FDA APPROVES EXACT SCIENCES’ COLOGUARD®: THE FIRST AND ONLY FDA APPROVED STOOL DNA NONINVASIVE COLORECTAL CANCER SCREENING TEST

First time in history a technology receives FDA approval and proposed national coverage by CMS on the same day

Screening test detects 92% of colorectal cancer

MADISON, WI — Exact Sciences Corp. (NASDAQ: EXAS) announced that the U.S. Food and Drug Administration (FDA) has approved Cologuard, the company’s noninvasive, stool DNA colorectal cancer screening test. Cologuard is the first noninvasive screening test for colorectal cancer that analyzes both stool DNA and blood biomarkers and has been proven to find 92 percent of cancers and 69 percent of the most advanced precancerous polyps in average risk patients. Cologuard, which is available through healthcare providers, offers people 50 and older at average risk for colorectal cancer an easy-to-use screening test they can do in the privacy of their own home.

Upon approval, Exact Sciences also received a proposed coverage memorandum from the Centers for Medicare and Medicaid Services (CMS). Cologuard is the first product to take part in the joint FDA and CMS parallel review pilot program in which both agencies simultaneously review medical devices to help reduce the time between FDA approval and Medicare coverage. A final National Coverage Determination is expected to be posted in October/November of this year after a public comment period.

Colorectal cancer is considered the most preventable, yet least prevented cancer due to the lack of patient compliance with screening. An estimated 23 million Americans between 50 and 75 are not getting screened as recommended and as a result, colorectal cancer remains the second–leading cancer killer in the U.S. For those whose cancer is detected at an earlier stage, the five–year survival rate can be greater than 90 percent.

“Colorectal cancer is highly preventable and following the recommended screening guidelines can lead to life-sparing early detection,” said Eric Hargis, CEO, Colon Cancer Alliance. “In more than 60 percent of all cases, colorectal cancer is not detected until its late stages, making treatment more challenging. New, patient–friendly screening options are desperately needed to prevent colorectal cancer or help identify it early, when it is most treatable. Given that more than half of colorectal cancer-related deaths could be avoided with regular screenings, having Cologuard as another option for people who have resisted getting a colonoscopy could result in many lives being saved and screening compliance rates to increase.”

Cologuard is designed to detect biomarkers from DNA in cancer that is shed from the colon as part of the digestive process and blood released in the stool. After the physician orders Cologuard, the kit is mailed directly to the patient’s home. The patient then collects a stool sample in the Cologuard Collection Kit and sends the kit back to the Exact Sciences lab for testing through a pre-paid mailer.

At the lab, the stool sample is analyzed in an automated system to yield a single test result—positive or negative for the presence of precancerous polyps or cancer. Results from the Cologuard test are turned around in as little as two weeks, and patients learn their results directly from their prescribing physician. Unlike many other screening options, Cologuard does not require medication or dietary restrictions, or bowel preparation prior to taking the test.

“The robustly conducted research as part of this FDA approval process has proven that this noninvasive test is highly sensitive in detecting both early stage colorectal cancer and the most advanced precancerous polyps most likely to develop into cancer,” said David Ahlquist, M.D., a Mayo Clinic gastroenterologist and co-inventor of the test. “The test is designed for high accuracy, ease of patient use, and wide accessibility. We hope that it will make a difference and save many lives.”

“The FDA approval of Cologuard represents a major achievement in Exact Sciences’ mission to make a noninvasive, patient-friendly screening test for colorectal...
cancer available,” said Kevin Conroy, President, CEO and Chairman of Exact Sciences. “Cologuard addresses a critical need for a more convenient screening option for patients to aid in prevention and early detection. Exact Sciences is committed to making Cologuard available and accessible to patients and looks forward to advancing cancer detection in other gastrointestinal cancers. On behalf of the Exact Sciences team, I would like to thank the FDA and CMS for allowing us to go through the parallel review process.”

Results from the company’s DeeP–C Study, prospective, 90–site, 10,000–patient pivotal study — one of the most extensive colorectal cancer screening studies ever conducted in the U.S. — were published in April 2014 in the New England Journal of Medicine’s, “Multi-target Stool DNA Testing for Colorectal Cancer Screening”.

Cologuard is available to patients through their healthcare providers in the U.S. for $599. Exact Sciences has plans to make Cologuard available in select countries in Europe pending CE Mark.

For more information, visit: www.CologuardTest.com or call 1-844-870-8870

More information on colon cancer and the importance of screening and early detection at: www.beseengetscreened.com

Visit www.exactsciences.com to to sign up for the company’s eNewsletter.

