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Swiss startup Arvelle preps for FDA decision on epilepsy drug

By Nuala Moran, Staff Writer

LONDON – The Swiss headquarter operations of Arvelle Therapeutics GmbH are taking shape as the company awaits the outcome later this month of the FDA's deliberations on its in-licensed asset, cenobamate, and prepares to apply for EMA approval for the novel epilepsy treatment in the first half of 2020.

Arvelle was formed earlier this year to take on European commercialization of cenobamate, a drug discovered and developed in the U.S. by SK Life Sciences, part of one of South Korea's largest industrial conglomerates.

Mark Altmeyer, CEO, Arvelle

SK Life Sciences filed the FDA new drug application in February, and with a PDUFA date of Nov. 21 promising short-term commercial returns, Arvelle was able to raise startup funding of $207.5 million, one of the largest series A rounds for a European biopharmaceutical company.

The NDA submission is based on data from trials in which more than 1,900 patients suffering from partial, or focal, seizures were treated. Arvelle has to put together a pediatric investigation plan for the EMA, but beyond that does not expect to have to generate any European data.

"We believe there's sufficient data on file already," said Arvelle co-founder and CEO Mark Altmeyer. "That's one reason why FDA approval will be so significant."

In addition to focal onset seizures, the drug also is being evaluated in adults with primary generalized epilepsy.

With a fair wind, Altmeyer expects to reach market in the next 18 months or so. "The nice thing about being a late-stage company is that $200 million gets us to initial launches," he said. "We will then have to have a separate financing to get through to profitability; given the late stage, we've got a clear sense of how much will be required," Altmeyer told *BioWorld*.

In addition to hiring key staff for the Zug, Switzerland-based headquarters, Arvelle has started to build commercial operations in Germany and the U.K., the two countries where it expects to get the fastest pricing decisions once cenobamate is approved.

Although the mechanism of action of cenobamate is not fully elucidated, it is thought to act both as a sodium channel blocker and by modulating GABAA receptors.

As a veteran of commercializing central nervous system (CNS) products, including leading the launch of the antipsychotic Abilify (aripiprazole, Otsuka Pharmaceutical Co. Ltd.), Altmeyer is not concerned that the precise mechanism of action is not clear. "I've worked in CNS for 25 years," he said. "I don't think anyone ever had a good idea about how any drug worked in the brain."

Whatever the gaps, Altmeyer said there is enough data to establish cenobamate as a useful addition to the current range of epilepsy treatments.

Around 60% of people with epilepsy suffer from focal seizures, located in just one part of the brain. Although there are a number of very effective generic drugs, some 40% of patients continue to have seizures after one or two lines of treatment, a statistic Altmeyer said hasn't shifted for 30 years.

"There is a need for agents with a novel mode of action," he said. That unmet need, coupled with the fact that countries in Europe have well-developed care pathways, provides a relatively easy route to build market share, Altmeyer said.

"[Patients] get referred to centers of excellence very quickly, so we don't need a large footprint on the commercial side; it's very manageable," he said.

In the U.S., SK Life Sciences has the aim of becoming a leader in CNS. In addition to epilepsy, cenobamate has data in treating neuropathic pain and bipolar disorder. The Fair Lawn, N.J.-based company also is working on four other CNS drugs. (See *BioWorld*, Feb. 9, 2019.)

While for now Arvelle is focusing solely on commercialization of cenobamate, in the future the intension is to leverage the marketing organization it is building to take in other CNS products. Altmeyer pointed in particular to the use of cenobamate in other indications. "Given the clinical data and the mechanistic rationale, it could be a pipeline in a product," he said.

Arvelle paid SK Life Sciences $100 million up front for the European license to cenobamate and could pay up to $430 million more in regulatory and commercial milestones. There will then be royalties on net sales.

Before forming Arvelle, Altmeyer and his two co-founders, Ilise Lombardo, chief medical officer, and Gregory Weinhoff, chief financial officer, worked for Axovant, the Switzerland-headquartered company that hit the rocks last year after a series of clinical trial failures, including in Alzheimer's disease, Lewy body dementia and Parkinson's disease. (See *BioWorld*, June 7, 2018.)

Axovant has since regrouped and emerged as a gene therapy specialist. There is no connection between Arvelle and Axovant. (See *BioWorld*, March 12, 2019.)

Arvelle's series A round was led by Amsterdam-based Life Science Partners with Novaquest Capital Management, BRV Capital Management, Andera Partners and H.I.G. Biohealth Partners. ♦