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FDA grants "fast track" status to Renova Therapeutics' heart failure drug

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US FDA grants Fast Track designation to Renova Therapeutics' RT-100 AC6 gene transfer for the treatment of heart failure

Renova Therapeutics is developing definitive, one-time gene therapies and peptide infusion treatments to restore the health of people suffering from cardiovascular and metabolic diseases.

This biotechnology company announced that the U.S. FDA has granted Fast Track designation for the company's lead product candidate, RT-100 AC6 gene transfer (Ad5.hAC6), to treat heart failure with reduced ejection fraction (HFrEF).

The FDA's Fast Track program is designed to expedite the development and review of drugs and biologics with the potential to treat serious or life-threatening conditions and address an unmet medical need.

The designation allows for Rolling Review of a New Drug Application (NDA) or Biologic License Application (BLA).

The designation also provides eligibility for Priority Review, if relevant criteria are met, potentially resulting in quicker access to patients.

RT-100 AC6 gene transfer involves infusing an inactivated adenovirus vector encoding human adenylyl cyclase type 6 (Ad5.hAC6) into the arteries that feed the heart during cardiac catheterization, a commonly performed procedure.

AC6 is a protein found in heart muscle cells that regulates heart function and appears to be down-regulated in heart failure patients.

Results of a Phase 2 clinical trial indicate that, through a one-time administration, RT-100 safely increased heart function beyond optimal heart failure therapy.

The treatment also lowered the heart failure hospitalization rate at 12 months, which will be the primary endpoint in the program's upcoming Phase 3 trial.

Renova Therapeutics will conduct a randomized, placebo-controlled, double-blind multicenter Phase 3 trial of intracoronary delivery of RT-100 to evaluate safety and efficacy.

This pivotal trial – known as FLOURISH (Heart **F**ailure with Reduced **L**eft Ventricular Ejection Fraction: **O**ne-time Gene Transfer **U**sing **R**T-100 – **I**ntracoronary Administration of Adenovirus **S** 5 encoding **H**uman AC6) – is expected to commence in Q1 2018 in the United States.