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Health Technology Briefing
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Ziltivekimab for reducing cardiovascular risk in patients with acute myocardial infarction

Company/Developer	Novo Nordisk Ltd.

☒ New Active Substance ☐ Significant Licence Extension (SLE)

NIHRIO ID: 38251	NICE ID: Not Available	UKPS ID: 675117

Licensing and Market Availability Plans

Currently in phase III clinical development

Summary

Ziltivekimab is currently in development for the reduction of cardiovascular risk in patients with acute myocardial infarction. A myocardial infarction (heart attack) happens when blood flow to the heart is suddenly blocked, usually by a blood clot. This can seriously damage the heart and can be life threatening. Even with current treatments, heart problems like heart failure still led to many deaths, and so there is a need for effective treatments.

Ziltivekimab is given as an injection under the skin. It is an antibody (type of protein) that targets a substance in the body called IL-6, which plays a key role in inflammation. Inflammation is part of the body's natural response to injury, but too much of it can damage the heart and blood vessels. By blocking IL-6, ziltivekimab may help reduce harmful inflammation and lower the risk of blood clots forming. Because it targets a very specific part of the immune system, it may work at lower doses and could cause fewer side effects than similar treatments. If approved (licensed), ziltivekimab would provide a new treatment option for patients with acute myocardial infarction.

This briefing reflects the evidence available at the time of writing and a limited literature search. It is not intended to be a definitive statement on the safety, efficacy or effectiveness of the health technology covered and should not be used for commercial purposes or commissioning without additional information. A version of the briefing was sent to the company for a factual accuracy check. The company was available to comment.

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Proposed Indication

Reduction of cardiovascular risk in patients with acute myocardial infarction.[1]

Technology

Description

Ziltivekimab (NN 6018) is a narrow-spectrum fully human monoclonal antibody targeting the Interleukin-6 (IL-6) ligand.[2] IL-6 is a critical inflammatory cytokine implicated in cardiovascular disease progression.[3] The direct inhibition of IL-6 reduces platelets reactivity to collagen, thereby blunting arterial thrombosis upon endothelial damage. This provides a potential mechanism to explain the reduction of cardiovascular risk associated with direct IL-6 inhibition.[4]

Ziltivekimab is currently in clinical development for the treatment of patients with acute myocardial infarction. In the phase III clinical trials (ARTEMIS, NCT06118281), participants are administered ziltivekimab via subcutaneous injection, monthly.[1,5,6]

Key Innovation

Despite advancements in the management of heart failure, the disease continues to be associated with high morbidity and mortality rates.[7] Patients who experience an acute myocardial infarction remain at risk of developing heart failure.[8] Heart failure occurring during admission with myocardial infarction is associated with a greater risk of mortality and the risk of the subsequent development of chronic heart failure.[9] The development of chronic heart failure and a hospitalisation for heart failure after myocardial infarction is associated with an increased risk of death, so the investigation of novel therapies for the prevention of heart failure are vital.[8,10]

IL-6–targeted therapy could represent the first precision anti-inflammatory approach broadly applicable in cardiovascular prevention.[11] As a monoclonal antibody targeting the IL-6 ligand rather than the IL-6 receptor, ziltivekimab used at lower doses could have fewer adverse effects on lipid levels, haematological indices, and hepatic function than other approved IL-6 agents.[2] If licensed, ziltivekimab would provide a new treatment option for patients with acute myocardial infarction.

Regulatory & Development Status

Ziltivekimab does not currently have Marketing Authorisation in the EU/UK for any indication.

