NSCLC, early stage

MAGRIT, A DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED PHASE III STUDY TO ASSESS THE EFFICACY OF THE RECMAGE-A3 + AS15 CANCER IMMUNOTHERAPEUTIC AS ADJUVANT THERAPY IN PATIENTS WITH RESECTED MAGE-A3-POSITIVE NON-SMALL CELL LUNG CANCER (NSCLC)


1Respiratory Oncology Unit (pulmonology), University Hospitals Leuven - Campus Gasthuisberg, Leuven, BELGIUM
2Division of Oncology, Department of Internal Medicine, Yonsei University, College of Medicine, Seoul, KOREA
3Cardiothoracic Surgery Network, North Estonian Medical Center, Tallinn, ESTONIA
4Servic Oncologi, Istituto Europeo di Oncologia, Milan, ITALY
5Thoracic Surgery, Pulmonary Hospital Zakopane, Zakopane, POLAND
6Center for Lung Cancer, National Cancer Center, Goyang, KOREA
7Oncology and Radiotherapy, Medical University of Gdańsk, Gdańsk, POLAND
8Thoracic Surgery, Hyogo Cancer Center Akashi, JAPAN
9Thoracic Oncology, Karagava Cancer Center Hospital, Yokoahama, JAPAN
10Dept of Pneumonology and Thoracic Surgery, Fakultni Nemocnice Na Bulovce, Prague, CZECH REPUBLIC
11General Thoracic Surgery, Kyorin University, School of Medicine, Tokyo, JAPAN
12Thoracic Surgery, Kinki University Faculty of Medicine, Osaka-Sayama, JAPAN
13G. Papanikolaou Hospital, Pulmonary Department, Aristotle University of Thessaloniki, Thessaloniki, GREECE
14Chemotheapy, Regional Oncology Center, Chejilabinsk, RUSSIAN FEDERATION
15Medical Governance and Bioethics, GSK vaccines, Rixensart, BELGIUM
16Dept. Clinical Oncology, GlaxoSmithKline Biologicals, Rixensart, BELGIUM
17Thoracic Division, Department of Cardiothoracic Surgery, New York, NY, USA

Aim: Adjuvant chemotherapy (ACT) is the standard of care for Stage II and IIIA NSCLC, and for high risk Stage IB NSCLC. However, the 5-year disease-free survival remains poor (35-50%) and about half of the patients will not receive ACT for various reasons. This Phase III trial investigated whether the recMAGE-A3 + AS15 cancer immunotherapeutic (MAGE-A3 CI) as adjuvant therapy improved disease-free survival (DFS) in patients with resected NSCLC.

Methods: MAGRIT was a randomized, double-blind, placebo-controlled trial in patients with completely resected MAGE-A3-positive NSCLC stages IB, II, and IIIA (TNM version 6) and who did or did not receive ACT. Patients were randomly assigned (2:1) to receive 13 intramuscular injections of MAGE-A3 CI or placebo over a 27-month (m) treatment period. The three co-primary endpoints were DFS in the overall and in the no-ACT population and DFS in patients with a potentially predictive gene signature (GS).

Results: Out of 13,849 patients screened, 4,210 patients had a MAGE-A3 positive tumour sample and 2,272 patients were randomised and treated. Overall, 52% of the patients received ACT; 47%, 36% and 17% were Stage IB, II and IIIA, respectively. Median age was 63 years and 24% of patients were females. Mean relative dose intensity was above 98% in both groups throughout the treatment period. Median follow-up at the time of final analysis was 38.8m. Median DFS was 60.5m and 57.9m respectively for MAGE-A3 CI and placebo (HR 0.970, 95% CI 0.797-1.179; p = 0.7572). The rate of grade ≥3 adverse events (16%) did not differ between treatment groups.

Conclusions: Treatment of NSCLC patients with MAGE-A3 CI did not increase DFS compared to placebo in either the overall population or in patients who did not receive ACT. Due to the absence of treatment effect, a GS predictive of clinical benefit to MAGE-A3 CI could not be identified. Funding Source: GlaxoSmithKline Biologicals SA.

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