

Media Release

Ventana licenses Gen-Probe IP for measuring ERG protein in prostate cancer patients

Emerging biomarker will enable novel clinical assays and Personalized Healthcare for prostate cancer

Ventana Medical Systems, Inc. (Ventana), a member of the Roche Group, announced today that it has co-exclusively sub-licensed certain patents and patent applications from Gen-Probe Incorporated (GPRO) for the worldwide *in vitro* diagnostic (IVD) rights for measuring ERG protein expression through immunohistochemistry (IHC) in prostate tissue. The license complements the existing Ventana worldwide co-exclusive sublicense under certain patents and patent applications for *in situ* hybridization (ISH) rights for measuring ETS gene rearrangements, including ERG gene rearrangements in tissue.

“We believe ERG testing by IHC and ISH will play an important role in novel diagnostic, prognostic, and predictive tests for prostate cancer,” says Mara G. Aspinall, President of Ventana Medical Systems, Inc. *“This license gives us a unique position for this important biomarker as we see the opportunity to incorporate the ERG marker into VENTANA assays that can benefit hundreds of thousands of prostate cancer patients each year.”*

Prostate Cancer is the highest incidence cancer in the United States and Western Europe, with approximately 1 in 6 men having a lifetime risk of being diagnosed. Additionally, prostate cancer is clinically and pathologically a heterogeneous disease which is in great need for improved diagnostic and prognostic assays for positive confirmation of prostate cancer and identification of aggressive or indolent forms of the cancer.

In the journal *Science*, October 2005, researchers from University of Michigan, in collaboration with scientists from Brigham and Women's Hospital, identified that ERG, a known oncogene, rearranges and fuses with androgen response elements including TMPRSS2. Since then, translational research has demonstrated that this rearrangement occurs in approximately 50 percent of prostate cancer patients, does not occur in healthy tissue and describes a molecular subtype of prostate cancer that is associated with androgen driven prostate cancer. As this subtype is the most prevalent in prostate cancer, there has been tremendous diagnostic, prognostic and predictive interest in the ERG biomarker.

“We are extremely enthusiastic to see the rapid development of robust clinical tests to determine the ERG rearrangement status in patient samples,” says Mark A. Rubin, M.D., Horner T. Hirst, Professor of Oncology in Pathology, Weill Cornell Medical College of Cornell University and New York Presbyterian Hospital. *“Emerging molecular and clinical data strongly support the view that prostate cancer is a collection of molecularly distinct diseases that will have different disease trajectories and responses to treatment. Accurately defining the ERG rearrangement class, the largest molecular subclass known to date, is a critical step towards precision health care for prostate cancer.”*

Ventana has ERG IVD assays available globally-- including assays for ERG protein via IHC (worldwide IVD) and assays for ERG gene rearrangements via Quantum Dot FISH (CE-IVD)--and the company is developing multivariate assays for novel clinical indications. These assays are

available for use on the VENTANA [BenchMark](#) line of fully-automated advanced staining instrumentation utilized by thousands of anatomic pathology labs worldwide.

About Ventana Medical Systems, Inc.

Ventana Medical Systems, Inc. (“VMSI”) (SIX: RO, ROG; OTCQX: RHHBY), a member of the Roche Group, innovates and manufactures instruments and reagents that automate tissue processing and slide staining for cancer diagnostics. VENTANA solutions are used in clinical histology and drug development research laboratories worldwide. The company’s intuitive, integrated staining, workflow management platforms, and digital pathology solutions optimize laboratory efficiencies to reduce errors, support diagnosis and inform treatment decisions for anatomic pathology professionals. Together with Roche, VMSI is driving Personalized Healthcare through accelerated drug discovery and the development of “companion diagnostics” to identify the patients most likely to respond favorably to specific therapies. Visit www.ventana.com to learn more.

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