23andMe announces further expansion of 23ME-00610 Phase 1/2a clinical trial in advanced neuroendocrine and ovarian cancer patient cohorts

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Thirty additional patients with advanced neuroendocrine and advanced ovarian cancer will be enrolled in the study of 23ME-00610, an investigational antibody targeting CD200R1

A second potentially efficacious dose level to characterize safety and efficacy will be evaluated to identify the optimal dose in alignment with recently published regulatory guidance

SOUTH SAN FRANCISCO, Calif., Dec. 19, 2023 (GLOBE NEWSWIRE) -- 23andMe Holding Co. (Nasdaq: ME) (23andMe), a leading human genetics and biopharmaceutical company, announced the further expansion of the ongoing 23ME-00610 Phase 1/2a study to include an additional 30 patients with advanced neuroendocrine and ovarian cancers, above the original enrollment goals. The ongoing study has been enrolling the Phase 2a portion of the Phase 1/2a clinical trial evaluating the anti-CD200R1 monoclonal antibody since February 2023.

As previously presented at a scientific conference in November 2023, 23ME-00610 has an appropriate safety profile in the highest doses tested, and met pharmacodynamic biomarker and pharmacokinetic objectives, while not reaching a maximum tolerated dose in the Phase 1 study. The Phase 2a portion of the study is being conducted with the highest tested dose from the Phase 1, 1400 mg intravenously every 3 weeks. In order to characterize potential optimal dosing of 23ME-00610, and aligned with recent regulatory guidelines, 23andMe is utilizing this clinical trial to further characterize safety and efficacy of a second potentially efficacious dose of 600 mg intravenously every 3 weeks in these additional patients.

“23ME-00610 has been well-tolerated with a very manageable side effect profile and we've also seen some encouraging signs of activity, particularly in neuroendocrine cancers that we've previously presented,” said Drew W. Rasco, MD, Associate Director of Clinical Research at the START Center for Cancer Care, and a principal investigator for the 23ME-00610 study. “CD200R1 is an exciting new target in the immuno-oncology landscape, and we are looking forward to enrolling additional patients in the neuroendocrine and ovarian cancer expansion cohorts.”

“We are gratified by the patient and investigator enthusiasm with this clinical trial, that allows us to continue enrolling additional patients to better understand the potential for our anti-CD200R1 program,” said Jennifer Low, MD, PhD, Head of Therapeutics Development, 23andMe. “We look forward to evaluating this new data as it emerges, in order to plan for the future of this program.”

23andMe and the investigators for this clinical trial plan to share Phase 2a data from the ongoing Phase 1/2a study at scientific conferences in 2024.

About 23ME-00610
23ME-00610 is a high-affinity, fully humanized monoclonal antibody that is designed to bind to CD200R1 and prevent the interaction of CD200R1 with CD200. The CD200–CD200R1 axis is an immunological checkpoint that plays a pivotal role in maintenance of immune tolerance. CD200R1 is an inhibitory receptor expressed on T cells and myeloid cells while CD200, the ligand for CD200R1, is highly expressed on certain tumors. Binding of tumor associated CD200 to CD200R1 leads to immune suppression and decreased immune cell killing of cancer cells. Preclinical data indicate that this mechanism has the potential to restore the ability for both T-cells and myeloid cells to kill cancer cells.

The Phase 1/2a study is an open-label study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and clinical activity of 23ME-00610 monotherapy in patients with advanced solid malignancies who have progressed on all available standard therapies. Clinical trials registry (clinicaltrials.gov): NCT05199272.

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 strategy, the results of its clinical trials, 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.

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