Evaluate Vantage

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Bavarian Nordic gets a vaccine booster

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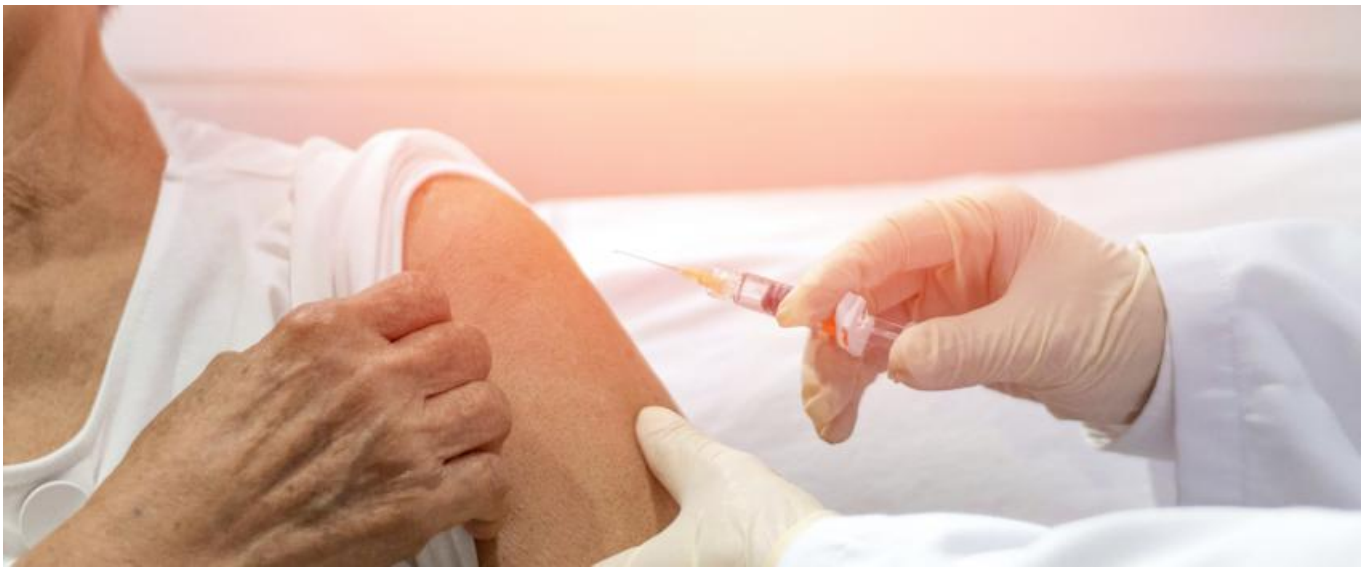

The Danish group reports promising mid-stage data with its respiratory syncytial virus vaccine, but competition is fierce.

There is no approved vaccine for respiratory syncytial virus, but several companies are hoping to change this. Bavarian Nordic marked itself out as a contender today with promising data from a mid-stage study of its candidate, MVA-BN RSV.

The Danish group could soon go toe-to-toe with the likes of Pfizer, Glaxosmithkline and Johnson & Johnson, but speed is of the essence, and Bavarian will need a partner to be able to compete. With RSV cases rising as post-Covid lockdown restrictions ease, at least carrying out trials might be getting easier.

Challenge accepted

The company's chief executive, Paul Chaplin, reckons the latest data should reignite partnering discussions, having sent Bavarian's stock up 9% today. The results come from a phase 2 trial in which 61 healthy adults received either MVA-BN RSV or placebo, followed by an intranasal challenge with RSV 28 days later.

The study met its primary endpoint, showing a significant reduction in viral load, measured by PCR testing, with MVA-BN RSV versus placebo over 12 days.

Furthermore, MVA-BN RSV was found to be 79% effective in preventing moderately symptomatic RSV, with a case defined as two positive PCR tests plus at least one grade two RSV symptom. Only two cases of moderate disease were seen with Bavarian's vaccine.

The project was less effective at preventing mildly symptomatic disease, or all cases including those that were asymptomatic, with efficacy of 76% and 52% respectively.