Ziltivekimab is also in phase II/III clinical development for chronic kidney disease and heart failure.[12]

Patient Group

Disease Area and Clinical Need

A myocardial infarction (heart attack) is a serious medical emergency in which the supply of blood to the heart is suddenly blocked, usually by a blood clot. A lack of blood to the heart may seriously damage the heart muscle and can be life threatening.[13] The risk of myocardial infarction is increased by atherosclerosis, which is where the arteries become narrowed, making it difficult for blood to flow through them. Atherosclerosis happens when fatty deposits build up in the arteries, which causes them to narrow. Risk factors of atherosclerosis include being over the age of 65, smoking, having high cholesterol, having high blood pressure and having close relatives who have cardiovascular disease.[14] Symptoms of a heart attack

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can include chest pain, pain in other parts of the body, sweating, shortness of breath, nausea or vomiting, and pale, blue or grey skin.[13]

It is estimated that there are more than 7 million people living with cardiovascular disease in England, with an estimated 1.1 million people alive in England today who have survived a heart attack. Cardiovascular disease causes just over a quarter (26%) of all deaths in England, which is around 140,000 deaths each year.[15] In England, 2024-25, there were 170,210 finished consultant episodes (FCEs) and 81,047 admissions for Indication (ICD-10 code I21) which resulted in 554,018 FCE bed days and 577 day cases.[16]

Recommended Treatment Options

The National Institute for Health and Care Excellence (NICE) currently recommends the following treatment options:

- Myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction.[17]
- Ticagrelor for preventing atherothrombotic events after myocardial infarction.[18]
- Streptokinase, alteplase, reteplase, and tenecteplase.[19]
- Angiotensin-converting enzyme inhibitor, dual antiplatelet therapy (aspirin plus a second antiplatelet) (unless they have a separate indication for anticoagulation), beta-blocker, and statin.[20]

Clinical Trial Information

Trial	**ARTEMIS; NCT06118281;** ARTEMIS - Effects of Ziltivekimab Versus Placebo on Cardiovascular Outcomes in Patients With Acute Myocardial Infarction **Phase III -** Recruiting **Locations:** 10 EU countries, UK, USA, Canada and other countries **Primary completion date:** December 2026
Trial Design	Randomised, parallel assignment, quadruple masked, placebo-controlled
Population	N = 10,000 (estimated); adults hospitalised for acute myocardial infarction with evidence of type 1 myocardial infarction; aged 18 years and over.
Intervention(s)	A defined dose of ziltivekimab, subcutaneously, as early as possible after invasive procedure, and latest within 36 hours of hospitalisation for ST-elevation myocardial infarction (STEMI) and within 48 hours of hospitalisation for non-ST-elevation myocardial infarction (NSTEMI), followed by a defined dose once monthly, estimated up to two years.
Comparator(s)	Matched placebo
Outcome(s)	Primary outcome measure: Time to first occurrence of a 3-component major adverse cardiovascular event endpoint comprising: cardiovascular death, non-fatal myocardial infarction, non-fatal stroke [Time frame: up to 25 months] See trial record for full list of other outcomes.
Results (efficacy)	-
Results (safety)	-

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Estimated Cost

The cost of ziltivekimab is not yet known

Relevant Guidance

NICE Guidance

- NICE technology appraisal. Ticagrelor for preventing atherothrombotic events after myocardial infarction. TA420. December 2016
- NICE technology appraisal. Myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction. TA73. July 2011.
- NICE technology appraisal. Guidance on the use of drugs for early thrombolysis in the treatment of acute myocardial infarction. TA52. October 2002.
- NICE guideline. Acute coronary syndromes. NG185. November 2020.
- NICE quality standard. Secondary prevention after a myocardial infarction. QS99. September 2015.

NHS England (Policy/Commissioning) Guidance

- NHS England. NHS standard contract for ventricular assist devices (VADs) as a bridge to heart transplantation or myocardial recovery (all ages). A18/S(HSS)/b. 2013.

Other Guidance

- European Society of Cardiology (ESC). 2023 ESC Guidelines for the management of acute coronary syndromes: Developed by the task force on the management of acute coronary syndromes of the European Society of Cardiology (ESC). 2023.[21]
- British Journal of General Practice. Secondary prevention following myocardial infarction: a clinical update. 2018.[22]

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