SUPPLEMENTARY TABLE. Safety of one dose of Moderna mResvia respiratory syncytial virus vaccine in adults aged ≥60 years — Phase 1 and 2/3 pivotal efficacy trials, multiple countries, 2021–2024

Safety event	Risk for event, by group, n/N (%)		Relative risk (95% CI)[§]
	mResvia recipients*	Placebo recipients[†]	
Serious adverse event[¶]	2,300/18,416 (12.5)	2,299/18,375 (12.5)	1.00 (0.95–1.05)
Severe reactogenicity event**	1,120/18,221 (6.1)	726/18,160 (4.0)	1.54 (1.40–1.68)
Adverse events of special[††] interest	3/18,369 (<0.1)	9/18,316 (<0.1)	N/A

Abbreviation: RSV = respiratory syncytial virus.

* Represents number of events and percentage of all participants experiencing safety events among mResvia vaccine recipients across phase 2/3 and phase 1 trials.

[†] Represents number of events and percentage of all participants experiencing safety events among placebo recipients across phase 2/3 and phase 1 trials.

[§] Pooled relative risk of events in phase 2/3 and phase 1 trials.

[¶] Serious adverse events were defined as any untoward medical occurrence during all available follow-up time that resulted in death, was life threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent disability or incapacity, or was a congenital anomaly or birth defect.

** Severe reactogenicity events were defined as grade 3 or higher solicited local reactions (injection site pain, redness, swelling/induration, and ipsilateral axillary swelling or tenderness) or systemic reactions (fatigue, fever, headache, nausea/vomiting, arthralgia, myalgia, and chills) recorded during days 0–7 after vaccination. For injection site redness and swelling, grade 3 or higher corresponded to a diameter >100 mm. For fever, grade 3 or higher corresponded to a temperature >102°F (>39°C). For nausea/vomiting, grade 3 or higher corresponded to prevention of daily activity or requirement of outpatient intravenous hydration. For all other reactions, grade 3 corresponded to reactions that prevented daily activities, required use of prescription pain reliever, or required medical intervention.

[††]Adverse events of special interest include myocarditis, pericarditis, thrombocytopenia, neurologic events (Guillain-Barre syndrome, acute disseminated encephalomyelitis, Bell's palsy, and seizures), and anaphylaxis. Among mResvia recipients a total of 3 adverse events of special interest were observed as follows: 1 case of anaphylactic reaction (bee venom), 1 case of Bell's palsy, and 1 case of facial paralysis. The case of facial paralysis had onset four days after vaccination assessed as related to mResvia. Within 28 days and 42 days post vaccination, there was no imbalance in reports of facial paralysis (including Bell's palsy) between treatment groups.