



## Intravenous dofetilide formulation designed to enable faster, more controlled initiation of therapy



### ABOUT

Dofetilide IV is a differentiated intravenous formulation of Dofetilide developed to provide a faster, more controllable alternative to the currently available oral-only route. It is intended to support the restoration and maintenance of normal heart rhythm in patients with atrial fibrillation and atrial flutter, while improving the practicality of treatment initiation in the hospital setting.

### STAGE

The pivotal clinical trial has been completed successfully, and U.S. regulatory submission is expected in Q2 2026. A meeting with the FDA held in February 2026 confirmed the proposed regulatory strategy.

### INDICATION

Dofetilide IV is intended for the same core indications as oral dofetilide, with added utility for: IV loading to achieve therapeutic concentrations more efficiently, potentially reducing hospital stay associated with initiation, re-titration or re-initiation of therapy, facilitating IV-to-oral transition.

### BENEFIT

Initiation of oral dofetilide currently requires three or more days of in-hospital monitoring. Dofetilide IV has the potential to reduce this to one day, lowering resource utilization and improving treatment efficiency. Intravenous administration may also allow more controlled management of exposure and safety, including immediate interruption of dosing if QTc prolongation or other adverse effects occur.

### IP RIGHTS / EXCLUSIVITY

Granted patents with expiry dates between 2039 and 2043, with additional pending applications, including protection relating to one-day loading approaches, aqueous IV dofetilide compositions, and additional uses supporting the dosing and treatment advantages of the IV formulation.

# Forward-Looking Statements



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# Value Starts Here

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