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FDA gives orphan-drug designation to treatment for kidney transplant patients

By Alaric DeArment

FREMONT, Calif. (Feb. 17) The Food and Drug Administration has given orphan-drug designation to an investigational preventive treatment for delayed graft function in kidney transplant patients made by Quark Pharmaceuticals, Quark announced Tuesday.

The FDA gave the designation to QPI-1002. The company, which develops therapies that switch genes on and off through a process known as RNA interference, said it had completed enrollment and dosing in a phase 1/2 study of the drug.

Delayed graft function, also known as DGF, is a form of kidney failure that increases the risk of rejection of transplanted kidneys and considered an unmet medical need. The FDA grants orphan-drug designation to products for treating rare diseases and conditions affecting fewer than 200,000 people in the United States. Companies that get orphan-drug designation qualify for tax credits and longer market exclusivity periods following approval of the drug.

"We are confident that obtaining orphan status will facilitate the rapid development of this innovative compound and hope that ultimately, we can reduce the wait time for kidney transplants with fewer failed grafts," Quark Pharmaceuticals president and CEO Daniel Zurr said in a statement.