23andMe Announces Phase 1 Results from the First-in-Human Phase 1/2a Study of 23ME-00610, an Investigational Antibody Targeting CD200R1

April 14, 2023

- *First clinical results to be presented at the AACR Annual Meeting 2023 showed 23ME-00610 demonstrated an acceptable safety and tolerability profile, with favorable pharmacokinetics and peripheral CD200R1 saturation in patients with advanced solid malignancies*
- *Recommended dose selected for evaluation of anti-tumor activity in the ongoing Phase 2a portion of the Phase 1/2a study*

ORLANDO, Fla., April 14, 2023 (GLOBE NEWSWIRE) -- 23andMe Holding Co. (Nasdaq: ME) (23andMe), a leading human genetics and biopharmaceutical company, today announced results from the Phase 1 portion of its Phase 1/2a study evaluating 23ME-00610, an investigational antibody targeting CD200R1. 23ME-00610 demonstrated an acceptable safety and tolerability profile, with favorable pharmacokinetics (PK) and peripheral saturation of the CD200R1 target. Based on the Phase 1 data, a dose of 23ME-00610 given at 1400 mg intravenously every 3 weeks was selected for evaluation of anti-tumor activity in the ongoing Phase 2a portion of the Phase 1/2a (Phase 2a) 23ME-00610 study.

23andMe plans to present these data at the American Association for Cancer Research (AACR) Annual Meeting 2023 in Orlando, Florida on April 18, 2023, from 9:00 AM - 12:30 PM ET (poster section 45, #CT174). The poster presentation will be available on the 23andMe Therapeutics and Investor websites at 9:00 AM ET on April 18, 2023, and will contain updated data obtained after the abstract submission cut-off date. The abstract that was released today is available on the AACR website.

“We are pleased to present the first clinical data from a wholly-owned asset in our immuno-oncology portfolio. Data from the Phase 1 portion of our 23ME-00610 study included an acceptable safety profile along with saturation of the intended target, and support 23ME-00610’s further development in patients with advanced cancer,” said Jennifer Low, MD, PhD, Head of Therapeutics Development at 23andMe. “The Phase 2a portion of the study is now underway and we look forward to further evaluation of 23ME-00610 in the trial’s expansion cohorts.”

23ME-00610 Phase 1 Results:
Participants with histologically diagnosed locally advanced (unresectable), or metastatic carcinoma or sarcoma who progressed on standard therapies with an Eastern Cooperative Oncology Group (ECOG) score of 0 or 1 were enrolled across the 2 mg to 1400 mg cohorts. Participants received 23ME-00610 intravenously every 3 weeks (Q3W) infused over 30 minutes.

Key results from the study include:

- No dose limiting toxicities were observed. Among study participants, most experienced at least 1 treatment related adverse event (TRAE); the majority were Grade 1 or 2.
- Investigator-assessed immune-related AEs including hypothyroidism, pruritis, fatigue and chills were observed at higher pharmacologically relevant dose levels (doses 60 mg and above).
- The PK of 23ME-00610 were dose-proportional at doses 60 mg and above, with a median terminal half-life of ~12 days at 1400 mg, supporting administration of 23ME-00610 every three weeks.
- Peripheral saturation of CD200R1 was observed at doses 60 mg and above, as measured by receptor occupancy on T cells and neutrophils, and levels of free soluble CD200R1.

A RP2D of 1400 mg 23ME-00610 was selected for evaluation in the Phase 2a portion of the study.

23ME-00610 Phase 2a:
The Phase 2a portion of the Phase 1/2a study is currently underway, evaluating the anti-tumor activity of the 23ME-00610 monotherapy in a number of expansion cohorts, and further characterizing the safety, tolerability, PK and PD profile of 23ME-00610. The Phase 2a portion will include assessment of objective response rate (ORR), progression-free survival (PFS) and overall survival (OS) in the expansion cohorts.

The expansion cohorts will enroll patients with clear cell renal cell carcinoma; epithelial ovarian, fallopian tube or primary peritoneal carcinoma; neuroendocrine cancers; small cell lung cancer; and microsatellite instability-high (MSI-H) or tumor mutational burden-high (TMB-H) cancers that have progressed on standard therapies. A cohort of adolescents with locally advanced unresectable, or metastatic solid malignancies will also be enrolled.

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. 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 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, the growth and potential of its proprietary research platform and its future clinical trial results. All statements, other than statements of historical fact, included or incorporated in this press release, including statements regarding 23andMe's clinical trials, 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.

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