23andMe Releases New FDA-Cleared Genetic Report on Simvastatin, a Commonly Prescribed Statin

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23andMe is the first and only direct-to-consumer product to offer a suite of FDA-authorized pharmacogenetics reports, with medication insights

Lipid-lowering statins are one of the most commonly prescribed medications in the United States, and genetics can play a major role on the body's response to these drugs

SOUTH SAN FRANCISCO, Calif., July 20, 2023 (GLOBE NEWSWIRE) -- 23andMe Holding Co. (Nasdaq: ME) (23andMe), a leading human genetics and biopharmaceutical company, released a new Simvastatin Medication Insight report as part of its 23andMe+ membership service that reports on a person's likelihood of experiencing side effects from this commonly prescribed statin drug.

The new Medication Insight report is part of a suite of 23andMe reports that examine how a person's genetics may impact their response to certain medications and their chance of experiencing possible side effects. These are the first and only direct-to-consumer pharmacogenetic reports authorized by the FDA. Under the recent FDA 510(k) clearance, which modifies the labeling of the previously authorized SLCO1B1 Drug Transport report, there is no additional confirmatory testing requirement for this report, and a healthcare provider can use the results from the report to guide care. Simvastatin is a commonly prescribed statin drug used to lower cholesterol in the blood and reduce the risk of heart attacks, strokes, or other heart problems.

"People respond differently to the same medication due to many factors such as age, weight, liver and kidney function, diet, or even other medications they might be taking," said Dr. Noura Abul-Husn, 23andMe's Vice President of Genomic Health. "But we have also known for some time that genetic differences play a major role in the effectiveness of many medicines. In some cases, those differences lead to medication side effects or adverse reactions."

This new Simvastatin Medication Insight report* available for 23andMe+ members looks at how individuals respond to simvastatin, known by the brand names such as Flolipid® and Zocor®. The insight report provides clear information about whether an individual has an increased chance of experiencing side effects.

One in four Americans over 40 use a statin to lower their cholesterol. About 8 million people in the US were prescribed the statin simvastatin in 2020, amounting to about 36 million prescriptions, making it among the most prescribed medications in the United States.

Genetic differences in the SLCO1B1 gene affect a protein involved in moving some medications, including statins, from the blood to the liver, where they are processed and removed from the body. When the gene function is reduced, statin levels in the blood rise, increasing the likelihood of side effects like muscle pain, weakness, or both, a condition known as myopathy.

Muscle pain or weakness is one of the most common side effects of statins, including simvastatin. About one in ten people on statins discontinue its use, and most, about 60 percent, report that they stopped because of muscle pain. Having one or two copies of the SLCO1B1 variant included in 23andMe's report increases the risk of developing simvastatin-associated myopathy, muscle pain and weakness, from two to six times. Importantly, studies have shown that patients who received SLCO1B1 genotype-guided therapy were more likely to take their medication, had improved perceptions of statin therapy, and had better health outcomes.

About half of the people in the United States use at least one prescription drug in any given month. Millions of these individuals have one of the common genetic variants that impact how they process those medications, whether a blood thinner, an antidepressant, or pain medication. The list of medications that the Food and Drug Administration labels with a known genetic variant that impacts their efficacy now includes hundreds of drugs, and it continues to grow. Knowing beforehand whether a prescription drug is likely to work, or trigger an adverse reaction, offers a tremendous public health benefit.

The 23andMe+ membership offers information about how your DNA may affect the processing of almost two dozen medications used in treatments that range from depression, high cholesterol, and anti-clotting drugs to certain medications used in chemotherapy. The reports look specifically at how variants in three genes — CYP2C19, DPYD, and SLCO1B1 — affect the body's ability to metabolize or transport those medications.

Remember that other factors besides your genetics can also affect how your body processes medications, and customers should not change their medications without first consulting their healthcare provider.

About 23andMe
23andMe is a genetics-led consumer healthcare and biopharmaceutical company empowering a healthier future. For more information, please visit www.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 products, 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.

Important Test Information

*23andMe PGS Pharmacogenetics reports: The 23andMe test uses qualitative genotyping to detect 3 variants in the CYP2C19 gene, 2 variants in the DPYD gene and 1 variant in the SLCO1B1 gene in the genomic DNA of adults from saliva for the purpose of reporting and interpreting information about the processing of certain therapeutics to inform discussions with a healthcare professional. It does not describe if a person will or will not respond to a particular therapeutic. Our CYP2C19 Pharmacogenetics report provides certain information about variants associated with metabolism of some therapeutics and provides interpretive drug information regarding the potential effect of citalopram and clopidogrel therapy. Our SLCO1B1 Pharmacogenetics report provides certain information about variants associated with the processing of some therapeutics and provides interpretive drug information regarding the potential effect of simvastatin therapy. Our DPYD Pharmacogenetics report does not describe the association between detected variants and any specific therapeutic. Results for DPYD and certain CYP2C19 results should be confirmed by an independent genetic test prescribed by your own healthcare provider before taking any medical action. **Warning:** Test information should not be used to start, stop, or change any course of treatment and does not test for all possible variants that may affect metabolism or protein function. The PGS test is not a substitute for visits to a healthcare professional. Making changes to your current regimen can lead to harmful side effects or reduced intended benefits of your medication, therefore consult with your healthcare professional before taking any medical action. For important information and limitations regarding Pharmacogenetic reports, visit www.23andme.com/test-info.

Contacts

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