23andMe Receives FDA Clearance for Direct-to-Consumer Genetic Test on a Hereditary Prostate Cancer Marker

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The clearance allows 23andMe to report on the G84E mutation in the HOXB13 gene, clinically shown to significantly increase the risk of developing prostate cancer in men with the mutation

SUNNYVALE, Calif., Jan. 10, 2022 (GLOBE NEWSWIRE) -- 23andMe Holding Co. (Nasdaq: ME) ("23andMe"), a leading consumer genetics and research company, today received FDA clearance for a genetic health risk report on a hereditary prostate cancer marker.

This is the Company's third cancer risk report clearance, following the FDA's prior authorization for 23andMe's BRCA1/BRCA2 (Selected Variants) Genetic Health Risk report and its clearance for MUTYH-Associated Polyposis (MAP), a hereditary colorectal cancer syndrome. These two reports along with the new Hereditary Prostate Cancer (HOXB13-Related) report have been included by the FDA in a single "Cancer Predisposition Risk Assessment System" regulation.

These three 23andMe reports are the only direct-to-consumer genetic health risk reports for inherited cancers that have been authorized by the FDA for use without prescription.

"We continue to work closely with the FDA in order to provide individuals with direct access to impactful health information that can help them make important life decisions," said Anne Wojcicki, CEO and Co-Founder of 23andMe. "23andMe remains the only company with multiple FDA authorizations for direct-to-consumer genetic health reports. These reports provide our customers with the knowledge that they might be at risk for certain diseases, including hereditary cancers, empowering them to take appropriate preventative action with their healthcare provider."

This report is not yet available, but as soon as it is ready for release, it will be offered to eligible Health + Ancestry Service customers who have been genotyped on the company's most recent platform.

As with other genetic health risk reports for inherited cancers, 23andMe customers must choose whether or not they want to view the information contained in this report. Also similar to other 23andMe Genetic Health Risk reports, the Hereditary Prostate Cancer report will include an education module to ensure customers are informed on what they can learn from this report and how to interpret the results, as well as its limitations.

The G84E variant included in 23andMe's Hereditary Prostate Cancer (HOXB13-Related) report is most prevalent [1] in people with Northern European ancestry. Among people of European descent, up to 1 in 70 people has the HOXB13 G84E variant. This variant has also been found in people of other ethnicities. Studies[2] suggest that 33–53% of males with the G84E variant develop prostate cancer during their lifetime, compared to about 12% of males in the general population. In addition, males with this variant who develop prostate cancer also tend to do so at an earlier age.

23andMe now has three FDA 510(k) clearances, in addition to four separate FDA *de novo* authorizations, including:

- Carrier Screening reports
- Genetic Health Risk reports
- BRCA1/BRCA2 (Selected Variants)
- Pharmacogenetic metabolism
- Pharmacogenetic interpretative drug information
- MUTYH-Associated Polyposis (MAP) report (hereditary colorectal cancer syndrome)
- Hereditary Prostate Cancer (HOXB13-Related) report

Each authorization has included an extensive FDA review process in which 23andMe submitted studies and evidence demonstrating that its reports are scientifically valid and understandable for consumers, and that the results are analytically reliable. For this newest clearance, the Hereditary Prostate Cancer (HOXB13-Related) report adhered to the same standards used in other reports, including greater than 99 percent accuracy and utilization of key informational concepts that achieved 90 percent or greater comprehension in a demographically diverse population.

The 23andMe Hereditary Prostate Cancer (HOXB13-Related) report test does not include all genetic risk variants for hereditary prostate cancer, and does not take into account lifestyle factors that may contribute to risk for the disease. If a customer does not have the particular risk variant found in this report, that does not mean they should forgo recommended cancer screenings. This report is not a diagnostic test, customers should consult with a healthcare provider before making decisions based on the results.

[1]Prevalence: Karlsson 2014 (PMID 22841674)

[2]Risk range: Karlsson 2014 (PMID 22841674) and Nyberg 2019 (PMID 30527799)

About 23andMe
23andMe, Inc., headquartered in Sunnyvale, CA, is a leading consumer genetics and research company. Founded in 2006, the company's mission is to help people access, understand, and benefit from the human genome. 23andMe has pioneered direct access to genetic information as the only company with multiple FDA clearances for genetic health reports. The Company has created the world's largest crowdsourced platform for genetic research, with 80% of its customers electing to participate. The 23andMe research platform has generated more than 180 publications on the genetic

underpinnings of a wide range of diseases. The platform also powers the 23andMe Therapeutics group, currently pursuing drug discovery programs rooted in human genetics across a spectrum of disease areas, including oncology, respiratory, and cardiovascular diseases, in addition to other therapeutic areas. More information is available at 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. 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 and the availability and timing of certain direct-to-consumer genetic health reports, are forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "could," "should," "potential," "likely," "projects," "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 be materially different from those expressed or implied by these forward-looking statements. These risks include, among others, the risk that such report does not include all genetic risk variants for hereditary prostate cancer. The forward-looking statements contained herein are also subject to other risks and uncertainties that are described in 23andMe's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 filed with the Securities and Exchange Commission ("SEC") on November 10, 2021 and in the reports subsequently filed by 23andMe with the SEC. Investors are cautioned not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. Except as required by law, 23andMe does not undertake any obligation to update or revise any forward-looking statements whether as a result of new information, future events, or otherwise.

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