23andMe Therapeutics Announces Positive Preliminary Phase 2 Safety and Efficacy Results for 23ME-00610, targeting CD200R1, at the 2024 ASCO Annual Meeting

June 3, 2024

– 23ME-00610 monotherapy demonstrates preliminary evidence of clinical benefit, including one confirmed partial response

– 23ME-00610 monotherapy continues to demonstrate acceptable safety and tolerability, and achieves the prespecified targets for maximal pharmacology at 1400 mg dosed Q3W

– Tumor CD200 is emerging as a potential biomarker associated with 23ME-00610 monotherapy efficacy

SOUTH SAN FRANCISCO, Calif., June 03, 2024 (GLOBE NEWSWIRE) -- 23andMe Holding Co. (Nasdaq: ME) ("23andMe"), a leading human genetics and biopharmaceutical company, announced positive preliminary Phase 2 safety and efficacy data from 23ME-00610, a first-in-class anti-CD200R1 antibody, presented at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, May 31-June 4.

23andMe presented two posters on 23ME-00610, one each from neuroendocrine and ovarian cancer patient cohorts in its ongoing Phase 1/2a clinical trial.

Key takeaways:

- Confirmed partial response (PR) in patient with well-differentiated pancreatic neuroendocrine cancer (pNET) (> 24 cycles at data cut-off) and qualitative clinical benefit with durable treatment duration (> 12 cycles at data cut-off) and tumor shrinkage in patient with mesonephric adenocarcinoma (a form of ovarian cancer).
- 23ME-00610 monotherapy demonstrates acceptable safety and tolerability, and achieves the prespecified targets for maximal pharmacology at 1400 mg dosed every three weeks.
- From archival tumor immunohistochemistry (IHC) analyses, over 70% of patients had detectable tumor cell CD200, and higher expression tended to trend with clinical benefit.
- In addition to CD200, histology data suggest that immunosuppressed ("cold") tumors may be more likely to exhibit disease control with 23ME-00610.
- Emerging data shows preliminary evidence of clinical benefit from 23ME-00610 treatment associated with lower risk for chronic immune-mediated diseases (e.g., psoriasis, asthma, eczema), yet higher risk for acute immune reactivity and cancer. This aligns with the 23andMe Immuno-oncology Signature, which identifies promising IO targets by pinpointing areas of the genome associated with opposing risk for auto-immune disease and cancer.

"We continue to be pleased with the progress of 23ME-00610 as monotherapy, which continues to demonstrate therapeutic potential for inhibiting CD200R1 in cancer patients," said Jennifer Low, M.D., Ph.D, Head of Therapeutics Development. "We are also seeing evidence of CD200 emerging as a potential biomarker associated with 23ME-00610 monotherapy efficacy. Further, we are encouraged by the continued safety and tolerability profile of 23ME-00610 which, as presented at AACR earlier this year, points to potential combination strategies for added therapeutic benefit in cancer patients."

Further details - neuroendocrine cancers cohort

- Between February 23, 2023 and April 1, 2024, 16 adult patients with advanced neuroendocrine neoplasms who received a median of 3.5 prior treatment lines (range: 1 to 10), were enrolled and received ≥ 1 dose of 23ME-00610.
- A patient from the Phase 1 portion of the Phase 1/2a trial with well-differentiated pancreatic neuroendocrine cancer (pNET) and high tumor CD200 expression has a confirmed partial response (PR) and remains on treatment (> 21 months).
- Among the N=16 expansion cohort, the disease control rate was 50% (n=8), and 25.3% of patients were free from clinical progression at 6 months, per RECIST v1.1.
- The safety and tolerability profile remains acceptable and promising for potential anti-cancer combinations in neuroendocrine patients.
    - No treatment-emergent adverse events (TEAEs) leading to 23ME-00610 discontinuation were reported.
    - Related treatment-emergent adverse events (TRAEs) occurred in 8 patients (50%); all were G1/G2, and the most common were maculopapular rash (18.8%), pruritus (18.8%), nausea (12.5%), and fatigue (12.5%).
- Patients with moderate to high tumor CD200 expression tended to be more likely to derive clinical benefit (PR or durable SD) relative to patients with low or undetectable tumor CD200.

Further details - ovarian cancer cohort

- Between March 27, 2023 and April 1, 2024, 16 adult patients with advanced ovarian cancer who received a median of 4 prior treatment lines (range: 1 to 12), were enrolled and received ≥ 1 dose of 23ME-00610.

- The safety and tolerability profile remains acceptable and promising for potential anti-cancer combinations in ovarian cancer patients.
    - No TRAEs ≥ G4 or AEs leading to 23ME-00610 discontinuation or death were reported.
    - Related TEAEs occurred in 7 patients (43.8%); most were G1 (12.5%) and G2 (25.0%), and the most common were maculo-papular rash (12.5%) and pruritus (12.5%). Immune-related AEs (irAEs) were ≤ G2 in severity and generally dermatologic and thyroid in nature.
- A patient with well-differentiated mesonephric adenocarcinoma progressing prior to study enrollment has shown qualitative clinical benefit and durable treatment duration (> 12 cycles), including decreasing CA-125, substantial decreases in malignant ascites, and tumor reduction while on 23ME-00610 treatment.

Additional data from the 23andMe poster presentations at ASCO 2024

- Eligible patients had histologically diagnosed locally advanced (unresectable) or metastatic 1) neuroendocrine cancers who had progressed on standard therapies, or 2) metastatic platinum-resistant epithelial ovarian, fallopian tube, or peritoneal carcinoma who have progressed on standard therapies.
- Exploratory biomarkers included CD200R1 and CD200 tumor expression, germline genotyping, and polygenic risk score calculation for immune-mediated and cancer phenotypes.
- Patients received 1400 mg given IV every 3 weeks until disease progression, and CT/MRI scans were conducted every ~ 8 weeks.

Posters are available on the 23andMe Therapeutics and Investor websites.

About 23ME-00610
23ME-00610 binds to CD200R1 to prevent the interaction of CD200R1 with CD200. Using the world's largest proprietary database of health and genetic information, 23andMe identified genetic variants of CD200R1, CD200, and DOK2, the downstream signaling protein, associated with higher risks of immune disease and lower risks of cancer, pinpointing CD200R1 as a promising immuno-oncology target.

Additional preclinical data validated the CD200-CD200R1 pathway as an immune checkpoint, and potential target for reversing immune tolerance in cancer as a monotherapy, or in combination with other therapies. Clinical data from the dose escalation cohort of patients with advanced solid tumors has shown 23ME-00610 has favorable pharmacokinetics (PK) for dosing once every three weeks, expected on-target pharmacologic activity, and a promising safety and tolerability profile at the preliminary recommended phase 2 dose of 1400 mg.

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.

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