Corlanor® Approved to Reduce Risk of Hospitalizations for Heart Failure

Amgen announced that the U.S. Food and Drug Administration has granted approval of Corlanor® (ivabradine), an oral medication to reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction (LVEF) ≤35%, who are in sinus rhythm with resting heart rate ≥70 beats per minute (bpm) and either are on maximally tolerated doses of beta blockers or have a contraindication to beta blocker use. Corlanor blocks the hyperpolarization-activated cyclic nucleotide-gated channel responsible for the cardiac pacemaker, which regulates heart rate, and reduces the spontaneous pacemaker activity of the cardiac sinus node by selectively inhibiting the If current to slow the heart rate with no effect on ventricular repolarization and myocardial contractility.

The approval is based on global clinical trial data including a large, multicenter, randomized, double-blind, placebo-controlled, outcomes trial. The phase 3 SHIFT (Systolic Heart Failure Treatment With the If Inhibitor Ivabradine Trial) study compared Corlanor to placebo in addition to standard of care therapies, including beta blockers, in more than 6,500 clinically stable patients in sinus rhythm with reduced LVEFs and heart rates ≥70 bpm, with hospitalizations for heart failure within the past 12 months.

Results showed Corlanor significantly reduced the risk of the primary composite endpoint of hospitalization or cardiovascular death for worsening heart failure, with 18% relative risk reduction. The treatment effect reflected only a reduction in the risk of hospitalization for worsening heart failure; there was no favorable effect on the mortality component.

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Azeliragon to Treat Mild Alzheimer’s Disease

vTv Therapeutics announced enrollment of the first patients into STEADFAST (Single Trial Evaluating Alzheimer’s Disease Following Addition to Symptomatic Therapy), the phase 3 placebo controlled trial of azeliragon, an oral antagonist of the receptor for advanced glycation endproducts (RAGE) for treatment of mild Alzheimer’s disease.

STEADFAST will investigate the efficacy of azeliragon compared with placebo in the treatment of patients with mild Alzheimer’s disease already receiving cholinesterase inhibitors and/or memantine. The trial targets enrollment of 800 patients in the United States and Canada who will receive 18 months of treatment.

Azeliragon, also known as TTP488, is a novel orally active small-molecule antagonist of RAGE. In a double-blind phase 2 clinical trial where data were collected over 18 months, azeliragon 5 mg/day slowed cognitive decline, as measured by the Alzheimer’s Disease Assessment Scale—cognitive subscale, in patients with mild to moderate Alzheimer’s disease. The effect on cognition, statistically significant in patients with mild-to-moderate disease, was more pronounced in patients with mild Alzheimer’s disease.