FDA communicated that GALACTIC-HF is not sufficiently persuasive to establish substantial evidence of effectiveness for reducing the risk of heart failure events and cardiovascular death in adults with chronic heart failure with reduced ejection fraction, in lieu of evidence from at least two adequate and well-controlled clinical investigations. FDA stated that results from an additional clinical trial of omecamtiv mecarbil are required to establish substantial evidence of effectiveness for the treatment of HFrEF, with benefits that outweigh the risks. GALACTIC-HF (Global Approach to Lowering Adverse Cardiac Outcomes Through Improving Contractility in Heart Failure) was a Phase 3 clinical trial of omecamtiv mecarbil that enrolled patients with HFrEF at risk of hospitalization and death, despite being treated with standard-of-care therapy.

设计、设置和参与者：GALACTIC-HF研究是一个全球性的双盲、安慰剂对照的第3期随机临床试验，于2017年1月至2020年8月在多个中心进行。共有8232名有症状的心力衰竭患者（定义为纽约心脏协会症状分级II-IV）和左心室射血分数≤35%的患者被随机分配接受omecamtiv mecarbil或安慰剂治疗，并进行了中位随访21.8个月（范围15.4-28.6个月）。这项后续分析评估了omecamtiv mecarbil治疗在被分类为重度心力衰竭的患者中的疗效和安全性，与没有重度心力衰竭的患者进行比较。重度心力衰竭的定义为具有以下所有标准：纽约心脏协会症状分级III至IV，左心室射血分数≤30%，并且在前6个月内因心力衰竭住院。

结果：在GALACTIC-HF临床试验中，共有8232名患者入组，其中2258名患者（27.4%；平均[标准差]年龄，64.5 [11.6]岁；男性1781名[78.9%]）符合重度心力衰竭的指定标准。其中，1106名患者随机分配到omecamtiv mecarbil组，1152名分配到安慰剂组。接受omecamtiv mecarbil治疗的重度心力衰竭患者在主要终点上显著获益（风险比[HR]，0.80；95%置信区间[CI]，0.71-0.90），而没有重度心力衰竭的患者则没有显著的治疗效益（HR，0.99；95% CI，0.91-1.08；交互作用的P = 0.005）。对于心血管死亡，结果类似（有重度心力衰竭患者与没有重度心力衰竭患者的HR分别为0.88 [95% CI，0.75-1.03]与1.10 [95% CI，0.97-1.25]；交互作用的P = 0.03）。在重度心力衰竭患者中，omecamtiv mecarbil治疗耐受性良好，与安慰剂相比，血压、肾功能或钾水平均未发生显著变化。

Conflict of interest statement?

<https://pubmed.ncbi.nlm.nih.gov/34643642/>

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