First Antibody Therapy for Acute Myocardial Infarction Granted FDA Fast Track Designation

If approved, this novel monoclonal antibody therapy could become a standard of care emergency option for patients with acute myocardial infarction, which affects millions in the United States and across the world.

The FDA has granted fast track designation (FTD) to SGC001 (Sungen Biomedical) for the emergency treatment of acute myocardial infarction (AMI), which, according to a news release from Sungen Biomedical, is the world's first monoclonal antibody drug being developed for the treatment of AMI.[1]

According to a presentation from Wei Zeng, MD, from the 43rd Annual JP Morgan Healthcare Conference in San Francisco, SGC001 is designed to inhibit the apoptosis of cardiomyocytes that are induced by target molecules in the heart. Through this process, the monoclonal antibody reduces the oxidative stress damage of cardiomyocytes while blocking a downstream inflammatory response and increasing blood perfusion in ischemic areas, thereby reducing the size and impact of myocardial infarction.[1,2]

Preclinical data from studies indicate SGC001 can induce therapeutic effects on patients with heart failure and aid in remodeling after MI, while meaningfully reducing the mortality rate in patients with MI. Sungen Biomedical has been cleared to proceed with a currently ongoing phase 1 clinical trial to further evaluate the efficacy and safety of SGC001; thus far, the therapy has led to positive safety indications, according to Zeng.[1,2]

SGC001 was previously granted an investigational new drug (IND) application by the FDA to proceed with a clinical trial and further research in the AMI space. With no antibody therapies approved for clinical use by the FDA, the possible approval of SGC001 could prove revolutionary for patients with the debilitating cardiovascular condition. The burden of AMI is immense, with approximately a million deaths in the United States each year attributed to the condition.[3,4]

AMI occurs in patients because of reduced coronary blood flow, which leads to an insufficient supply of oxygen to the heart. Symptoms of AMI include chest discomfort, diaphoresis, and nausea, and it is detected through electrocardiography and the presence of biomarkers indicating disease. AMI is considered a form of acute coronary syndrome, which collectively stems from the acute obstruction of a coronary artery. The condition comprises both non-ST-segment elevation myocardial infarction (NSTEMI) and ST-segment elevation myocardial infarction (STEMI), and each necessitates varying treatment strategies for patients.[4]

This new designation for SGC001 will provide the drug with expedited review and more frequent FDA check-ins, putting it on a strong path to an eventual full regulatory approval. Features of FDA FTD that will now apply to SGC001 include facilitated interactions and communication with the FDA through the duration of the development process, a rolling review throughout the market application submission process, and access to accelerated review and priority review approval pathways. Overall, these factors help reduce the timeline to approval for SGC001.[1,2]

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