FoundationOne® Heme manuscript outlining analytical validation and clinical experience published in Blood

FoundationOne Heme, a Laboratory Developed Test, has demonstrated highly accurate detection of genomic alterations known to impact diagnosis, therapy selection and prognosis in hematologic cancers. It is one of the only marketed tests of its kind with a published analytical validation.

**Analytical Validation Summary**

- FoundationOne Heme demonstrated 99% concordance with CLIA-certified diagnostic assays, including Sequenom, RT-PCR, FISH, and PCR fragment analysis in 11 genes that are known and routinely tested in clinical practice in AML, ALL and MDS (FLT3, NPM1, CEBPA, BCR-ABL1, KIT, IDH2, IDH1, JAK2, MPL, PML-RARA, MLL)
- FoundationOne Heme demonstrated >99% concordance with FoundationOne®. Compared to FoundationOne, FoundationOne Heme contains an additional 90 genes relevant to hematologic malignancies
- Combined DNA and RNA sequencing approach accurately detects a wide variety of genomic rearrangements and gene fusions with immediate clinical value in hematologic malignancies (Sensitivity of 100% at 20-100% tumor fraction and 98% at 10% tumor fraction)

**Clinical Summary**

- Clinical experience described in 3,696 patients showcases diverse use of the platform across hematologic malignancies
- At least one driver alteration was identified in 3246/3433 (95%) tumor specimens, and 2650 (77%) cases harbored at least one alteration linked to a commercially-available targeted therapy or one that is in clinical development. In addition, 61% of cases harbored at least one alteration with known prognostic relevance in that tumor type
- In a subset analysis of patients with high-risk “Philadelphia chromosome-like” ALL, FoundationOne Heme identified a spectrum of alterations in kinase signaling pathways that can guide the use of molecularly targeted therapies

**Conclusion**

FoundationOne Heme, an integrated DNA/RNA profiling platform using targeted next-generation sequencing, has proven effective in detecting all types of genomic alterations including single-nucleotide substitutions, insertions and deletions, copy number alterations, and rearrangements, which increases its ability to identify clinically-relevant genomic alterations with therapeutic relevance. Further, these results indicate that FoundationOne Heme can robustly detect a wide range of alterations in potential driver genes not fully evaluable using conventional methods.

2. FoundationOne® Heme is a laboratory developed test that was developed and its performance characteristics determined by Foundation Medicine. FoundationOne Heme has not been cleared or approved by the U.S. Food and Drug Administration. For more information on FoundationOne Heme, please see its Technical Specifications at http://www.foundationmedicine.com
4. FoundationOne® was a laboratory developed test commercially sold by Foundation Medicine from 2010 to 2017.