Korean biotech buys GMP-ready production facility in California

by Eric Palmer | Aug 22, 2018 12:21pm

Korean biotech ViroMed has acquired a manufacturing facility in the U.S. for production of the gene therapies its is developing. (Public Domain Pictures)

Korean biotech ViroMed has seen companies miss out on approvals for novel therapies because the FDA had problems with their manufacturing processes. With its first treatment nearing the completion of phase 3 trials, the company says it has taken steps to avoid that trap.

The Seoul-based biotech this week said that in a joint venture partnership with a private equity investment firm, it had acquired a GMP ready facility in San Diego, California, from Vical Inc. Terms of the deal were not disclosed.

Until recently, the production site was used for clinical studies that included phase 3 trials in the U.S. of DNA-based investigational drugs, ViroMed said. The Korean company's lead product VM202 (donaperminogene seltoplasmid) is a gene therapy for the treatment of painful diabetic peripheral neuropathy (PDPN).

The facility in San Diego has a 500 L fermenter, cell culture lab and quality control test lab, as well as space for expansion, ViroMed said in its announcement. With plans for test runs within this year and GMP production in the first half of 2019, the company said it is hiring key personnel to operate the facility and expects to have 25 people on board in the next few months.

The company said a comparability test will be required by regulatory authorities for the facility since the production site is different from the ones that manufactured the drug used in past and current clinical studies. ViroMed CEO Sunyoung Kim said he does not expect that to be an issue.

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ViroMed said it is currently the only company conducting phase 3 trials in the U.S. involving plasmid DNA. It acknowledged that manufacturing will be a key consideration for approval of plasmid DNA-based gene medicines since they have never been approved and commercialized. It also expects having a manufacturing site will "boost in the company's bargaining power for potential out-licensing and marketing partnership deals."

If approved, ViroMed's treatment would be up against Pfizer blockbuster Lycra and Neurontin (gabapentin). Both are taken orally, while VM202 in injected, but the two marketed drugs treat only symptoms, where VM202 is designed to get at the underlying cause of the pain. ViroMed's candidate works by inducing angiogenesis and acts as a neurotrophic factor, leading to the formation of new microvasculature and induces regeneration of nerve cells.

The FDA path to approval has certainly been littered by drugs sidelined by complete response letters tied to manufacturing problems. AstraZeneca in 2015 paid $2.7 billion for ZS Pharma to get its hands on Lokelma, formerly known as ZS-9. The treatment for hyperkalemia was expected to be a blockbuster but was twice rejected by the FDA over problems before being approved in May.

Source: https://www.fiercepharma.com/manufacturing/korean-biotech-buys-gmp-ready-production-facility-california

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