Dr. David Ahlquist, professor of medicine at Mayo Clinic, is the inventor of the technology that has been licensed to Exact Sciences from Mayo Clinic. Under that licensing agreement, Mayo Clinic and Dr. Ahlquist share in equity and royalties. Revenue Mayo Clinic receives is used to support Mayo’s not–for–profit mission in patient care, education and research.

About Exact Sciences Corp.

Exact Sciences Corp. (NASDAQ: EXAS) is a molecular diagnostics company focused on the early detection and prevention of colorectal cancer. The company has exclusive intellectual property protecting its noninvasive, molecular screening technology for the detection of colorectal cancer. Stool DNA technology is included in the colorectal cancer screening guidelines of the American Cancer Society and the U.S. Multi–Society Task Force on Colorectal Cancer.

For more information, please visit the company’s website at: www.exactsciences.com

AMERICAN REGENT HIGHLIGHTS CHALLENGES AND TREATMENT OPTIONS FOR GASTROINTESTINAL-RELATED IRON DEFIciENCY ANEMIA AT DIGESTIVE DISEASE WEEK 2014

Iron deficiency anemia common but underdiagnosed and undertreated in patients with gastrointestinal conditions; high-dose intravenous iron an effective treatment option

CHICAGO, IL – American Regent, Inc., a subsidiary of Luitpold Pharmaceuticals, Inc. (a Daiichi Sankyo Group Company), announced the presentation of new data at Digestive Disease Week 2014 in Chicago, IL, showing the efficacy and safety of high-dose injectable iron (Injectafer® [ferric carboxymaltose injection]) in patients with gastrointestinal-related iron deficiency anemia, as well as outlining the economic and medical resource use burden of iron deficiency anemia among inflammatory bowel disease and bariatric surgery patients in the United States. The three posters and key findings presented at the conference last week were:

Ferric Carboxymaltose: Efficacy and Safety in Patients with Gastrointestinal-Related Iron Deficiency Anemia: A Pooled Analysis

Injectafer® (ferric carboxymaltose injection) is effective in patients with gastrointestinal-related iron deficiency anemia and has an improved safety profile compared to other IV irons, such as Venofer® (iron sucrose injection, USP).

Economic and Medical Resource Use Burden of Iron Deficiency Anemia in an Inflammatory Bowel Disease (IBD) Population in the United States

IBD patients who develop iron deficiency anemia may have higher medical resource use and direct medical costs compared to those who do not develop this condition. Although most IBD patients who develop iron deficiency anemia are tested for their iron, most are not treated with oral or intravenous iron, and do not receive blood transfusions within the first year of developing iron deficiency anemia.

Economic and Medical Resource Use Burden of Iron Deficiency Anemia in a Bariatric Surgery Population in the United States

Bariatric surgery patients who develop iron deficiency anemia may have higher complication rates, medical resource use, and direct medical costs compared to those who don’t develop iron deficiency anemia. Although most bariatric surgery patients who develop iron deficiency anemia are tested for their iron, most are not treated with oral or intravenous iron and do not receive blood transfusions in the first two years after surgery.
“The treatment of iron deficiency anemia is an important, unmet medical need. Gastrointestinal conditions that are associated with iron deficiency anemia include chronic inflammatory bowel diseases such as Crohn’s disease and ulcerative colitis. In addition, iron deficiency anemia can be associated with certain surgical procedures, such as bariatric surgery,” said blood disease expert Dr. Lawrence Goodnough, Director of Transfusion and Professor of Pathology and of Medicine at Stanford University Medical Center. “These patients need help to meet their minimum daily iron needs.”

All three studies presented at the conference were sponsored by Luitpold Pharmaceuticals.

Full abstracts can currently be found on the Digestive Disease Week website at http://www.ddw.org/program/abstracts

“We are pleased to help support this research and raise awareness of the impact that iron deficiency anemia can have on gastrointestinal patients,” commented Jacalyn Beltrani, MBA, Vice President of Commercial Operations of American Regent.

About Iron Deficiency Anemia
There are over 7.5 million people in the US with iron deficiency anemia (IDA), a condition that occurs when body iron stores are inadequate for normal red blood cell production. Fatigue, difficulty concentrating, shortness of breath, and dizziness are common symptoms, significantly impacting patients’ quality of life. IDA is a common complication of many diseases and conditions, including cancer, chronic kidney disease, gastrointestinal conditions, obstetric and gynecological conditions and congestive heart failure. It affects up to one-third of inflammatory bowel disease patients and nearly one-quarter of patients who have undergone gastric bypass surgery. IDA is prevalent in women, affecting over 3 million US women of childbearing age due to conditions such as heavy uterine bleeding, postpartum anemia, and pregnancy. Blood disease expert Lawrence Goodnough, MD, from Stanford University Medical Center and Lynell D’Sylva, RN, BSN, from American Regent recently discussed the importance of maintaining sufficient iron levels on Lifetime’s special, The Balancing Act.

