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Foundation Medicine Discovers High Incidence of Clinically Actionable ERBB2 (HER2) Alterations in Aggressive Form of Bladder Cancer; Data Published in Clinical Cancer Research

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Foundation Medicine, Inc. (NASDAQ:FMI) today announced the discovery of a high incidence of *ERBB2* (*HER2*) extracellular domain alterations in patients with micropapillary urothelial carcinoma (MPUC), a particularly aggressive form of urinary bladder cancer, using FoundationOne™. The research was published in the current edition of *Clinical Cancer Research*[1].

"This study identifies a recurrent clinically actionable[2] genomic alteration in an extremely aggressive subtype of urinary bladder cancer and opens the door for the use of targeted therapies to treat a significant proportion of patients with this disease," said Jeffrey S. Ross, M.D., medical director, Foundation Medicine and co-lead author of the study. "By using FoundationOne, a highly sensitive, fully informative genomic profile, we were able to identify an alteration that is not typically tested for in the routine care of these patients. We believe this discovery may enable new opportunities for treating patients with this rapidly progressive form of cancer with anti-*ERBB2* targeted therapies."

In this study, Foundation Medicine researchers conducted comprehensive genomic profiling using FoundationOne on 15 MPUC and 64 non-micropapillary urothelial bladder carcinomas (non-MPUC) FFPE tumor samples. Mutations in the extracellular domain of *ERBB2* were identified in six of 15 (40%) MPUC samples. All six cases of MPUC with an *ERBB2* mutation were negative for *ERBB2* amplification and *ERBB2* overexpression. In contrast, six of 64 (9.4%) non-MPUC samples harbored an *ERBB2* alteration, including base substitutions (three cases), amplifications (two cases), and gene fusion (one case), which is higher than the two of 159 (1.3%) protein-changing *ERBB2* alterations reported for urinary bladder cancer in COSMIC. The enrichment of *ERBB2* alterations in MPUC compared with non-MPUC is statistically significant both between this series ($P < 0.0084$) and for all types of urinary bladder cancer in COSMIC ($P < 0.001$).

MPUC is an uncommon subtype of urothelial carcinoma with an incidence of 3,000 to 4,000 cases per year in the United States.

About Foundation Medicine

Foundation Medicine® (NASDAQ: FMI) is a molecular information company dedicated to a transformation in cancer care in which treatment is informed by a deep understanding of the genomic changes that contribute to each patient's unique cancer. The company's clinical assays, FoundationOne™ for solid tumors and FoundationOne™ Heme for hematologic malignancies, sarcomas and pediatric cancers, each provide a fully informative genomic profile to identify a patient's individual molecular alterations and match them with relevant targeted therapies and clinical trials. Foundation Medicine's molecular information platform aims to improve day-to-day care for patients by serving the needs of clinicians, academic researchers and drug developers to help advance the science of molecular medicine in cancer. For more information, please visit www.FoundationMedicine.com or follow Foundation Medicine on Twitter (@FoundationATCG).

Cautionary Notes Regarding Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the anticipated recurrence of a clinically actionable genomic alteration in patients with a form of micropapillary urinary bladder cancer, the ability of Foundation Medicine's genomic profile to identify this genomic alteration, the use of targeted therapies to treat patients with this form of urinary bladder cancer, and the enablement of new opportunities for treating patients with this form of urinary bladder cancer. All such forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include the risk that Foundation Medicine's genomic profile may not properly or fully identify the relevant genomic alteration; targeted therapies to treat such patients may not be available or may not be responsive to patients with this disease; and the risks described under the caption "Risk Factors" in Foundation Medicine's Form 10-Q, which is on file with the Securities and Exchange Commission, as well as other risks detailed in Foundation Medicine's subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Foundation Medicine undertakes no duty to update this information unless required by law.

1. Ross, J. and Wang, K. et al. A High Frequency of Activating Extracellular Domain ERBB2 (HER2) Mutation in Micropapillary Urothelial Carcinoma. *Clin Cancer Res*; 20(1); 68—75.

2. Alterations are defined as clinically actionable if linked to an FDA approved targeted therapy in the tumor under study or to another tumor type, or to an open clinical trial targeting a relevant pathway.

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