Foundation Medicine CGP assay available in U.S., 5/18

May 2018—Foundation Medicine announced that FoundationOne CDx, an FDA-approved comprehensive genomic profiling assay for all solid tumors incorporating multiple companion diagnostics, is available in the United States. FoundationOne CDx is a test for patients with advanced cancer and is offered as a nationally covered benefit across all solid tumors for Medicare and Medicare Advantage beneficiaries who meet eligibility requirements.

The assay is an NGS-based in vitro diagnostic for the detection of substitutions, insertion and deletion alterations, and copy number alterations in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability and tumor mutational burden using DNA isolated from FFPE tumor tissue specimens. It is also FDA approved as a broad companion diagnostic for patients with certain types of non-small cell lung cancer, melanoma, colorectal cancer, ovarian cancer, or breast cancer to identify patients who may benefit from treatment with one of 17 on-label targeted therapies, 12 of which are approved as first-line therapy for their respective indications.

***Foundation Medicine**, 888-988-3639*