

Morphotek, Fujirebio collaborate on companion Dx, 10/17

October 2017—Morphotek, a subsidiary of Eisai, has entered into a collaboration and license agreement with Fujirebio Diagnostics to validate and commercialize the CA125 II assay for use on the Lumipulse system as a companion diagnostic to aid in the selection of ovarian cancer patients who may best respond to farletuzumab. Morphotek's farletuzumab is an investigational, humanized, monoclonal antibody that binds to folate receptor alpha, which is highly expressed in ovarian cancer and some other epithelial tumors but generally absent from normal tissue. The agreement provides Fujirebio with a worldwide license to develop, manufacture, and commercialize the CA125 II assay as a companion diagnostic.

Farletuzumab (MORAb-003) has been evaluated in a randomized, placebo-controlled phase three trial in combination with carboplatin plus taxane in patients with relapsed platinum-sensitive ovarian cancer. Prespecified subset analyses demonstrated that farletuzumab-treated subjects with low CA125 levels (less than three times the upper limit of normal) correlated with longer progression-free survival and overall survival than those treated with placebo. CA125 is a tumor-shed protein that is elevated in the blood of most ovarian cancer patients and is used clinically as a standard to monitor an ovarian cancer patient's response to therapy. CA125 has been reported to suppress farletuzumab-mediated natural killer cell function, suggesting that higher CA125 levels may suppress the immune-effector response mechanism of farletuzumab's antitumor activity.

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