## Eli Lilly Acquires Pegilodecakin, Potential Immunotherapy Now in Phase 3 Trial

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Eli Lilly announced that it is acquiring ARMO BioSciences and its lead treatment candidate pegilodecakin (AM0010), an investigational immunotherapy that has shown clinical benefit in multiple types of cancer and is now in a pivotal study in advanced pancreatic cancer patients.

Lilly paid about \$1.6 billion in cash to ARMO, a California-based company. A number of other immunotherapies in pre-clinical testing were included in the sale.

Pegilodecakin is a long-acting form of PEGylated Interleukin-10 (IL-10), designed to activate the immune system of cancer patients to recognize and destroy tumors.

IL-10 is a naturally occurring protein that regulates the activity of various immune cells. The protein is linked to a molecule called polyethylene glycol (PEG). The attachment of PEG to IL-10 increases its size, working to prevent or delay its breakdown to prolong the time it circulates in the body.

Upon administration, pegilodecakin works by stimulating the survival, proliferation and killing potential of immune cells known as killer T-cells, which are able to recognize and eliminate cancer cells. Increasing the number of killer T-cells within a tumor is believed to improve a patient's prognosis and survival.

In studies, pegilodecakin demonstrated clinical benefit as a single agent and in combination with both chemotherapy and checkpoint inhibitor therapy across several tumor types.

The potential therapy is currently being evaluated in a Phase 3 clinical trial (NCT02923921) in some 560 patients with metastatic pancreatic cancer. This trial, which ends in January 2020, is now recruiting at multiple sites across the U.S., Europe, Canada and select Asian countries; information can be found here.

Trials testing pegilodecakin are also underway in patients with non-small cell lung cancer and advanced solid tumors. A clinical trials list is available here.

Immuno-oncology candidates in pre-clinical development include an anti-PD-1 monoclonal antibody (AM0001), an anti-LAG-3 checkpoint inhibitor (AM0003), a form of recombinant human IL-15 (AM0015) and a form of recombinant human IL-12 (AM0012).

"The acquisition of ARMO BioSciences adds a promising next generation clinical immunotherapy asset to Lilly's portfolio of innovative oncology medicines," Sue Mahony, a senior vice president and president of Lilly Oncology, said in a press release.

"We believe that pegilodecakin has a unique immunologic mechanism of action that could eventually allow physicians to offer new hope for many cancer patients," added Levi Garraway, MD, PhD, senior vice president of global development and medical affairs at Lilly Oncology.

Pegilodecakin was given orphan drug status as a potential pancreatic cancer treatment by both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

The FDA also granted it fast track status as a second-line therapy used with the chemotherapy FOLFOX in patients with pancreatic cancer.

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