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by Alexander Schlachterman, Asyia S. Ahmad

A CASE REPORT
AN UNUSUAL FINDING OF COLONIC SCHWANNOMA
by Mark Friedman, Veena Nannegari, Dave Jones, Seth Richter

Crossword Puzzle
See Page 68
OraSure Technologies Receives CLIA Waiver for OraQuick® HCV Rapid Test

BETHLEHEM, PA. OraSure Technologies, Inc. (NASDAQ:OSUR) announced that the U.S. Food and Drug Administration ("FDA") has granted a waiver under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") for its OraQuick® HCV Rapid Antibody Test for use with fingerstick whole blood and venous whole blood specimens.

The OraQuick® HCV Rapid Antibody Test is the first and only FDA-approved rapid test for the detection of antibodies to the hepatitis C virus ("HCV"). The test, which utilizes the OraQuick® technology platform, provides results in 20 minutes. With this waiver, the OraQuick® HCV test now can be used by more than 180,000 sites in the United States to test persons who are at risk for hepatitis C or have signs or symptoms of hepatitis. These sites now extend to facilities that can perform CLIA-waived tests, such as outreach clinics, community-based organizations and physician offices.

“Today, more than 4 million Americans are infected with hepatitis C and the vast majority do not know it,” said Dr. Willis C. Maddrey, President of the Chronic Liver Disease Foundation. “Hepatitis C is a leading cause of chronic liver disease, cirrhosis and liver cancer. However, new therapies are now available that can effectively treat a high percentage of people with HCV infection, making expanded and accessible testing for HCV a critical step in fighting this epidemic.”

“A CLIA waiver for our OraQuick® HCV test represents a critical milestone in our quest to make the test available to the widest possible range of at risk individuals in the U.S.,” said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. “The CLIA waiver will enable healthcare providers, those on the front lines of fighting this devastating disease, to use this simple and accurate test in physician offices and outreach settings so more individuals infected with hepatitis C can be diagnosed and treated.”

As previously announced, OraSure has entered into agreements with Merck & Co. (NYSE:MRK) to collaborate on the development and promotion of the OraQuick® HCV test. Under these agreements, Merck will provide detailing and other promotional support for the test in the physicians’ office markets in the United States and internationally. The approval of the CLIA waiver will now enable physicians to utilize the test in their office settings.

(continued on page 64)