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AstriVax: thermostable, plug-and-play vaccines using plasmids

V-Bio Ventures and Fund+ lead €30M seed round for KU Leuven spinout

BY RICHARD GUY, BIOPHARMA ANALYST

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Backed by V-Bio Ventures and Fund+, AstriVax is aiming to reduce the cold chain requirements and simplify manufacturing of live-attenuated virus vaccines with its plug-and-play DNA plasmid platform.

The Belgian company was co-founded by KU Leuven academics Johan Neyts and Kai Dallmeier, along with CEO Hanne Callewaert, a six-year alum of GlaxoSmithKline plc (LSE:GSK; NYSE:GSK) vaccines. Callewaert told BioCentury that AstriVax's €30 million ($29.8 million) seed round, announced last month, was the largest-ever financing for a company spun out of the university.

Callewaert said AstriVax's plasmid-launched live-attenuated virus (PLLAV) platform is based on plasmids that encode live-attenuated versions of the yellow fever virus or Japanese encephalitis virus, with or without antigens from other pathogens. The plasmids are produced in bacteria and are delivered naked, without the need for a vector. After administration, their transcription results in production of attenuated viruses that trigger an immune response against the viruses themselves and any additional antigens encoded by the vaccine.

Callewaert said the attenuated viruses are capable of replicating and do so to a similar extent as approved live-attenuated vaccines made by other methods.

Live-attenuated virus vaccines against yellow fever date back to the 1930s, Callewaert said. "It's a great vaccine and can trigger both humoral and cellular immunity, but it's produced using chicken egg embryos, which is very labor-intensive." The nearly century-old production method also constrains supplies, she said.

The advantages of AstriVax's technology include the fact that DNA plasmids are naturally thermostable, removing cold chain requirements; they are easier to manufacture than the live-attenuated viruses themselves; and they "do not require a complex formulation," Callewaert said.

AstriVax's lead programs are prophylactic vaccines targeting yellow fever and rabies; it's also developing a therapeutic vaccine to treat hepatitis B.

The company selected its first two indications based on the availability of correlates of protection, as well as the track record of live-attenuated vaccines in preventing yellow fever. A successful yellow fever vaccine would validate the company's platform technology, said Callewaert.

In 2017, a coalition of Gavi, UNICEF and WHO launched a 10-year strategy to eliminate epidemics; the first of five "competencies of success" is facilitating creation of "affordable vaccines and sustained vaccine market."

The established correlates of protection in AstriVax's lead indications should obviate the need for the company to do efficacy studies, with approval instead based on demonstrating the vaccines elicit an immune response comparable to that of existing yellow fever and rabies vaccines.

Callewaert said that the company's rabies vaccine employs a plasmid encoding a live-attenuated yellow fever virus plus rabies antigens, so it should protect against both diseases, which could give it a market advantage over existing single vaccines.

In addition, if a single dose of the company's prophylactic rabies vaccine proves protective, she said it could "change the landscape of travel rabies vaccination."

Approved rabies vaccines are given prophylactically on a three-dose schedule, which can make them difficult to implement, Callewaert said. AstriVax has preclinical data showing that one dose of its rabies vaccine elicited levels of neutralizing antibodies similar to two doses of a commercial rabies vaccine.

AstriVax hopes its therapeutic vaccine for hepatitis B will prove the company's technology can induce $CD8^+$ T cells, which Callewaert said, "may be a very important component in the development of a functional cure."

Beyond its three disclosed programs, the company is developing a range of undisclosed prophylactic and therapeutic vaccines made possible by the plug-and-play nature of the platform, which enables DNA sequences encoding antigens from virtually any virus, as well as other pathogens, to be incorporated into the plasmids.

Callewaert declined to specify which additional indications the company is targeting, but she did say that AstriVax hopes to get its lead programs into the clinic by 2025. The company's seed funding should be sufficient to fund initial clinical studies, she added.

Callewaert believes AstriVax is the only company developing DNA vaccines that produce self-amplifying attenuated viruses that can carry additional antigens. Inovio Pharmaceuticals Inc. (NASDAQ:INO), for example, is developing DNA plasmid vaccines that code for antigens, not attenuated viruses. Inovio is also developing DNA-encoded mAbs therapies.

Flanders Future TechFund, Thuja Capital, Ackermans & van Haaren, Mérieux Equity Partners, BNP Paribas Fortis Private Equity and the KU Leuven Gemma Frisius Fund participated in AstriVax's financing.

AstriVax said Monday that Jeanne Bolger, former VP of alliance management at the Janssen Alzheimer Immunotherapy of Johnson & Johnson (NYSE:JNJ) and 13-year veteran of GSK, will chair its board as a non-executive independent director.

COMPANY PROFILE

AstriVax N.V.
Leuven, Belgium
Technology: Prophylactic and therapeutic DNA plasmid vaccines
Origin of technology: KU Leuven
Disease focus: Infectious
Clinical status: Preclinical
Founded: 2022 by Johan Neyts, Kai Dallmeier and Hanne Callewaert
Academic collaborators: KU Leuven Rega Institute
Corporate partners: None
Number of employees: 5-10
Funds raised: €30 million ($29.8 million)
Investors: V-Bio Ventures, Fund+, Flanders Future TechFund, Thuja Capital, Ackermans & van Haaren, Mérieux Equity Partners, BNP Paribas Fortis Private Equity and the KU Leuven Gemma Frisius Fund
CEO: Hanne Callewaert
Patents: Several issued covering product and production