

## Corlanor<sup>®</sup> (ivabradine) — New Drug Approval

- On April 15, 2015, the [FDA approved Amgen's Corlanor \(ivabradine\)](#) to reduce the risk of hospitalization for worsening heart failure (HF) in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction (LVEF)  $\leq$  35%, who are in sinus rhythm with resting heart rate  $\geq$  70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use.
- HF is a condition in which the heart cannot pump enough blood to meet the demand of the body. It affects approximately 5.7 million people in the United States and about half of these patients have reduced LVEF.
  - Despite the number of standard treatments available, there is significant morbidity and mortality associated with HF and the prognosis of patients is poor.
- Corlanor works by blocking the cardiac pacemaker I<sub>f</sub> ion current, thereby slowing the heart rate.
- The safety and efficacy of Corlanor were based on a placebo-controlled trial, known as the SHIFT study, which involved 6,558 patients with stable New York Heart Association (NYHA) Class II to IV HF. The primary composite endpoint was the first occurrence of either hospital admission due to worsening HF or cardiovascular death.
  - Fewer patients treated with Corlanor experienced the primary endpoint compared to placebo (24.5% vs. 28.7%; [HR = 0.82; 95% CI: 0.75, 0.90]).
  - The treatment effect reflected only a reduction in the risk of hospitalization for worsening HF. There was no favorable effect on the mortality component of the primary endpoint.
  - In the overall treatment population, Corlanor had no significant benefit on cardiovascular death.
  - In other trials, Corlanor did not significantly affect the primary composite endpoint of first cardiovascular death, hospitalization for acute myocardial infarction, or hospitalization for new-onset or worsening HF.
- Corlanor is contraindicated in patients with acute decompensated HF, blood pressure < 90/50 mmHg, sick sinus syndrome or sinoatrial block or 3<sup>rd</sup> degree AV block (unless a functioning pacemaker is present), resting heart rate < 60 beats per minute (bpm) prior to treatment, severe hepatic impairment, pacemaker dependence (heart rate maintained exclusively by the pacemaker), and in combination with strong CYP3A4 inhibitors.
- Warnings and precautions for Corlanor include fetal toxicity, atrial fibrillation, and bradycardia and conduction disturbances.
- The most common adverse events ( $\geq$  1%) with Corlanor use were bradycardia, hypertension, atrial fibrillation, and luminous phenomena (phosphenes).
- The recommended starting dose of Corlanor is 5 mg orally twice daily. After 2 weeks of treatment, the patient should be assessed and the dose adjusted to achieve a resting heart rate between 50 – 60 bpm.

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- Dosing should be initiated at 2.5 mg twice daily in patients with conduction defects or in whom bradycardia could lead to hemodynamic compromise.
- The maximum dose is 7.5 mg twice daily.
- Amgen plans to launch Corlanor in approximately one week. Corlanor will be available as 5 mg and 7.5 mg tablets.



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