LT3001 Podcast–Transcript

Welcome to our discussion exploring the clinical development and impact of LT3001, a novel therapy for acute ischemic stroke patients who fall outside traditional treatment windows.

Today's overview draws from the recent ISC Late Breaking Science session presented by Thomas Devlin. We're focusing on the document detailing both phase 2 studies evaluating LT3001 across multiple regions.

The purpose of this document is to highlight LT3001's development, its underlying mechanism, and how it was tested in two significant multicenter trials. We'll cover study designs, patient selection, safety findings, and early efficacy signals.

Central to this investigation is the idea that LT3001 could offer a new pathway for stroke management, specifically for patients arriving too late for conventional thrombolytic therapies such as T P A or T N K.

The importance here lies in helping clinicians understand who may benefit most from LT3001 and what the next steps look like as global phase 3 studies are prepared.

To begin, let's look at the preclinical foundation. LT3001 was designed from a thrombolytic peptide, then modified to add both free radical scavenging and vessel-active properties. That means it's intended to promote reperfusion while reducing the risk of injury after vessels reopen.

Right. In rat models, the molecule outperformed T P A, especially at delayed intervention points. It produced lower infarct volumes and improved neuroprotective outcomes even when administered up to twenty-four hours after stroke onset.

Clinical testing moved quickly, with two randomized, placebo-controlled phase 2 trials: Study 202 in China and Study 205 across the US, Europe, and Taiwan. Both enrolled patients ineligible for T P A or endovascular therapy, focusing on those treated within twenty-four hours of symptom onset.

The safety profile is noteworthy. Across all arms and doses, zero cases of symptomatic intracranial hemorrhage were observed. Mortality rates were similar between groups, and asymptomatic hemorrhage occurred infrequently, never showing treatment-related patterns.

Exploratory efficacy signals showed promise: functional outcomes improved for moderate and severe strokes, especially in patients with disabling deficits and large artery

involvement. Looking ahead, the strongest response was seen when combining these characteristics, guiding the target population for phase 3 trials.

In summary, LT3001 appears safe and shows preliminary benefits in a carefully defined stroke population. It holds potential for those outside typical thrombolysis windows.

With global phase 3 studies ahead, clinicians may soon have expanded options for acute stroke intervention. Thanks for joining us for this concise overview.