30 September 2016

Abcodia Statement on the ROCA Test for Ovarian Cancer Screening in the UK

Abcodia acknowledges the recent statement issued by the U.S. Food and Drug Administration (FDA) regarding the use of blood tests for ovarian cancer screening. Notwithstanding our confidence in the clinical utility of the ROCA Test, we have voluntarily decided to temporarily limit the availability of the ROCA Test in the United Kingdom.

Ovarian cancer is the fifth leading cause of cancer-related death among women. As part of our mission to provide additional screening tools for this devastating disease, we will continue to partner with the medical community on ongoing clinical evaluation of the ROCA Test.

The ROCA Test is a risk estimation tool – not a standalone diagnostic test – developed with the goal of identifying asymptomatic women with an elevated risk for ovarian cancer. It is offered as a doctor-prescribed testing service intended to be used in conjunction with transvaginal ultrasound as the follow up test. The ROCA Test is not intended to replace patient self-assessment of symptoms, nor is it intended as the sole test to determine whether a patient should proceed to surgery, nor is it intended as a replacement for risk-reducing surgery in women with known risk factors. The ROCA Test is not recommended for general population screening.

The clinical utility of the ROCA Test has been investigated in large scale clinical trials in the UK called the UK Collaborative Trial for Ovarian Cancer Screening (UKCTOCS). Results reported in the *Lancet* and the *Journal of Clinical Oncology* indicate that the ROCA Test, when used in combination with transvaginal ultrasound images and professional judgement, has a sensitivity of 85.8% and specificity of 99.8% for ovarian cancer.[i,ii] These data compare favourably with currently approved and widely adopted screening modalities used as an aid in the detection of other cancers, and support the clinical utility of the ROCA Test to aid doctors in clinical referral decision making.

In addition, the Company supports the statement from the UKCTOCS trialists made in response to the FDA alert on 12 September 2016,[iii] reinforcing the current state of evidence and the position of the ROCA Test in guiding health decisions for women concerned about their individual risk of ovarian cancer.

Abcodia is deeply committed to its dedicated partners including patients, clinicians, advocacy groups, and professional societies, and we are grateful for the support we continue to receive from many individuals and groups.

i. Jacobs IJ, Menon U, Ryan A, et al. Ovarian cancer screening and mortality in the UK Collaborative Trial of Ovarian Cancer Screening (UKCTOCS): a randomised controlled trial. Lancet. 2016;387(10022):945-56

ii. Menon U, Ryan A, Kalsi J, et al. Risk Algorithm Using Serial Biomarker Measurements Doubles the Number of Screen-Detected Cancers Compared With a Single-Threshold Rule in the United Kingdom Collaborative Trial of Ovarian Cancer Screening. J Clin Oncol. 2015;33(18):2062 - 71.

iii. Clarification with regard to UKCTOCS/UKFOCSS results following FDA recommendation on ovarian cancer screening tests http://www.instituteforwomenshealth.ucl.ac.uk/womens-cancer/gcrc/ukctocs