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IQVIA supports path to label expansion

May 31, 2019 | News

Previously announced FDA approval of IBRANCE (palbociclib) for the treatment of men with metastatic breast cancer based in part on IQVIA real world analytics; Pfizer Oncology to present analysis at ASCO



IQVIA has announced that it is pleased to have provided support towards the approval from the U.S. Food and Drug Administration to expand the indications for IBRANCE (palbociclib) in combination with an aromatase inhibitor or fulvestrant to include the treatment of men with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer. Pfizer Oncology will present the results as a poster at the upcoming 2019 American Society of Clinical Oncology (ASCO) Annual Meeting, May 31 to June 4 in Chicago, Illinois.

Pfizer Oncology's IBRANCE is indicated for the treatment of adult patients with HR+, HER2- advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine based therapy in postmenopausal women or in men; or with fulvestrant in patients with disease progression following endocrine therapy. IQVIA delivered deep analytics to support Pfizer's submission which led to the expanded approval. The use of IQVIA's innovative approach helped enable Pfizer Oncology to offer IBRANCE as a treatment option for this underserved patient population where, due to the rarity of the disease, fewer large, randomized clinical trials are conducted.

IQVIA is at the forefront of using advanced real world capabilities for regulatory requirements – combining sophisticated analytics, access to a global network of providers, and deep clinical expertise to deliver innovative study designs. Powered by the IQVIA CORE, IQVIA is driving innovation within the regulatory environment with its oncology expertise and advanced analytics.