23andMe Announces First Patient Dosed for the Phase 2a Portion of its Phase 1/2a Study of 23ME-00610, an Investigational Antibody Targeting CD200R1 in Patients with Advanced Solid Malignancies

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The expansion portion of the study will evaluate the anti-cancer activity of 23ME-00610 in specific tumor indications, and will further characterize the safety, tolerability, pharmacokinetic and pharmacodynamic profile of 23ME-00610

SOUTH SAN FRANCISCO, Calif., Feb. 28, 2023 (GLOBE NEWSWIRE) -- 23andMe Holding Co. (Nasdaq: ME) (23andMe), a leading human genetics and biopharmaceutical company, with a mission to help people access, understand and benefit from the human genome, dosed the first patient in the Phase 2a portion of its Phase 1/2a (Phase 2a) study evaluating 23ME-00610, an investigational antibody targeting CD200R1, in patients with advanced solid malignancies.

The Phase 2a portion of the study will evaluate the anti-tumor activity of the 23ME-00610 monotherapy in a number of previously disclosed expansion cohorts and will further characterize the safety, tolerability, pharmacokinetic and pharmacodynamic profile of 23ME-00610. 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.

The tumor indications for the expansion phase were selected based on pre-clinical and published data of the activity and expression of CD200R1 and its ligand, CD200, together with immune cell and tumor characteristics that have the potential to increase the likelihood of a response to CD200R1 inhibition.

“We’re pleased that 23ME-00610 has reached this next phase of clinical development, and look forward to evaluating this drug candidate in a number of cancers that are inadequately treated with existing therapies,” said Jennifer Low, MD, PhD, Head of Therapeutics Development at 23andMe. “Our mission in therapeutics is to help patients derive benefit from our insights from the human genome. The initiation of the next phase in our evaluation of 23ME-00610 marks an important milestone on this journey, and we appreciate the dedication and contributions of the patients and investigators to our ongoing clinical trial.”

The 23ME-00610 first-in-human dose escalation phase successfully identified a dose level and schedule for the Phase 2a portion of this study. The Phase 2a component will include assessment of objective response rate (ORR), progression-free survival (PFS) and overall survival (OS) in the expansion cohorts. 23andMe anticipates that it will present an update from the Phase 1 dose escalation portion of the study at a scientific conference this year.

23andMe has more than 13.4 million genotyped customers, over 80% of whom consent to participate in research. 23andMe scientists study the aggregate, de-identified genetics of these participants, alongside more than 4 billion self-reported health data points. Using these data and sophisticated bioinformatic analyses, 23andMe has discovered an immuno-oncology genetic signature to pinpoint genes that may be promising targets for cancer immunotherapies. One of these targets, CD200R1, is a receptor found predominantly on immune cells; by targeting this receptor, 23ME-00610 blocks CD200R1 on T-cells and myeloid cells, which may restore their ability to kill cancer cells.

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 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, 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

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