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Bavarian Nordic leaps ahead in Ebola race



Shares of the North American biotechs iBio, Tekmira Pharmaceuticals and Chimerix have soared and then deflated in the midst of the biggest-ever Ebola outbreak in the hope that their technologies could produce a winner in this space. But it is a European group, Bavarian Nordic, that has been first to deliver the goods.

The Denmark-based company licensed its preclinical vaccine MVA-BN Filo to Johnson & Johnson for nearly \$100m up front and a \$43m equity investment. The collaborators plan to deliver a million doses next year of an inoculation that is hoped will work against two strains of Ebola and the related filovirus Marburg.

News of the first big Ebola deal since the beginning of the outbreak gave a lift to shares in companies active in the space. Along with Bavarian's 26% jump to DKr189.00, shares in Tekmira rose 9% to \$19.58, iBio climbed 14% to \$1.99, while Chimerix was up 1% to \$30.57.

The possibility of a preventive vaccine being ready for clinical trials in May 2015 will come as cold comfort to the thousands living in areas affected by the virus and offers little hope to anybody who currently is suffering from the disease, but it is a sign of how this outbreak has kick-started a moribund area of research (*Therapeutic focus – Tekmira setback a sign of little Ebola progress, July 7, 2014*).

To name just a couple of developments, Mapp Biopharmaceuticals' ZMapp has been used in Western patients who have contracted the virus while on aid missions, exhausting the supply. Tekmira's RNAi project TKM-Ebola was rescued from clinical hold for use in patients, and Chimerix's cytomegalovirus vaccine brincidofovir (CMX001) has been accelerated into phase II development in Ebola with permission from the FDA.

Big pharma enters

The Bavarian-J&J agreement marks the first big pharma deal reached on any treatment or preventive project in this space. It comprises a \$25m up-front fee for commercial rights, a supply agreement worth \$70.8m immediately and a \$43m stake in Bavarian Nordic, equalling about 6.4% of the company.

Development and regulatory milestones worth \$20m are part of the agreement, as well as pro rata supply agreement payments worth \$28.5m as vaccine is delivered in 2015. Undisclosed commercial milestones outside Africa will be paid.

The supply agreement was based on the estimated cost of producing a million doses, which is a stockpile that J&J decided was necessary to help contain the disease based on discussions with the World Health Organization and other health groups, Bavarian's chief executive, Paul Chaplin, said in a conference call with analysts.

The collaboration plans on producing a two-part vaccination – priming with a J&J adenovirus vector based on the AdVac technology it acquired with the buyout of Crucell, and a boost from the MVA-BN Filo.

The combination has already been tested in animals, and is necessary to induce a long-term immune response, which the AdVac-based vector is unable to do alone, Mr Chaplin said. Safety and immunogenicity studies in healthy volunteers will begin in January; by May, 250,000 doses are expected to be available for broad clinical trials.

If this vaccine combination is part of a strategy to arrest the disease's spread, the two partners would also be in position to sign contracts with Western governments to fill biodefence stockpiles, but Mr Chaplin said the priorities were now on containing the current outbreak, which has infected more than 9,000 and killed 4,600, mostly in Guinea, Liberia and Sierra Leone.

"We both believe this is a commercially attractive position but we're also driven by the need to act responsibly and take our platforms forward in a way where we can help in a public outbreak situation," Mr Chaplin said.

With many thousands dead and many more worried about global spread, the immediate hope has been for a magic bullet treatment to emerge from a biotech laboratory. In the absence of that, a vaccine that holds the promise of limiting future outbreaks is the next best solution; J&J and Bavarian Nordic have taken a stride forward in that mission.

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