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Adult drug effective for pediatric patients with dilated cardiomyopathy and heart failure

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The Food and Drug Administration (FDA) has approved ivabradine (Corlanor) for treatment of heart failure (HF) in children with dilated cardiomyopathy (DCM).

Pediatric DCM typically has a poor prognosis with significant morbidity. About 40% of children progress to cardiac transplant or death within five years after diagnosis (Pahl E, et al. *J Am Coll Cardiol*. 2012;59:607-615).

Because approved drug therapies for pediatric HF have not been available, children with HF due to DCM are treated primarily off-label with drugs approved for adult HF.

In a study of adults with HF from multiple etiologies including DCM, ivabradine reduced HF hospitalization (Swedberg K, et al. *Lancet.* 2010;376:875-885). Heart rate (HR) reduction was the plausible mechanism for ivabradine's benefit in this study. Thus, if a randomized, controlled trial demonstrated HR reduction in treated pediatric patients, benefit could be inferred and efficacy could be extrapolated from adults to pediatric patients.

The primary efficacy endpoint, 20% reduction in HR without inducing bradycardia, was assessed in a study of 116 children ages 6 months and older with HF due to DCM and elevated baseline HR. This HR reduction was attained in 70% of the ivabradine group compared to 12% on placebo ($p<0.0001$). No novel safety issues were discovered. A new oral solution was developed for use in pediatric patients.

Resources

- More information about FDA approval of ivabradine, including the trial in adult HF patients
- Additional FDA Update columns