NEWS RELEASE

Quest Diagnostics to Introduce Ki-67 IHC MIB-1 pharmDx, the First Companion Diagnostic for Eli Lilly and Company's Verzenio® (abemaciclib), a CDK4/6 Inhibitor for Certain People with HR+ HER2- High Risk Early Breast Cancer

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As the First Laboratory to Validate Ki-67 IHC MIB-1 pharmDx (Dako Omnis), Quest Plans to Make Testing Available Nationally by the End of October

SECAUCUS, N.J., Oct. 18, 2021 /PRNewswire/ -- Quest Diagnostics (NYSE: DGX), the world's leading provider of diagnostic information services, today announced that it will provide clinical laboratory testing using the Ki-67 IHC MIB-1 pharmDx (Dako Omnis) immunohistochemistry companion diagnostic.

On October 13, the U.S. Food and Drug Administration (FDA) approved **Eli Lilly and Company's** Verzenio® (abemaciclib), in combination with endocrine therapy (tamoxifen or an aromatase inhibitor), for the adjuvant treatment of adult patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-), node-positive, early breast cancer (EBC) at high risk of recurrence and a Ki-67 score of ≥20% as determined by an FDA-approved test. Ki-67 is a marker of cellular proliferation. Verzenio is the first and only CDK4/6 inhibitor approved for this patient population.

In aligned actions, the FDA also granted pre-market approval to Ki-67 IHC MIB-1 pharmDx (Dako Omnis) from **Agilent Technologies, Inc.** as a companion diagnostic for Verzenio. Quest is the first laboratory to have validated the test in conjunction with Agilent. Since the validation of an IVD assay can take weeks, Quest is committed to providing the test as soon as possible, with plans to make it nationally available by the end of the month.

"The imminent addition of Ki-67 IHC MIB-1 pharmDx (Dako Omnis) testing to our oncology menu underscores our

commitment to providing precision medicine innovations with potential to improve outcomes for patients with cancer," said Kristie Dolan, General Manager, Oncology Franchise, Quest Diagnostics. "It also reflects our ability to create value-producing relationships across healthcare, building on our long-standing precision medicine collaboration with Agilent."

Quest Diagnostics is a leading diagnostics services provider in oncology and genetics. Covering the breadth of diagnostic services, from screening and diagnosis to treatment selection, prognosis and monitoring recurrence, the company's expertise spans nearly all cancers, including breast, thyroid, lung cancer, colorectal, prostate, cervical, multiple myeloma and leukemia/lymphoma, among others.

About Early Breast Cancer and Risk of Recurrence

It is estimated that 90 percent of all breast cancers are detected at an early stage. Although the prognosis for HR+ HER2- EBC is generally positive, 20 percent of patients will experience recurrence potentially to incurable metastatic disease.1 Risk of recurrence is greatest within the initial two to three years post-diagnosis, particularly in patients with node-positive, high risk EBC.2 Factors associated with high risk of recurrence include: positive nodal status, large tumor size (≥5 cm), high tumor grade (Grade 3), and high rate of cellular proliferation [Ki-67 score (≥20%)].3

Node-positive means that cancer cells from the tumor in the breast have been found in the lymph nodes in the armpit area. Although the breast cancer is removed through surgery, the presence of cancer cells in the lymph nodes signifies that there is a higher chance of the cancer returning and spreading.

About Breast Cancer

Breast cancer has now surpassed lung cancer as the most commonly diagnosed cancer worldwide in females, according to GLOBOCAN. With approximately 685,000 deaths in 2020, breast cancer is the fifth-leading cause of cancer death worldwide.4 In the U.S., it is estimated that there will be 281,550 new cases of breast cancer in 2021.5 Approximately 70 percent of all breast cancers are of the HR+ HER2- subtype.5

About Verzenio® (abemaciclib)

Verzenio® abemaciclib is a targeted treatment known as a CDK4/6 inhibitor. Verzenio is a non-chemotherapy oral tablet.

Verzenio works inside the cell to block CDK4/6 activity and help stop the growth of cancer cells, so they may eventually die (based on preclinical studies).* Cyclin-dependent kinases (CDK)4/6 are activated by binding to D-cyclins. In estrogen receptor-positive (ER+) breast cancer cell lines, cyclin D1 and CDK4/6 promote phosphorylation of the retinoblastoma protein (Rb), cell cycle progression, and cell proliferation.

In vitro, continuous exposure to Verzenio inhibited Rb phosphorylation and blocked progression from G1 to S

phase of the cell cycle, resulting in senescence and apoptosis (cell death). Preclinically, Verzenio dosed daily without interruption resulted in reduction of tumor size. Inhibiting CDK4/6 in healthy cells can result in side effects, some of which may be serious. Clinical evidence also suggests that Verzenio crosses the blood-brain barrier. In patients with advanced cancer, including breast cancer, concentrations of Verzenio and its active metabolites (M2 and M20) in cerebrospinal fluid are comparable to unbound plasma concentrations.

Verzenio is Lilly's first solid oral dosage form to be made using a faster, more efficient process known as continuous manufacturing. Continuous manufacturing is a new and advanced type of manufacturing within the pharmaceutical industry, and Lilly is one of the first companies to use this technology.

INDICATIONS FOR VERZENIO

Verzenio® (abemaciclib) in combination with endocrine therapy (ET) is indicated for the adjuvant treatment of adult patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-), node-positive, early breast cancer (EBC) at high risk of recurrence and a Ki-67 score of ≥20% as determined by an FDA-approved test.

Verzenio is indicated for the treatment of HR+ HER2- advanced or metastatic breast cancer:

- in combination with an aromatase inhibitor for postmenopausal women, and men, as initial endocrine-based therapy
- in combination with fulvestrant for adult patients with disease progression following endocrine therapy
- as a single agent for adult patients with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting

Please see full **Prescribing Information** for Verzenio.

About Quest Diagnostics

Quest Diagnostics empowers people to take action to improve health outcomes. Derived from the world's largest database of clinical lab results, our diagnostic insights reveal new avenues to identify and treat disease, inspire healthy behaviors and improve health care management. Quest annually serves one in three adult Americans and half the physicians and hospitals in the United States, and our nearly 50,000 employees understand that, in the right hands and with the right context, our diagnostic insights can inspire actions that transform lives. **www.QuestDiagnostics.com**.

1 Early Breast Cancer Trialists' Collaborative Group (EBCTCG). Effects of chemotherapy and hormonal therapy for early breast cancer on recurrence and 15-year survival: an overview of the randomised trials. Lancet. 2005;365(9472):1687-1717. doi:10.1016/S0140-6736(05)66544-0.

2 Verzenio [package insert]. Indianapolis, IN: Eli Lilly and Company.
3 Cheng L, Swartz MD, Zhao H, et al. Hazard of recurrence among women after primary breast cancer treatment--a 10-year follow-up using data from SEER-Medicare. Cancer Epidemiol Biomarkers Prev. 2012;21:800-809.
4 Sung H, Ferlay J, Siegel RL, et al. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2021;71(3):209-249
5 National Cancer Institute, SEER. Cancer Stat Facts: Female Breast Cancer. **https://seer.cancer.gov/statfacts/html/breast.html**. Accessed September 14, 2021.

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