On a cross-trial basis the results look better than those seen with Johnson & Johnson's candidate, Ad26.RSV.preF, which was 52% effective in preventing moderate disease in its phase 2 challenge trial.

However, MVA-BN RSV's efficacy appears to fall short of that seen with Pfizer's PF-06928316. The pharma giant recently said its contender was 100% effective in its phase 2 challenge trial, but did not give many details.

Cross-trial phase 2 human challenge data with RSV vaccine candidates			
Project	**Company**	**Trial, N**	**Vaccine efficacy**
MVA-BN	Bavarian Nordic	NCT04752644, 61	79%*
PF-06928316	Pfizer	NCT04785612, 62	100%*
Ad26.RSV.preF	Johnson & Johnson	NCT03334695, 53	52%**
Note: efficacy figures given for moderately symptomatic disease (assumed for PF-06928316). *Sources: *company presentations; **Sadoff et al, Journal of Infectious Diseases, Jan 2021.*			

Mr Chaplin said during a conference call today that he assumed that the 100% figure quoted by Pfizer referred to prevention of moderately symptomatic RSV. He then questioned whether a difference of two cases between PF-06928316 and MVA-BN RSV was meaningful given the small study sizes involved.

MVA-BN RSV works differently versus the other late-stage candidates. While PF-06928316, Ad26.RSV.preF and Glaxosmithkline's GSK3844766A are based on the prefusion form of RSV's F protein, MVA-BN RSV incorporates five different RSV antigens including the F protein.

Bavarian says its candidate spurs a broad T-cell response, which could in turn help prevent severe disease.

Chasing

This needs to be proven, of course, and perhaps larger phase 3 trials will answer the question of which RSV vaccine is best. And here Bavarian is behind the pack. The company plans initially to develop MVA-BN RSV for elderly people, where Ad26.RSV.preF and GSK3844766A are already in pivotal trials. Meanwhile, PF-06928316 is set to enter a phase 3 study in adults this quarter.

Bavarian knows it needs to move fast, with Mr Chaplin saying: "It's all about time to market." The company had previously planned to run its pivotal study over two RSV seasons, but now looks likely to opt for a one-season trial in order to keep its rivals in sight.

Now all it needs to do is find a partner. The adult RSV vaccine market could be worth $7bn per year at peak, according to Leerink analysts, so interest could be high.

Selected RSV projects approved and in clinical development				
Product	**Company**	**Description**	**2026e sales ($m)**	**Trial details**
Marketed				
Synagis	Abbvie/Sobi	Fusion antibody	797	Indicated for prevention of RSV infections in high-risk infants
Phase 3				
Nirsevimab (SP0232)	Sanofi/Astrazeneca	Fusion antibody	715	Succeeded in Melody in healthy infants; Medley in sick infants ongoing; filing planned 2022
GSK3844766A	Glaxosmithkline	Protein subunit vaccine, adjuvanted	1,028	Aresvi 004 in adults ≥60; interim data H2 2022
GSK3888550A	Glaxosmithkline	Protein subunit vaccine	108	Grace maternal protection trial; interim data H2 2022
PF-06928316	Pfizer	Protein subunit vaccine	222	Maternal protection trial; adult trial planned
Ad26.RSV.preF	Johnson & Johnson	Adenovirus type 26 viral vector vaccine	16	Evergreen in adults ≥60
Clesrovimab (MK-1654)	Merck & Co	Fusion antibody	21	MK-1654-007 in infants, not yet recruiting
Phase 2				
MVA-BN RSV	Bavarian Nordic	Modified vaccinia Ankara viral vector vaccine	-	Human challenge trial completed; ph3 in elderly people planned for 2022
GSK3389245A	Glaxosmithkline	Chimpanzee adenoviral vector vaccine	-	Discontinued; had been in ph2 in infants
Phase 1				
mRNA-1345	Moderna	mRNA vaccine	-	NCT04528719 in adults & children
Source: Evaluate Pharma & clinicaltrials.gov.				