

**SUPPLEMENTARY TABLE 2. Prespecified outcomes\*<sup>†</sup> for recombinant zoster vaccine (RZV) in reports submitted to the Vaccine Adverse Events Reporting System (VAERS) — United States, October 2017–June 2018**

| Pre-specified outcome  | No. (%)   | Reporting rate <sup>§</sup> | Physician reviewer impression and description of selected reports  |
|--|-----------|-----------------------------|--|
| Herpes zoster (HZ)   | 196 (4.5) | 6.1                         | 110 reports of physician-diagnosed cases of HZ; 4 reports were not physician-diagnosed; 82 reports were misclassified  |
| Post-herpetic neuralgia  | 49 (1.1)  | 1.5                         | 45 reports of neuralgia or nerve pain, 15 of which were physician-diagnosed cases of post-herpetic neuralgia; 4 reports were misclassified   |
| Autoimmune disorders   | 20 (0.46) | 0.7                         | 8 reports of Guillain-Barré syndrome; 3 reports of patients with pre-existing autoimmune disorders; 1 report each of uveitis, transverse myelitis, and Steven-Johnson syndrome; 6 reports were misclassified   |
| Neuropathy   | 16 (0.37) | 0.5                         | 10 reports of neuropathy, 5 of which were physician-diagnosed; 6 reports were misclassified  |
| Inflammatory eye disease   | 14 (0.32) | 0.4                         | 9 reports of HZ near the eye, with subsequent ocular involvement (e.g., keratitis); 2 reports of primary HZ iridocyclitis; 1 report each of ocular HZ, HZ keratoconjunctivitis, and pre-existing ophthalmic HZ   |
| Acute myocardial infarction (AMI)  | 11 (0.25) | 0.3                         | 2 reports of AMI (83-year-old female and a 65-year-old female); 9 reports described either “rule out” AMI or history of ischemic cardiomyopathy  |
| Seizures/convulsions   | 11 (0.25) | 0.3                         | 2 reports met Brighton Level (BL) 1; 9 reports did not meet BL criteria  |
| Bell’s palsy   | 10 (0.23) | 0.3                         | 2 reports met BL3; 8 reports did not meet BL criteria  |
| Death  | 8 (0.18)  | 0.3                         | [described in the Results section]   |
| Guillain-Barré syndrome  | 8 (0.18)  | 0.3                         | 5 reports met BL2, 1 report met BL3, 2 reports did not meet BL criteria; these are the same 8 Guillain-Barré syndrome reports as in the autoimmune disorders   |
| Anaphylaxis  | 7 (0.16)  | 0.2                         | 1 report met BL1, with symptom onset the day after vaccination; 2 reports met BL2, with symptom onset “45 minutes” and “within hours;” 4 reports were misclassified  |
| Lymphadenitis  | 7 (0.16)  | 0.2                         | Reports primarily captured as a finding on physical exam, but not as the primary complaint or adverse event itself   |
| Stroke/cerebrovascular event (CVA)   | 7 (0.16)  | 0.2                         | 4 reports of CVA (51-year-old female with dyslipidemia and CVA the day after vaccination, 70-year-old female with hypercholesterolemia and CVA 2 days after vaccination, and incomplete information on remaining 2 reports); 3 reports were not CVA, but CVA was mentioned in the differential diagnosis |
| Co-administration of RZV with adjuvanted influenza vaccine and/or adjuvanted hepatitis B vaccine | 3 (<0.1)  | 0.09                        | All 3 reports described injection site swelling and pain; in 1 report, vaccines were given in the same arm   |
| Gout   | 3 (<0.1)  | 0.09                        | 2 reports of gout in the adverse event description; 1 report of a patient with pre-existing gout   |
| Autoimmune vasculitis  | 2 (<0.1)  | 0.06                        | Both reports were misclassified  |
| Idiopathic thrombocytopenic purpura  | 2 (<0.1)  | 0.06                        | 1 report of idiopathic thrombocytopenic purpura that responded to intravenous immunoglobulin and steroids; 1 report was misclassified  |
| Meningitis   | 2 (<0.1)  | 0.06                        | 1 report of presumed viral encephalitis and aseptic meningitis; 1 report of a patient with mental status changes – meningitis considered, but no explanation for symptoms found  |
| Supraventricular tachyarrhythmias  | 1 (<0.1)  | 0.03                        | Report of a patient who experienced a supraventricular tachyarrhythmia during hospitalization for septic shock   |
| Amyotrophic lateral sclerosis  | 0         | 0                           | No reports identified  |
| Optic ischemic neuropathy  | 0         | 0                           | No reports identified  |
| Osteonecrosis  | 0         | 0                           | No reports identified  |

\* Reports of pre-specified outcomes were identified using the search strategy described in the electronic Appendix; a single report could include multiple pre-specified outcomes because the patient experienced multiple adverse events or because a single MedDRA Preferred Term used to code the adverse event maps to multiple different pre-specified outcomes

<sup>†</sup> Brighton Collaboration standardized case definitions were available for seizures/convulsions, Bell’s palsy, Guillain-Barré syndrome, and anaphylaxis; Brighton Level (BL) 1 represents the highest level of diagnostic certainty, followed by 2, 3 and 4

<sup>§</sup> Reports of pre-specified outcomes per 100,000 RZV doses distributed in the United States during the analytic period.