23andMe Announces Extension of GSK Collaboration and Update on Joint Immuno-oncology Program

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GSK extends exclusive target discovery period of collaboration for a fifth year to discover and validate novel drug targets using 23andMe's proprietary genetic and health survey database

23andMe elects for royalty option as GSK advances immuno-oncology antibody collaboration program targeting CD96 into development

Company will discuss at its R&D Day event today at 8:00 a.m. Pacific Time

SUNNYVALE, Calif., Jan. 18, 2022 (GLOBE NEWSWIRE) -- 23andMe Holding Co. (Nasdaq: ME) ("23andMe"), a leading consumer genetics and therapeutics company, today provided an update on its collaboration with GlaxoSmithKline plc ("GSK"). GSK has elected to exercise its option to extend the exclusive target discovery period of the ongoing collaboration with 23andMe for an additional year to July 2023. 23andMe will receive a one-time payment of $50 million to extend the period. In addition, 23andMe has elected to take a royalty option on its joint immuno-oncology antibody collaboration program with GSK targeting CD96 (GSK6097608, a.k.a. GSK'608), currently in Phase 1 studies. GSK will be solely responsible for GSK'608's subsequent development in later-stage clinical trials, including full development costs moving forward.

"The collaboration with GSK has been very productive. In less than four years, under this collaboration, we have identified over 40 therapeutic programs and have advanced an immuno- oncology antibody targeting CD96 into clinical development," said Kenneth Hillan, Head of Therapeutics at 23andMe. "GSK's decision to extend the exclusive target discovery period of our collaboration for an additional year demonstrates the enthusiasm for our collaboration and the value our database provides for identifying targets and advancing new medicines based on human genetics."

"Our collaboration with 23andMe continues to exceed expectations, with more than 40 genetically validated drug discovery programs in the GSK portfolio that were initiated under the collaboration," said John Lepore, SVP and Head of Research at GSK. "Evidence shows that genetically validated drug targets have at least double the probability of success in becoming medicines; today more than 70% of our targets in research have genetic validation. Working with 23andMe for an additional year will continue to strengthen the quality and breadth of our pipeline and reinforce GSK's long-term focus on human genetics, the immune system and advanced technologies to discover and develop transformational new medicines for patients."

"The CD96 program is a prime example of the potential value we bring to drug discovery and development. Through our genetic validation and based on the Phase 1a data, we are hopeful that targeting CD96 will have the potential to provide cancer patients with a new medicine in the fight against cancer," states Hillan. "We believe GSK is in the best position to move this program forward because of its leading portfolio of antibodies targeting the CD96 axis, and their ability to conduct the complex clinical studies of combination therapies that the development plan will require. This decision also allows 23andMe to strategically invest capital and resources into advancing our diverse portfolio of therapeutic programs."

23andMe's Therapeutics team was established in 2015 with the goal to improve the way drug discovery is currently conducted by starting with human genetic information. With approximately 12 million genotyped customers, of which approximately 80 percent consent to research, 23andMe has the world's largest set of genotypic information paired with billions of phenotypic data points contributed by engaged research participants.

About the GSK and 23andMe Collaboration
In July 2018, GSK and 23andMe entered into a collaboration which included an initial four-year exclusive target discovery period, with GSK having the option to extend that period for a fifth year. In order to jointly discover novel targets for drug development, 23andMe performs proprietary statistical analysis in-house using de-identified data from 23andMe's consenting research participants. Together 23andMe and GSK review the summary results that can be used to progress new medicines into development. GSK and 23andMe collaborate, using their combined resources, to identify new targets and prioritize them based on the strength of the biological hypothesis, possibility to find a medicine, and clinical opportunity and progress programs to generate lead compounds, perform preclinical research and progress into clinical development.

For joint projects, program costs and profits in relevant territories (US, UK and EU) are split (50% / 50%), with each company having certain rights to opt-out of further funding or reduce its funding share for any joint collaboration program at certain defined development milestones. The company that opts out of the cost/profit split is eligible to receive a worldwide royalty, or in the case of reduced funding, an adjusted percentage of profits or royalty outside the relevant territories, if the program is successfully commercialized.

