23andMe to Present Updates on Clinical Immuno-oncology Programs 23ME-00610 and 23ME-01473 at ESMO Congress 2024

September 3, 2024

Preliminary data from renal cancer and TMB-H/MSI-H cohorts in the Phase 1/2a clinical trial of 23ME-00610 to be presented

Analysis of CD200 as an exploratory tissue-based biomarker associated with 23ME-00610 efficacy to be presented

Preclinical murine data on 23ME-01473 to be presented; Phase 1/2a dose escalation study ongoing

SOUTH SAN FRANCISCO, Calif., Sept. 03, 2024 (GLOBE NEWSWIRE) -- 23andMe Holding Co. (Nasdaq: ME) ("23andMe"), a leading human genetics and biopharmaceutical company, today announced that it will display three poster presentations on 23ME-00610, a first-in-class anti-CD200R1 antibody, and two on 23ME-01473, an anti-ULBP6 monoclonal antibody, at the European Society for Medical Oncology (ESMO) Congress 2024, taking place September 13 – September 17 in Barcelona, Spain.

23andMe will present additional preliminary clinical data, including efficacy data, for the clear-cell renal-cell carcinoma and high tumor microsatellite instability and/or high tumor mutational burden patient cohorts in the Phase 2a portion of its ongoing Phase 1/2a clinical trial evaluating 23ME-00610, as well as share further analyses on an exploratory tissue-based biomarker, CD200.

In Phase 2 data presented at the American Society of Clinical Oncology (ASCO) in June, monotherapy 23ME-00610 demonstrated a continued acceptable safety and tolerability profile and preliminary evidence of clinical benefit in neuroendocrine and ovarian cohorts, including one confirmed partial response in a patient with well-differentiated pancreatic neuroendocrine cancer. Additionally, data showed early evidence pointing to CD200 as a potential tissue-based biomarker.

The Company will present preclinical data on the 23ME-01473 program, as well as a trials in progress presentation on the Phase 1 clinical trial that began in March 2024. 23ME-01473 targets soluble ULBP6, which is released by cancer cells to promote an immunosuppressive tumor microenvironment. It is also Fc-effector enhanced to provide an additional mechanism for NK cells to induce cell death of ULBP6-expressing cancer cells.

23andMe scientists discovered the targets for 23ME-00610 and 23ME-01473 through the Company's proprietary database of human genetic and health information. 23andMe has more than 15 million genotyped customers, roughly 80 percent of whom consent to participate in research. 23andMe is able to study the de-identified genetic information of research participants in combination with billions of health data points to identify potential pathways for novel therapeutic targets rooted in human genetic information.

Details on the ESMO posters are below.

Posters will be available on the 23andMe Therapeutics and Investor websites following the presentations.

Abstract: 1069TiP
Title: A Phase 1/2a Dose Escalation and Expansion Study of 23ME-01473, an anti-ULBP6/2/5 Antibody, for Patients with Advanced Solid Malignancies
Session Type: Poster Session – Investigational Immunotherapy
Date and Time: September 14, 9:00-17:00 Central European Summer Time (CEST)

Abstract: 620P
Title: Efficacy, safety and PKPD of 23ME-00610, a first-in class anti-CD200R1 antibody, in patients with tumor mutational burden-high (TMB-H) and/or microsatellite instability-high (MSI-H) cancers: Results from an expansion cohort
Session Type: Poster Session – Developmental Therapeutics
Date and Time: September 14, 9:00-17:00 Central European Summer Time (CEST)

Abstract: 153P
Title: 23ME-01473, an Fc-enhanced anti-ULBP6/2/5 antibody, restores anti-tumor NK cell function through NKG2D and FcgRIIIa activation
Session Type: Poster Session – Biomarkers and Translational Research (agnostic)
Date and Time: September 15, 9:00-17:00 Central European Summer Time (CEST)

Abstract: 1706P
Title: Efficacy, safety and PKPD of 23ME-00610, a first-in-class anti-CD200R1 antibody, in patients with advanced or metastatic clear-cell renal cell carcinoma (ccRCC): Results from a multi-center multi-country Phase 1/2a expansion cohort
Session Type: Poster Session – Renal Cancer
Date and Time: September 15, 9:00-17:00 Central European Summer Time (CEST)

Abstract: 150P
Title: Phase 1/2a trial of CD200R1 inhibitor 23ME-00610; exploratory analyses of tissue-based and genetic biomarkers
Session Type: Poster Session – Biomarkers and Translational Research (agnostic)
Date and Time: September 15, 9:00-17:00 Central European Summer Time (CEST)

About 23ME-00610

23ME-00610 is a first-in-class anti-CD200R1 monoclonal antibody in the Phase 2a portion of Phase 1/2a clinical development for advanced solid malignancies. CD200R1 was identified as an immuno-oncology (I/O) target from the 23andMe database, with pleiotropic causal variants that have opposing effect on risks for cancer and immune diseases, referred to as an I/O signature, observed in 3 components in this pathway.

23ME-00610 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. In preclinical studies, 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. Clinical trials registry (clinicaltrials.gov): NCT05199272.

About 23ME-01473
23ME-01473 targets ULBP6 to restore anti-tumor immunity through NK and T cells. ULBPs are stress-induced ligands found on the surface of cancer cells that bind to their receptor, NKG2D, on NK and T cells. Cancers escape immune cell recognition by shedding ULBP ligands from their cell surface, which act as immunosuppressive molecular decoys.

Blocking the binding of soluble ULBP6 to NKG2D through 23ME-01473 may restore immune cell recognition and killing of cancers. Further, 23ME-01473 is Fc-effector enhanced, which provides an additional mechanism for NK cells to induce cell death of ULBP6-expressing cancer cells.

ULBP6 was identified as a potential cancer drug target using the 23andMe immuno-oncology (I/O) genetic signature, an approach developed by 23andMe to identify evidence for genetic variants that increase immune function while decreasing cancer risk. Using genetic data, 23andMe can identify immune-related genes that are expected to have an impact on cancer biology. Specifically, germline genetics can reveal which of the immune-related genes harbor genetic variants that also alter an individual's predisposition for developing cancer.

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. All statements, other than statements of historical fact, included or incorporated in this press release 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.

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