Evaluate Vantage

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Moderna looks to spoil GSK and Pfizer's respiratory disease party

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Just when something was finally going right for GSK, with its adult respiratory syncytial virus vaccine, here comes a new contender. Based on interim pivotal data released yesterday, it looks like Moderna's mRNA-1345 could compete with both GSK and Pfizer's candidates on efficacy – although the cross-trial comparison is complicated by the companies' use of different disease definitions. In terms of timelines, Moderna is only slightly behind: it plans regulatory submissions this half, and could use a priority review voucher to speed the approval process, SVB analysts believe. GSK and Pfizer, meanwhile, are due FDA decisions by May. One fly in the ointment for Moderna could be toxicity, based on an another admittedly imperfect cross-trial comparison that gives Pfizer's jab the edge. Another question is how durable mRNA-1345 might prove, especially given the experience with the mRNA Covid vaccines. Both GSK and Pfizer are due to report two-season data by the June 2023 meeting of the Advisory Committee on Immunization Practices (ACIP); these results will indicate whether GSK's vaccine, being adjuvanted, might be longer lasting. Pivotal data are also expected soon with Johnson & Johnson's contender, Ad26.RSV.preF, and in mid-2023 with Bavarian Nordic's MVA-BN RSV.

Cross-trial comparison for RSV vaccines in ≥60 year olds

	Moderna	**GSK**	**Pfizer**
Candidate vaccine	mRNA-1345	RSVPreF3 OA (GSK3844766A)	RSVpreF (PF-06928316)
Pivotal study	ConquerRSV	Aresvi 006	Renoir
Vaccine efficacy*	83.7%	82.6%	66.7%
- Cases	9 vs 55 with placebo	7 vs 40 with placebo	11 vs 33 with placebo
Vaccine efficacy in severe disease	82.4%^	94.1%^^	85.7%^
- Cases	3 vs 17 with placebo	1 vs 17 with placebo	2 vs 14 with placebo
Any systemic AEs	?	33.6% vs 16.1% with placebo	27.4% vs 25.7% with placebo
≥Grade 3 systemic AEs	4.0% vs 2.8% with placebo	Myalgia: 1.4% vs 0.3% with placebo	Any SAE: 2.3% vs 2.3% with placebo
≥Grade 3 local AEs	3.2% vs 1.7% with placebo	Pain: 1.0% vs 0.0% with placebo	

**≥2 symptoms; ^≥3 symptoms; ^^severe disease according to clinical signs/investigator assessment or supportive therapy. Source: company releases.*

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