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Earlier diagnosis of lung cancer in a randomised trial of an autoantibody blood test followed by imaging

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ABSTRACT The EarlyCDT-Lung test is a high-specificity blood-based autoantibody biomarker that could contribute to predicting lung cancer risk. We report on the results of a phase IV biomarker evaluation of whether using the EarlyCDT-Lung test and any subsequent computed tomography (CT) scanning to identify those at high risk of lung cancer reduces the incidence of patients with stage III/IV/unspecified lung cancer at diagnosis compared with the standard clinical practice at the time the study began.

The Early Diagnosis of Lung Cancer Scotland (ECLS) trial was a randomised controlled trial of 12 208 participants at risk of developing lung cancer in Scotland in the UK. The intervention arm received the EarlyCDT-Lung test and, if test-positive, low-dose CT scanning 6-monthly for up to 2 years. EarlyCDT-Lung test-negative and control arm participants received standard clinical care. Outcomes were assessed at 2 years post-randomisation using validated data on cancer occurrence, cancer staging, mortality and comorbidities.

At 2 years, 127 lung cancers were detected in the study population (1.0%). In the intervention arm, 33 out of 56 (58.9%) lung cancers were diagnosed at stage III/IV compared with 52 out of 71 (73.2%) in the

control arm. The hazard ratio for stage III/IV presentation was 0.64 (95% CI 0.41–0.99). There were nonsignificant differences in lung cancer and all-cause mortality after 2 years.

ECLS compared EarlyCDT-Lung plus CT screening to standard clinical care (symptomatic presentation) and was not designed to assess the incremental contribution of the EarlyCDT-Lung test. The observation of a stage shift towards earlier-stage lung cancer diagnosis merits further investigations to evaluate whether the EarlyCDT-Lung test adds anything to the emerging standard of low-dose CT.