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Bavarian Nordic goes it alone, for now

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Phase 3 in RSV will begin without a partner, while decent Covid-19 booster data pave the way for pivotal development.

Bavarian Nordic has always been open about needing a partner for its respiratory syncytial virus vaccine candidate MVA-BN RSV. The group does not have one – yet – but this morning it said it would press on alone with an upsized phase 3 study, and would raise money to do so.

Investors were unimpressed, sending the group's stock down 6%. 2022 is shaping up to be a big year for the company: it also plans a pivotal trial of its Covid-19 vaccine ABNCoV2, after encouraging mid-stage booster data were released yesterday.

Even if Bavarian can launch ABNCoV2 in 2023, as hoped, it will still be a latecomer to the Covid party. The group reckons its jab, which is based on virus-like particles, can provide broader and longer-lasting protection than currently approved shots, although this is something that it has yet to prove. ABNCoV2 can also be stored in the fridge, which could make it an appealing option for poorer countries.

RSV plans

The company does not want to suffer the same fate in RSV. "We've said all along that we need a partner, but we need to start this phase 3 so we don't get further and further behind the competition," Bavarian's chief executive, Paul Chaplin, said during a conference call today.

He added that the decision to go solo took the pressure off partnering discussions, which will continue in parallel.

With an eye on speed, Bavarian has also changed the design of its phase 3 trial: this had previously been set to include up to 14,000 elderly people and to run across two RSV seasons. Now it will enrol up to 20,000 subjects and span just one RSV season, changes hinted at when the group reported positive phase 2 human challenge data.

And today the company put a price on the study, which is slated to start in the first half of 2022: around $250m. This will be funded via an equity raise of up to 10% of Bavarian's share capital; the group's market cap is DKK18.4bn ($2.8bn).

RSV is becoming a busy space, with Glaxosmithkline, Pfizer and Johnson & Johnson all expecting pivotal results next year.

But another player in the disease, Swedish Orphan Biovitrum, saw an $8bn private equity takeover unravel on Friday. That group has US rights to the marketed RSV fusion antibody Synagis, as well as a stake in the phase 3 follow-on project nirsevimab, via a 2018 deal with Astrazeneca.

Covid booster

In Covid, Bavarian also plans a pivotal trial next year, although this will be funded by the Danish Ministry of Health.

The group is still discussing the design with regulators, but has proposed a non-inferiority study comparing the immune response with a ABNCoV2 booster versus an approved vaccine. This looks likely to be an mRNA jab, as Mr Chaplin noted the importance of using a widely approved comparator.

Yesterday's mid-stage data came from 103 people who had previously received an approved mRNA or adenoviral vector vaccine and who then got a 100µg booster dose of ABNCoV2.

A spokesperson for Bavarian previously told *Evaluate Vantage* that the group wanted to see at least a twofold boost in neutralising antibody levels; the study met this goal, with a two to 40-fold increase in NAbs at two weeks. Responses were highest among those with the lowest antibody titres at baseline.

Similar increases were seen across the variants tested, namely Wuhan, Alpha, Beta and Delta. No data are available on the new Omicron variant; Bavarian said it was encouraged by results seen with the Beta variant, which shares several mutations with Omicron. The group has already started work on a new construct that could be specific for Omicron, Mr Chaplin said.

Results from 90 subjects receiving a 50µg ABNCoV2 booster, and 30 vaccine and infection-naive participants receiving two 100µg doses of the jab, are expected in the first quarter of 2022.

On the booster front, Bavarian now has one up on Valneva, another Covid vaccine laggard. The latter's VLA2001 showed promising immunogenicity versus Astrazeneca's Vaxzevria in phase 3; however, the UK Cov-Boost trial, published last week in The Lancet, tested several vaccines as boosters and found disappointing results with VLA2001.

Stifel and Leerink both said the UK government had these data when it terminated its contract with the company, explaining the reason behind this decision.