23andMe Granted New FDA Clearance to Provide Interpretive Drug Information for a Commonly Prescribed Cholesterol Medication

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FDA 510(k) clearance allows 23andMe to report genetics associated with processing of certain statins, provides interpretive drug information for simvastatin, and removes the requirement for confirmatory testing of the 23andMe result

SOUTH SAN FRANCISCO, Calif., Oct. 27, 2022 (GLOBE NEWSWIRE) -- 23andMe Holding Co. (Nasdaq: ME) (“23andMe”), a leading human genetics and biopharmaceutical company with a mission to help people access, understand, and benefit from the human genome, today reported that the U.S. Food and Drug Administration (FDA) granted 510(k) clearance for its pharmacogenetics (PGt) report for SLCO1B1 to include interpretive drug information for simvastatin, a common drug used to treat high cholesterol and triglyceride levels. The 510(k) clearance modifies the labeling of the previously authorized 23andMe SLCO1B1 Drug Transport report, removing the need for confirmatory testing and allowing the company to provide interpretive drug information based on genetic factors for simvastatin.

“This is an important win for consumers, as they will have access to critical information on how they may respond to a commonly prescribed medication, based on their genetics,” said Noura Abul-Husn, M.D. Ph.D., Vice President of Genomic Health at 23andMe. “A complete health picture requires a number of inputs, including genetics, which too often are left off the table in healthcare. With this clearance we are continuing to champion access to actionable health information so that everyone can benefit from a personalized health care experience, and avoid negative side effects of medications where possible.”

Simvastatin is a medication in the statin family of drugs, commonly prescribed to lower cholesterol to help reduce the risk of heart attack and stroke. In 2020, simvastatin was the second-most commonly prescribed statin, and the thirteenth-most commonly prescribed medication overall, in the U.S.* A variation of a particular gene, SLCO1B1, influences the body’s response to simvastatin. In certain ethnicities, up to 38% of people have a SLCO1B1 genotype that increases the possibility of experiencing side effects related to taking simvastatin, particularly statin-associated musculoskeletal symptoms (SAMS) risk**.

23andMe underwent rigorous analytical validation in order to meet FDA requirements to remove the need for confirmatory testing of the 23andMe pharmacogenetics report for SLCO1B1. This included method comparison studies with expanded sample collection activities in order to further mitigate the risk for false positive and false negative results. Accuracy testing achieved 99% concordance with Sanger sequencing.

As with its previously authorized pharmacogenetics reports, both 23andMe and the FDA also want to ensure that consumers understand these reports and use them properly, which includes adhering to their current medications and consulting with their healthcare providers. Based on 23andMe's previous consumer comprehension studies, over 95 percent of users understood that they should not use the report to make any changes to treatment without consulting their doctor.

About 23andMe
23andMe is a genetics-led consumer healthcare and therapeutics company empowering a healthier future. For more information, please visit investors.23andme.com.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including, without limitation, statements regarding the future performance of 23andMe’s businesses in consumer genetics and therapeutics and the growth and potential of its proprietary research platform. All statements, other than statements of historical fact, included or incorporated in this press release, including statements regarding 23andMe’s strategy, financial position, funding for continued operations, cash reserves, projected costs, plans, and objectives of management, are forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "could," "should," "potential," "likely," "projects," “predicts,” "continue," "will," “schedule,” and "would" or, in each case, their negative or other variations or comparable terminology, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are predictions based on 23andMe’s current expectations and projections about future events and various assumptions. 23andMe cannot guarantee that it will actually achieve the plans, intentions, or expectations disclosed in its forward-looking statements and you should not place undue reliance on 23andMe’s forward-looking statements. These forward-looking statements involve a number of risks, uncertainties (many of which are beyond the control of 23andMe), or other assumptions that may cause actual results or performance to differ materially from those expressed or implied by these forward-looking statements. The forward-looking statements contained herein are also subject generally to other risks and uncertainties that are described from time to time in the Company’s filings with the Securities and Exchange Commission, including under Item 1A, “Risk Factors” in the Company’s most recent Annual Report on Form 10-K, as filed with the Securities and Exchange Commission, and as revised and updated by our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K.The statements made herein are made as of the date of this press release and, except as may be required by law, 23andMe undertakes no obligation to update them, whether as a result of new information, developments, or otherwise.

**Source: https://clincalc.com/DrugStats/*
***Source: Sychev DA et al. (2016). “The frequency of SLCO1B1*5 polymorphism genotypes among Russian and Sakha (Yakutia) patients with hypercholesterolemia.” Pharmgenomics Pers Med. 9:59-63.*

Contacts:
Investor Relations Contact: investors@23andMe.com
Media Contact: press@23andMe.com