

**Seroconversion rate****--- Difference in rate ---**

|                                     |     |              |                           |     |              |              |     |
|-------------------------------------|-----|--------------|---------------------------|-----|--------------|--------------|-----|
| Non-inferiority <sup>e</sup> A/H1N1 | 941 | 90.9         | Pooled TIV                | 466 | 89.3         | 1.6          | Yes |
|                                     |     | (88.8; 92.6) |                           |     | (86.1; 91.9) | (-1.6; 5.1)  |     |
| A/H3N2                              | 940 | 95.4         | Pooled TIV                | 466 | 92.5         | 2.9          | Yes |
|                                     |     | (93.9; 96.7) |                           |     | (89.7; 94.7) | (0.4; 5.9)   |     |
| B/Brisbane                          | 946 | 72.0         | Licensed TIV              | 225 | 64.9         | 7.1          | Yes |
|                                     |     | (69.0; 74.8) |                           |     | (58.3; 71.1) | (0.5; 14.1)  |     |
| B/Florida                           | 945 | 57.5         | Investigational           | 245 | 53.5         | 4.0          | Yes |
|                                     |     | (54.2; 60.6) | TIV                       |     | (47.0; 59.8) | (-2.9; 11.0) |     |
| Superiority <sup>f</sup> B/Brisbane | 946 | 72.0         | Investigational           | 245 | 14.7         | 57.3         | Yes |
|                                     |     | (69.0; 74.8) | TIV <sup>d</sup>          |     | (10.5; 19.8) | (51.5; 62.1) |     |
| B/Florida                           | 945 | 57.5         | Licensed TIV <sup>d</sup> | 225 | 6.7          | 50.8         | Yes |
|                                     |     | (54.2; 60.6) |                           |     | (3.8; 10.8)  | (45.7; 54.8) |     |

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Immunogenicity analyses were performed for subjects in the per-protocol analysis set, 6 months to < 36 months of age: QIV, N = 949; pooled TIV, N=470; licensed TIV, N=225; investigational TIV, N=245. M is the number of subjects with a valid serology result for the particular antigen.

Abbreviations: CI, confidence interval; GMT, geometric mean titer; QIV, quadrivalent influenza vaccine; TIV, trivalent influenza vaccine.

<sup>a</sup> Non-inferiority for GMT was met if the lower limit of the 2-sided 95% CI of the  $\text{GMT}_{\text{QIV}}/\text{GMT}_{\text{TIV}}$  ratio was  $> 0.66$ .

<sup>b</sup> The pooled TIV group includes subjects vaccinated with either licensed TIV or investigational TIV, combined.

<sup>c</sup> Superiority for GMT was met if the lower limit of the 2-sided 95% CI of the  $\text{GMT}_{\text{QIV}}/\text{GMT}_{\text{TIV}}$  ratio was  $> 1.5$ .

<sup>d</sup> Investigational TIV did not contain B/Brisbane; licensed TIV did not contain B/Florida.

<sup>e</sup> Non-inferiority for seroconversion rate (SCR) was met if the lower limit of the 2-sided 95% CI of the  $\text{SCR}_{\text{QIV}}$  minus  $\text{SCR}_{\text{TIV}}$  difference was  $> -10\%$ .

<sup>f</sup> Superiority for SCR was met if the lower limit of the 2-sided 95% CI of the  $\text{SCR}_{\text{QIV}}$  minus  $\text{SCR}_{\text{TIV}}$  difference was  $> 10\%$ .

**Supplementary Table 2b. GMT and seroconversion rate comparisons for QIV versus TIV in subjects 3 years to < 9 years of age.**

| Endpoint                     | Comparison | Strain | QIV          |                                     | Comparator vaccine |              |              | GMT ratio or<br>seroconversion<br>rate difference | Comparison<br>criteria met? |
|------------------------------|------------|--------|--------------|-------------------------------------|--------------------|--------------|--------------|---|-----------------------------|
|                              |            |        | M            | Value                               | Vaccine            | M            | Value        |   |                             |
|                              |            |        |              | (95% CI)                            |                    |              | (95% CI)     |   |                             |
| GMT                          |            |        |              |                                     |                    |              |              |   |                             |
| Non-inferiority <sup>a</sup> | A/H1N1     | 1390   | 1484         | Pooled TIV <sup>b</sup>             | 711                | 1453         | 1.02         | Yes   |                             |
|                              |            |        | (1380; 1595) |                                     |                    | (1312; 1609) | (0.90; 1.16) |   |                             |
|                              | A/H3N2     | 1390   | 1112         | Pooled TIV                          | 709                | 1058         | 1.05         | Yes   |                             |
|                              |            |        | (1046; 1183) |                                     |                    | (971; 1154)  | (0.95; 1.17) |   |                             |
|                              | B/Brisbane | 1390   | 96.6         | Licensed TIV                        | 356                | 71.2         | 1.36         | Yes   |                             |
|                              |            |        | (90.3; 103)  |                                     |                    | (62.6; 81.1) | (1.17; 1.57) |   |                             |
|                              | B/Florida  | 1390   | 88.5         | Investigational<br>TIV              | 353                | 86.9         | 1.02         | Yes   |                             |
|                              |            |        | (83.1; 94.1) |                                     |                    | (76.1; 99.2) | (0.89; 1.17) |   |                             |
| Superiority <sup>c</sup>     | B/Brisbane | 1390   | 96.6         | Investigational<br>TIV <sup>d</sup> | 354                | 27.3         | 3.54         | Yes   |                             |
|                              |            |        | (90.3; 103)  |                                     |                    | (23.4; 31.8) | (3.04; 4.13) |   |                             |