About Injectafer®
Injectafer® (ferric carboxymaltose injection) is the first non-dextran intravenous (IV) iron approved for the treatment of adult patients with iron deficiency anemia of various etiologies who are intolerant to or who have had an unsatisfactory response to oral iron, in addition to use in adult non-dialysis dependent chronic kidney disease (CKD) patients. A single dose of up to 750 mg of Injectafer® can be administered undiluted as an IV push injection at a rate of 100 mg/minute or as an IV infusion in up to 250 mL 0.9 % sodium chloride injection, USP, over at least 15 minutes. Injectafer® is reimbursable using Q code 9970 for product-specific reimbursement, C code C9441 (Medicare-only hospital outpatient settings), and J code J3490 (delivery in physician offices and non-Medicare outpatient settings).

The full prescribing information for Injectafer® is available at: http://www.injectafer.com/files/Prescribing_Information.pdf

The safety and efficacy of Injectafer® for treatment of iron deficiency anemia was evaluated in two clinical trials (Trial 1 and Trial 2) in which Injectafer® was administered at a dose of 15 mg/kg body weight up to a maximum single dose of 750 mg of iron on two occasions separated by at least 7 days up to a maximum cumulative dose of 1500 mg of iron. The inclusion / exclusion criteria for both studies allowed patients with various comorbidities, characteristic of this broad patient population. Additionally, patients with a history of drug allergies were included in the trials, providing robust safety data in this difficult-to-treat subset of patients.

Trial 1 compared two 750-mg doses of Injectafer® to either oral or IV iron (standard of care therapy) in patients with iron deficiency anemia of various etiologies and included approximately 1000 patients, half of whom received Injectafer®. In this trial, Injectafer® raised hemoglobin more than oral iron or IV standard of care therapy, with a mean change in hemoglobin of 1.57 g/dL vs. 0.80 g/dL when compared...
(continued from page 94)

...with IV standard of care therapy. These increases were statistically significant (p=0.001). In addition, a significantly higher proportion of patients who received Injectafer® achieved a hemoglobin of >12 g/dL during the course of treatment compared to both oral iron (57.0% vs. 29.1%, respectively) and IV standard of care (50.6% vs. 24.5%, respectively) (p=0.001 for both). Further, cardiovascular safety was evaluated based on an adjudicated composite safety endpoint comprised of death, myocardial infarction, stroke, unstable angina, congestive heart failure, arrhythmias, hypertension and hypotension. Rates of the composite safety endpoint were 3.95% for Injectafer® vs. 4.90% when compared to IV standard of care and 2.85% for Injectafer® vs. 1.58% when compared to oral iron.

Trial 2, the largest head-to-head study of IV iron in high-risk patients with iron deficiency anemia and CKD, compared Injectafer® to Venofer® (iron sucrose injection, USP; American Regent, Inc., Shirley, NY) and included 2561 patients, approximately half of whom received Injectafer®. In these high-risk patients, two 750-mg doses of Injectafer® increased hemoglobin more than five 200-mg doses of Venofer®, with a change in hemoglobin of 1.13 g/dL for Injectafer® vs. 0.92 for Venofer®. These increases were statistically significant (treatment difference [95% CI] = 0.21 [0.13 to 0.28]). Rates of the adjudicated composite safety endpoint comprised of death, myocardial infarction, stroke, unstable angina, congestive heart failure, arrhythmias, hypertension and hypotension were statistically similar at 13.71% for Injectafer® vs. 12.14% for Venofer® (treatment difference [95% CI] = 1.57% [-1.10% to 4.25%]). Rates of a composite of death, myocardial infarction and stroke were 1.88% for Injectafer® vs. 2.72% for Venofer®.

Injectafer® is manufactured and marketed under the name of Ferinject® (ferric carboxymaltose injection) by Vifor Pharma (Switzerland) outside of North America.

**Important Safety Information**

**Indications/Contraindications**

Injectafer® (ferric carboxymaltose injection) is an iron replacement product indicated for the treatment of iron deficiency anemia in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron, and in adult patients with non-dialysis dependent chronic kidney disease. Injectafer® is contraindicated in patients with hypersensitivity to Injectafer® or any of its inactive components.

**Warnings and Precautions**

Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving Injectafer®. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Monitor patients for signs and symptoms of hypersensitivity during and after Injectafer® administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer Injectafer® when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions. In clinical trials, serious, anaphylactic/anaphylactoid reactions were reported in 0.1% (2/1775) of subjects receiving Injectafer®. Other serious or severe adverse reactions potentially associated with hypersensitivity which included, but were not limited to, pruritus, rash, urticaria, wheezing, or hypotension were reported in 1.5% (26/1775) of these subjects.