Additionally, GSK made a $300M equity investment in 23andMe, Inc. in 2018.

About the CD96 Program
The CD96 program is an immuno-oncology therapeutic mAb targeting CD96 called GSK'608. CD96 sequesters a shared ligand, CD155, away from the costimulatory receptor, CD226, effectively attenuating T and NK cell antitumor immune responses. By blocking CD96, GSK'608 may allow activation of CD226 and enhance anti-tumor immunity through T and NK cells.

GSK'608 is now being dosed in combination with GSK's PD-1 blocking drug, dostarlimab, in a Phase 1 clinical trial. Additional studies will potentially also involve combinations with other anticancer treatments, such as anti-TIGIT and anti-PVRIG drugs.

Prior to taking the worldwide royalty election, the CD96 program was advanced under a 50/50 cost share and a profit share arrangement between 23andMe and GSK in the shared territories of US, UK and EU with a tiered royalty for other territories. With the worldwide royalty option, 23andMe will be eligible to earn tiered worldwide royalties up to the low double digits if GSK'608 is successfully brought to market. This option allows 23andMe to retain economic upside if GSK'608 is successfully brought to market but will no longer be contributing to the development costs as the program

advances into later, larger and more complex clinical studies. This allows 23andMe to invest further in its advancing pipeline of therapeutic programs, largely identified under the GSK collaboration. In addition, if GSK'608 is successful in achieving market authorization, 23andMe will not be required to contribute to marketing and commercialization costs.

R&D Day Event Information
To discuss the GSK collaboration updates and other developments from its Therapeutics and Consumer groups in more detail, the company is hosting a virtual R&D Day event today from 8:00 a.m. to 11:30 am Pacific Time. The webcast event can be accessed at https://investors.23andme.com/news-events/events-presentations. A webcast replay will be available at the same address for a limited time within 24 hours after the event.

About 23andMe
23andMe, headquartered in Sunnyvale, CA, is a leading consumer genetics and therapeutics company. Founded in 2006, the company's mission is to help people access, understand, and benefit from the human genome. 23andMe has pioneered direct access to genetic information as the only company with multiple FDA authorizations for genetic health risk reports. The company has created the world's largest crowdsourced platform for genetic research, with 80 percent of its customers electing to participate. The 23andMe research platform has generated more than 180 publications on the genetic underpinnings of a wide range of diseases, conditions, and traits. The platform also powers the 23andMe Therapeutics group, currently pursuing drug discovery programs rooted in human genetics across a spectrum of disease areas, including oncology, respiratory, and cardiovascular diseases, in addition to other therapeutic areas. More information is available at 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 opportunities related to and the benefits of 23andMe's collaboration with GSK, the discovery and the potential of genetically validated targets, and the development and commercialization of therapeutic programs. All statements, other than statements of historical fact, included or incorporated in this press release. 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, including, without limitation: (i) whether 23andMe's cash resources will be sufficient to fund the further development of therapeutic programs pursuant to the collaboration agreement with GSK or otherwise; (ii) whether results obtained in preclinical studies and clinical trials will be indicative of the results that will be generated in future clinical trials; (iii) whether any of the therapeutic programs will advance into or through the clinical trial process when anticipated or at all or warrant submission for regulatory approval; (iv) whether any such therapeutic programs will receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; (v) whether, if any such therapeutic programs receive approval, they will be successfully distributed and marketed; (vi) whether the collaboration with GSK will continue to be productive or will ultimately be successful in developing new medicines; (vii) collaborators' ability to successfully complete clinical development of, obtain regulatory approval for, and commercialize any therapeutic programs; and (viii) the impact of public health crises, including the coronavirus (COVID-19) pandemic. The forward-looking statements contained herein are also subject to other risks and uncertainties that are described in 23andMe's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 filed with the Securities and Exchange Commission ("SEC") on November 10, 2021 and in the reports subsequently filed by 23andMe with the SEC. 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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