CIRARA: The Most De-Risked Acute Stroke Drug In Development

CIRARA has compelling clinical data showing greatly reduced mortality and vastly improved clinical outcomes, a well-defined mechanism of action, and addresses a critical unmet medical need – large core ischemic strokes. With over $200 million invested in its clinical development to-date, we estimate 3.5 years and $50 million to readout. Once approved, CIRARA could generate annual peak revenues of $2 billion across the U.S, Europe, and Japan with patent and orphan drug exclusivity through 2049.

The Problem: Current Treatments For Large Hemispheric Infarction (LHI) Fall Short

Large Hemispheric Infarction (LHI) is a severe ischemic stroke subtype characterized by a large ischemic core, frequently leading to life-threatening cerebral edema, brain herniation, and death. Current treatment options, including thrombolytics, endovascular thrombectomy (EVT), and decompressive craniectomy (DC), improve outcomes, but even when all these measures are taken, over 30% of LHI patients die and only 30% regain the ability to walk unassisted.

The Solution: CIRARA Dramatically Reduces Mortality And Improves Clinical Outcomes

CIRARA blocks the SUR1-TRPM4 channel, which is upregulated after stroke and contributes to the formation of life-threatening edema. Unlike neuroprotective agents, which aim to preserve the health and function of neurons, CIRARA protects the blood-brain barrier. CIRARA acts on the capillary endothelium to reduce the formation of swelling and minimizes the secondary damage that swelling creates. When used alongside EVT, which restores blood flow to the brain by mechanical removal of the blood clot, the two treatments synergistically lead to better overall outcomes.

In the Phase 3 CHARM study, CIRARA, administered in-hospital up to 10 hours following stroke onset, demonstrated impressive efficacy in key subgroups. This is particularly the case among EVT-treated patients with lesion volumes ≤125 mL, where there was an 81% reduction in mortality ($p=0.05$), and a 100% increase in odds of walking independently ($p=0.02$). There were also fewer (0% vs. 25%) decompressive craniectomies ($p=0.02$), and the degree of edema as measured by midline shift was 45% lower ($p=0.02$).

The Opportunity: A High-Value Asset With A De-Risked Phase 3

FDA provided valuable feedback on the design of the Phase 3 STRONG study design. STRONG will enroll 260 patients undergoing EVT with lesions between 80-125 mL, mitigating risk by focusing on the patient population that has been shown to benefit most.

Market Impact And Commercial Viability

High Unmet Need: Approximately 70,000 LHI cases occur annually in the U.S. alone. Adoption will be driven by stroke centers eager to improve the dismal outcomes in LHI.

Cost Savings: CIRARA's ability to reduce disability translates to healthcare cost savings — shifting patients from needing assistance to walk to independent ambulation could save over $50,000 per patient annually.

Efficient Commercialization: Because of the severity of LHI strokes, in the U.S., Europe, Japan, and other advanced-care nations, patients are rapidly transferred to EVT-capable centers for treatment. In the U.S., CIRARA can be effectively marketed to the ~325 Comprehensive and Thrombectomy-Capable Stroke Centers that handle the majority of severe stroke cases with just a small team of sales representatives. A similar commercial approach can be used in other major markets.

Unique De-risking

Extensive Clinical Data: CIRARA is a highly targeted therapy with an excellent safety profile, and within its target population (lesions 80-125mL), it has a substantial effect on clinical outcomes, doubling the proportion of patients who can walk, while simultaneously reducing mortality.

Close To The Finish Line: Enrollment for the upcoming Phase 3 trial can be completed within 18-24 months. All activities, leading up to potential FDA approval, are estimated to cost $50 million to readout and can be completed within 3.5 years from the study's start.

Blockbuster Potential: U.S. sales can be handled with a 30-person team post-approval. Using this approach, revenues from the U.S., Europe, and Japan are expected to reach $2 billion annually.

Exclusivity In Place: Extensive portfolio of granted patents and orphan drug designation provide market exclusivity through 2049.

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