NEWS RELEASE

Castle Biosciences Launches Next-Generation Sequencing Test DecisionDx-CMSeq for Cutaneous Melanoma

5/30/2018

PDF Version

New test complements Castle's DecisionDx-Melanoma gene expression profile test

Friendswood, TX – May 30, 2018 – Castle Biosciences, Inc., the skin cancer diagnostics company providing molecular diagnostics to improve cancer treatment decisions, today announced the launch of the DecisionDx®-CMSeq test that uses next-generation sequencing (NGS) to identify somatic mutations in genes relevant to cutaneous (skin) melanoma (CM). The DecisionDx-CMSeq NGS test will provide additional information to complement Castle Biosciences' DecisionDx®-Melanoma gene expression profile (GEP) test that predicts individual risk of recurrence in patients with melanoma.

The DecisionDx-CMSeq test evaluates DNA mutations in two genes known to be relevant to melanoma, BRAF and NRAS. The test can be ordered in conjunction with the DecisionDx-Melanoma GEP test or as a standalone request.

"It is critical to understand as much as possible about a patient's melanoma in order to individualize care," said Federico A. Monzon, M.D., FCAP, Chief Medical Officer of Castle Biosciences. "The DecisionDx-Melanoma gene expression profile test is currently used to guide follow-up, surveillance and sentinel lymph node biopsy discussions based on metastatic risk. With the addition of mutational sequencing, we can provide actionable information for treatment options, including adjuvant therapy and clinical trials."

BRAF is the most commonly mutated gene in melanoma, with mutations found in approximately 40 to 50% of CM tumors. The DecisionDx-CMSeq test analyzes mutations in exon 15 of BRAF, where the most common and clinically actionable mutations occur. There are FDA-approved therapies for use in certain patients with particular BRAF mutations, as well as clinical trials underway evaluating new therapies.

Approximately 20% of melanoma tumors harbor mutations in NRAS. The DecisionDx-CMSeq test identifies mutations affecting codons G12, G13 and Q61 of the NRAS gene. Patients with NRAS mutations are likely to be resistant to single-agent BRAFtargeted therapy. There are several ongoing clinical trials evaluating compounds that target tumors with the NRAS mutation. Additional information about the genes in the DecisionDx-CMSeq test is available **here** on the www.SkinMelanoma.com website.

How to order DecisionDx-CMSeq

The DecisionDx-CMSeq test can be ordered on primary formalin-fixed paraffin embedded (FFPE) tumor tissue in conjunction with the DecisionDx-Melanoma GEP test to obtain both a prognostic and therapeutic profile of the tumor. The DecisionDx-CMSeq test can also be ordered separately on FFPE tissue from the primary tumor, lymph node or metastatic tissue. To order the DecisionDx-CMSeq test please call Castle Biosciences Customer Service at (866) 788-9007.

About DecisionDx-Melanoma

The DecisionDx-Melanoma test uses tumor biology to predict individual risk of melanoma recurrence and sentinel lymph node positivity independent of traditional factors. Using tissue from the primary melanoma, the test measures the expression of 31 genes. The test has been validated in three multi-center studies that have included 690 patients and have demonstrated consistent results. Performance has also been confirmed in four prospective studies including 702 patients. The consistent high performance and accuracy demonstrated in these studies, which combined have included over 1,300 patients, provides confidence in disease management plans that incorporate DecisionDx-Melanoma test results. Prediction of the likelihood of sentinel lymph node positivity has also been validated in two prospective multicenter studies that included over 1,400 patients. Clinical impact has been demonstrated in multi-center and single-center studies showing that test results impact clinical management decisions for one of every two patients tested. More information about the test and disease can be found at **www.SkinMelanoma.com**.

About Castle Biosciences

Castle Biosciences is a molecular diagnostics company dedicated to helping patients and their physicians make the best possible decisions about their treatment and follow up care based on the individual molecular signature of their tumor. The Company currently offers tests for patients with cutaneous melanoma (DecisionDx®-Melanoma,

DecisionDx®-CMSeq; www.SkinMelanoma.com) and uveal melanoma (DecisionDx®-UM, DecisionDx®-PRAME and DecisionDx®-UMSeq; www.MyUvealMelanoma.com), with development programs in other underserved cancers. Castle Biosciences is based in Friendswood, TX (Houston), and has laboratory operations in Phoenix, AZ. More information can be found at www.CastleBiosciences.com.

DecisionDx-Melanoma, DecisionDx-CMSeq, DecisionDx-UM, DecisionDx-PRAME and DecisionDx-UMSeq are the trademarks of Castle Biosciences, Inc. Any other trademarks are the property of their respective owners.

Contact

Derek Maetzold, President and CEO

866-788-9007

IR@castlebiosciences.com

PDF Version