



23andMe Announces Updated Safety and Preliminary Efficacy Data From the Phase 1/2a Study of 23ME-00610, an Investigational Antibody Targeting CD200R1

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- 23andMe presented data from the now completed dose escalation phase, and pharmacokinetic / pharmacodynamic (PK/PD) cohorts at the Society for Immunotherapy of Cancer Annual Meeting 2023
- Dosing with 23ME-00610 monotherapy in 28 patients with advanced solid tumors up to 1400 mg every three weeks (Q3W) showed tolerability consistent with expectation for on-target effects
- Peripheral pharmacodynamic data demonstrate that 23ME-00610 maximally inhibits signaling through CD200R1 on immune cells, which correlated with the presence of expected immune-related adverse events, at pharmacologically relevant doses
- Preliminary efficacy data from the Phase 1 dose escalation portion showed signs of clinical activity and a stable disease rate of 52%
- The PK, PD, safety, and preliminary efficacy data continue to support the ongoing Phase 2a study of 23ME-00610 in tumor-specific expansion cohorts at the preliminary recommended Phase 2a expansion dose (RP2D) of 1400 mg Q3W

SOUTH SAN FRANCISCO, Calif., Nov. 06, 2023 (GLOBE NEWSWIRE) -- 23andMe Holding Co. (Nasdaq: ME) (23andMe), a leading human genetics and biopharmaceutical company, announced data from its ongoing first-in-human Phase 1/2a clinical trial evaluating the safety and efficacy of 23ME-00610, an investigational antibody targeting CD200R1. Updated data from the now completed dose escalation phase continue to showcase the manageable safety profile of 23ME-00610 at the dose levels tested, and highlight preliminary efficacy results in patients with advanced solid tumors.

The data was presented in two posters at the Society of Immunotherapy in Cancer Annual Meeting 2023 on Friday, November 3, 2023. The poster presentations are available on the 23andMe [Therapeutics](#) and [Investor](#) websites.

The presentations include pharmacokinetic (PK), pharmacodynamic (PD), safety, and efficacy data from 28 patients that enrolled between January 5, 2022 and May 15, 2023 in the dose escalation portion of the 23ME-00610 Phase 1/2a clinical trial who had received a median of 3 prior anticancer treatment regimens, 54% of whom had prior immunotherapy. Of the phase 1 patients enrolled across all doses of the dose escalation, there was a 52% stable disease rate. One patient with pancreatic neuroendocrine cancer had a maximum reduction in sum of longest target lesion diameters of 19% and remained on treatment with stable disease at 40 weeks on study at the time of data cut off. One of the tumor lesions in this patient had a sustained 58% reduction in the longest diameter of the tumor on imaging scan.

23ME-00610 monotherapy was well-tolerated, with no dose-limiting toxicities or serious adverse events related to 23ME-00610, and no maximum tolerated dose (MTD) was reached up to the maximum tested dose of 1400 mg every 3 weeks. Immune-related adverse events (AE) were observed at pharmacologically relevant doses (≥ 60 mg), consistent with expected 23ME-00610-mediated immune modulation. Preliminary immunogenicity assessments showed no evidence of treatment-induced anti-drug antibodies (ADA). One treatment-related AE (600 mg dose) leading to discontinuation was observed: a non-serious grade 3 adverse event, maculopapular rash in Cycle 1, which resolved to baseline after treatment with oral and topical steroids.

Preliminary PK data support dosing 23ME-00610 every three weeks (Q3W). 23ME-00610 has a favorable PK and PD profile, with median half-life of 11 to 13 days for doses ≥ 200 mg, and saturated peripheral PD and dose-proportional exposure for doses greater than 60 mg. The combined safety, PK, PD, and preliminary efficacy data continue to support the evaluation of 23ME-00610 at the preliminary recommended Phase 2a expansion dose (RP2D) of 1400 mg every three weeks (Q3W), which is the dose expected to maximize CD200R1 inhibition in participants with cancer, based on the Cycle 1 predicted tumor concentration of 23ME-00610 that is above the tumor cell-killing EC_{90} for all participants with evaluable data.

"In this Phase 1 study, 23ME-00610 was well-tolerated with a very manageable side effect profile," 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. "We also saw some encouraging signs of activity, particularly in neuroendocrine cancers. CD200R1 is an exciting new target in the immuno-oncology landscape, and we look forward to seeing more results from the ongoing enrollment in disease-specific expansion cohorts."

"The Phase 1 data from our first 23andMe-sponsored clinical trial in patients with cancer continues to be encouraging," said Jennifer Low, MD, PhD, Head of Therapeutics Development at 23andMe. "Our data demonstrate that 23ME-00610 is able to be dosed in our participants over extended periods of time at the dose that should inhibit this pathway in tumors."

23ME-00610 Phase 2:

The Phase 2a portion of the Phase 1/2a study is currently enrolling, 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 first-in-class anti-CD200R1 monoclonal antibody in Phase 2 clinical development for advanced solid malignancies that has been shown to rescue T cell function in preclinical studies. CD200R1 was identified as an immuno-oncology (IO) target from the 23andMe database, with pleiotropic causal variants that have opposing effect on risks for cancer and immune diseases, referred to as an IO signature, observed in 3 components in this pathway.

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 plans, strategy, therapeutics development, clinical trials, projected costs, product development and launches, the successful commercialization and market acceptance of new products 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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