



Syndax Pharmaceuticals Signs Agreement with Ventana Medical Systems, Inc. to Develop Companion Diagnostic Test for Entinostat

– Assay to identify patients with E-cadherin high lung cancer –

Waltham, Mass. and Tucson, Ariz. – January 5, 2012 – [Syndax Pharmaceuticals, Inc.](#) and Ventana Medical Systems, Inc. announced that the companies have entered into an agreement to develop a companion diagnostic assay to select patients with non-small cell lung cancer (NSCLC) for treatment with erlotinib and Syndax's proprietary lead molecule entinostat.

"Syndax is pleased to partner with Ventana, a world leader and innovator of tissue-based diagnostic solutions for patients worldwide, as we advance the development of entinostat in NSCLC," said Joanna Horobin, MD, president and chief executive officer of Syndax. "In ENCORE 401, a randomized, phase 2 study comparing erlotinib plus entinostat to erlotinib plus placebo, the subset of patients with tumors expressing high levels of the protein E-cadherin experienced a more favorable overall survival and we therefore intend to select this patient population in the confirmatory study planned to start in the second half of the year."

Data from ENCORE 401 presented most recently at the 2011 World Conference on Lung Cancer indicated that a subset of advanced non-small cell lung cancer patients expressing high levels of the protein e-cadherin in their tumors derived a 4-month survival advantage with the combination treatment versus erlotinib plus placebo (HR 0.35 [95% CI:0.13-0.92] p=0.03).

In 2010, Ventana developed and launched an in vitro diagnostic kit for use on VENTANA platforms to measure levels of E-cadherin in epithelial tissues. Ventana plans to validate the assay in its own in-house CAP/ CLIA certified laboratory and may then serve as the central laboratory for the upcoming Syndax clinical trial.

"We are very pleased to be the companion diagnostic partner of choice for Syndax to collaborate on this important project," said Ventana President, Mara G. Aspinall. "The plan to develop a companion diagnostic for entinostat shows that our companies are aligned in their commitment to advancing personalized healthcare to improve the lives of patients afflicted with cancer."

About Entinostat

Syndax's lead product entinostat is a novel, oral small molecule inhibitor of class I histone deacetylases, key enzymes that alter the structure of chromatin to control gene expression. Entinostat is differentiated from other members of the class through its unique selectivity profile, pharmacokinetic properties and safety profile. Entinostat has been studied in more than 600 cancer patients where objective tumor responses have been observed in both solid and hematologic malignancies.

Randomized, placebo-controlled [phase 2 studies](#) with entinostat have demonstrated promising results in combination with aromatase inhibitors in breast cancer (ENCORE 301) and with the EGFR-TKI erlotinib (ENCORE 401) in non-small cell lung cancer. Results from the ENCORE clinical program have provided the basis for moving entinostat in pivotal, phase 3 testing across a platform of breast and lung cancer indications.

About Syndax

Syndax Pharmaceuticals, Inc. is a Waltham, MA-based, late-stage, oncology-focused pharmaceutical company. The company is building a portfolio of new oncology products to extend and improve the lives of patients by developing and commercializing novel cancer therapies in optimized, mechanistically driven combination regimens. Syndax has worldwide rights to develop and

commercialize entinostat which has shown promise in [randomized clinical trials](#) in solid tumors and in phase 2 clinical trials in Hodgkin's lymphoma. Syndax is backed by top-tier venture capital firms Domain Associates, MPM Capital, Avalon, Pappas and Forward Ventures. Formed in 2005, Syndax's intellectual property is based on work from scientific founder Ronald Evans, Ph.D., recipient of the 2004 Albert Lasker Prize for Basic Medical Research, a Member of the National Academy of Sciences, a professor at the Salk Institute for Biological Studies and a Howard Hughes Medical Institute Investigator. For more information please visit www.syndax.com.

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 "Smart Systems" – intuitive, integrated staining and workflow management platforms that optimize laboratory efficiencies to reduce errors – support diagnosis and inform treatment decisions for anatomic pathology professionals. Together with Roche, VMSI is driving personalized medicine 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. VENTANA is a trademark of Roche.

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