In clinical studies, hypertension was reported in 3.8% (67/1775) of subjects. Transient elevations in systolic blood pressure, sometimes occurring with facial flushing, dizziness, or nausea were observed in 6% (106/1775) of subjects. These elevations generally occurred immediately after dosing and resolved within 30 minutes. Monitor patients for signs and symptoms of hypertension following each Injectafer® administration. In the 24 hours following administration of Injectafer®, laboratory assays may overestimate serum iron and transferrin bound iron by also measuring the iron in Injectafer®.

**Adverse Reactions**

In two randomized clinical studies, a total of 1775 patients were exposed to Injectafer®, 15/mg/kg of body weight, up to a single maximum dose of 750 mg of iron on two occasions, separated by at least 7 days, up to a cumulative dose of 1500 mg of iron. Adverse reactions reported by ≥ 2% of Injectafer®-treated patients were nausea (7.2%); hypertension (3.8%); flushing/hot flush (3.6%); blood phosphorus decrease (2.1%); and dizziness (2.0%).

The following serious adverse reactions have been most commonly reported from the post-marketing spontaneous reports: urticaria, dyspnea, pruritus, tachycardia, erythema, pyrexia, chest discomfort, chills, angioedema, back pain, arthralgia and syncope.

See full prescribing information at www.injectafer.com

(continued on page 98)
ORASURE TECHNOLOGIES ANNOUNCES NEW CO-PROMOTION AGREEMENT FOR ORAQUICK® HCV RAPID ANTIBODY TEST

BETHLEHEM, Pa – OraSure Technologies (NASDAQ: OSUR), a market leader in point of care diagnostics, announced that it has entered into a Master Program Services and Co-Promotion Agreement with AbbVie under which AbbVie and OraSure will co-promote the Company’s OraQuick® HCV Rapid Test in the United States. The product will be used to test individuals at-risk for hepatitis C (HCV). OraSure will be responsible for manufacturing and selling the product directly into all markets.

Under the agreement, OraSure has granted exclusive promotion rights to AbbVie for the OraQuick® HCV test in certain markets and will provide certain additional services in support of HCV testing. In exchange for the exclusive rights granted to AbbVie, OraSure will receive up to $75 million in exclusivity payments over the term of the agreement, which runs through December 31, 2019. In addition, upon achievement of certain performance-based milestones, OraSure will be eligible to receive additional payments annually over the life of the agreement. Further information regarding the agreement will be available in the Company’s 8-K Report filed later today with the SEC.

According to the Centers for Disease Control and Prevention (CDC), HCV is the most common chronic blood-borne infection in the United States, with approximately 5 million people infected. It is estimated that one in 30 Baby Boomers (adults born between 1945 and 1965) have chronic hepatitis C and up to 75% of the people infected with HCV are unaware of their infection. The CDC, the U.S. Preventative Services Task Force (USPSTF), and the American Association for the Study of Liver Diseases (AASLD) have all issued guidance that recommends HCV testing for at-risk individuals including all Baby Boomers.

“We believe it is critical that at-risk individuals be tested for hepatitis C to prevent serious consequences from untreated infection,” said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. “This new collaboration allows us to educate healthcare professionals and the patients they treat about hepatitis C and provide them with a very important rapid diagnostic tool.”

The OraQuick® HCV test is the first and only FDA-approved and CLIA-waived point of care test for detection of HCV infection in at-risk individuals. The simple platform enables healthcare providers to deliver a diagnosis based on lab-accurate test results in 20 minutes, using fingerstick or venipuncture blood.

Updated Financial Guidance As a result of the new co-promotion agreement announced today, the Company has updated its financial guidance to reflect the initial impact of this arrangement and is now projecting consolidated net revenues ranging from $26.0 to $26.5 million and a consolidated net loss of approximately $0.08 to $0.09 per share for the second quarter of 2014.

About OraSure Technologies

OraSure Technologies is a leader in the development, manufacture and distribution of point of care diagnostic and collection devices and other technologies designed to detect or diagnose critical medical conditions. Its innovative products include rapid tests for the detection of antibodies to HIV and HCV at the point of care and testing solutions tests for detecting various drugs of abuse. The Company sells the OraQuick® In-Home HIV Test, the first and only rapid HIV test approved by the U.S. Food and Drug Administration for sale to the consumer over-the-counter market in the U.S. In addition, the Company is a leading provider of oral fluid sample collection, stabilization and preparation products for molecular diagnostic applications. OraSure’s portfolio of products is sold globally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, research and academic institutions, distributors, government agencies, physicians’ offices, and commercial and industrial entities. The Company’s products enable healthcare providers to deliver critical information to patients, empowering them to make decisions to improve and protect their health.

For more information on OraSure Technologies, please visit: [www.orasure.com](http://www.orasure.com)