|           |      |              |                           |     |              |              |     |
|-----------|------|--------------|---------------------------|-----|--------------|--------------|-----|
| B/Florida | 1390 | 88.5         | Licensed TIV <sup>d</sup> | 356 | 24.4         | 3.63         | Yes |
|           |      | (83.1; 94.1) |                           |     | (21.6; 27.5) | (3.16; 4.16) |     |

**Seroconversion rate****--- Difference in rate ---**

|                              |            |      |              |                           |     |              |              |     |
|------------------------------|------------|------|--------------|---------------------------|-----|--------------|--------------|-----|
| Non-inferiority <sup>e</sup> | A/H1N1     | 1390 | 93.4         | Pooled TIV                | 711 | 92.8         | 0.6          | Yes |
|                              |            |      | (91.9; 94.6) |                           |     | (90.7; 94.6) | (-1.6; 3.0)  |     |
|                              | A/H3N2     | 1389 | 83.0         | Pooled TIV                | 708 | 78.8         | 4.2          | Yes |
|                              |            |      | (80.9; 84.9) |                           |     | (75.6; 81.8) | (0.7; 7.9)   |     |
|                              | B/Brisbane | 1390 | 71.7         | Licensed TIV              | 356 | 58.7         | 12.9         | Yes |
|                              |            |      | (69.2; 74.0) |                           |     | (53.4; 63.9) | (7.4; 18.6)  |     |
|                              | B/Florida  | 1390 | 71.9         | Investigational           | 353 | 71.4         | 0.6          | Yes |
|                              |            |      | (69.5; 74.3) | TIV                       |     | (66.4; 76.0) | (-4.5; 6.0)  |     |
| Superiority <sup>f</sup>     | B/Brisbane | 1390 | 71.7         | Investigational           | 354 | 23.7         | 47.9         | Yes |
|                              |            |      | (69.2; 74.0) | TIV <sup>d</sup>          |     | (19.4; 28.5) | (42.6; 52.7) |     |
|                              | B/Florida  | 1390 | 71.9         | Licensed TIV <sup>d</sup> | 356 | 25.0         | 46.9         | Yes |
|                              |            |      | (69.5; 74.3) |                           |     | (20.6; 29.8) | (41.6; 51.7) |     |

Immunogenicity analyses were performed for subjects in the per-protocol analysis set, 3 years to < 9 years of age: QIV, N = 1390; pooled TIV, N=711; licensed TIV, N=357; investigational TIV, N=354. M is the number of subjects with a valid serology result for a particular antigen. Abbreviations: CI, confidence interval; GMT, geometric mean titer; QIV, quadrivalent influenza vaccine; TIV, trivalent influenza vaccine.

<sup>a</sup> Non-inferiority for GMT was met if the lower limit of the 2-sided 95% CI of the  $\text{GMT}_{\text{QIV}}/\text{GMT}_{\text{TIV}}$  ratio was  $> 0.66$ .

<sup>b</sup> The pooled TIV group includes subjects vaccinated with either licensed TIV or investigational TIV, combined.

<sup>c</sup> Superiority for GMT was met if the lower limit of the 2-sided 95% CI of the  $\text{GMT}_{\text{QIV}}/\text{GMT}_{\text{TIV}}$  ratio was  $> 1.5$ .

<sup>d</sup> Investigational TIV did not contain B/Brisbane; licensed TIV did not contain B/Florida.

<sup>e</sup> Non-inferiority for seroconversion rate (SCR) was met if the lower limit of the 2-sided 95% CI of the  $\text{SCR}_{\text{QIV}}$  minus  $\text{SCR}_{\text{TIV}}$  difference was  $> -10\%$ .

<sup>f</sup> Superiority for SCR was met if the lower limit of the 2-sided 95% CI of the  $\text{SCR}_{\text{QIV}}$  minus  $\text{SCR}_{\text{TIV}}$  difference was  $> 10\%$ .