Regeneron Forms Consortium of Leading Life Sciences Companies to Accelerate Largest Widely-Available 'Big Data' Human Sequencing Resource with UK Biobank

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TARRYTOWN, N.Y., Jan. 8, 2018 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN), along with new collaborators AbbVie, Alnylam Pharmaceuticals, AstraZeneca, Biogen and Pfizer Inc., today announced the formation of a major 'pre-competitive' consortium to fund the generation of genetic exome sequence data from the 500,000 volunteer participants who make up the UK Biobank health resource. The newly announced collaborators will each commit $10 million to enable a dramatic acceleration of sequencing timelines, and additional companies are considering joining the consortium. Regeneron will conduct the sequencing effort. The sequencing data will be paired with detailed, de-identified medical and health records within the UK Biobank resource, including enhanced measures such as brain, heart and body imaging, to create an unparalleled resource for linking human genetic variations to human biology and disease.

It was originally planned that sequencing of all 500,000 samples in the UK Biobank would be completed by 2022, with the first 50,000 people sequenced during 2017 with funding from Regeneron and GlaxoSmithKline. Now, by engaging several leading Life Sciences companies to form this new consortium, it will be possible to complete the exome sequencing of all 500,000 participants by the end of 2019, with all data made broadly available by UK Biobank to researchers by the end of 2020. This consortium effort thus greatly accelerates delivery to the global scientific community of the largest 'big data' resource linking human sequence data to other health-related information. Sequencing of UK Biobank's samples will continue to be performed at the Regeneron Genetics Center (RGC) facility, one of the world's largest and most sophisticated human genetics sequencing centers.

"With mounting national and global health concerns due to widespread increases in obesity-related diseases like diabetes, and age-related diseases such as dementia, together with the ongoing threats of cardiovascular disease, cancer and infectious agents, it is a great statement that so many leading Life Sciences companies are willing to put aside their individual differences and come together to bring this unprecedented, pre-competitive 'big data' resource to the world. We all hope and believe this will greatly accelerate our collective efforts to make a profound impact on human health," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron. "This effort is a tribute to the incredible vision of UK Biobank's funders - the Wellcome Trust and the UK Medical Research Council - in creating UK Biobank, as well as to the high-throughput and automated gene sequencing capabilities built by our team at the Regeneron Genetics Center, which is enabling the scale and speed of the project."

"UK Biobank is truly a world-class resource thanks to the multitude of volunteer participants who have enabled us to build one of the world's largest secure databases of health, lifestyle, medical and biological data," said Sir Rory Collins, UK Biobank Principal Investigator and British Heart Foundation Professor of Medicine & Epidemiology at Oxford University. "We welcome the collaboration and commitment of this industrial consortium, which will yield exome sequence data for all 500,000 participants over the next few years, maximizing the potential of these data for researchers. I cannot overstate the impact this information is likely to have on improving the treatment and prevention of disease."

Consortium members will have a limited period of exclusive access to the sequencing data, before the data will be made available to other health researchers by UK Biobank. Consortium members have committed to make all significant research findings public.

"We're proud to have gathered a consortium of industry leaders who recognize the significance of early-stage, transparent research, and who want to make a difference for patients by developing this resource together with UK Biobank," said Aris Baras, M.D., Vice President and Head of the Regeneron Genetics Center. "We look forward to the trove of meaningful data that this effort will yield, given our shared belief in the power of genetics to deliver innovative new medicines."

Genetic evidence has revolutionized scientific discovery and drug development in recent years by providing clear links between certain genes and disease. Currently, an estimated 90 percent of potential medicines entering clinical trials fail to demonstrate the necessary efficacy and safety[1], and never reach patients. Many of these failures are due to incomplete understanding of the link between the biological target of a drug and human disease. By contrast, medicines developed with human genetic evidence have had substantially higher success rates and patient care has benefited.[2] Many of Regeneron's approved and investigational drugs have been informed by human genetics data. In addition, the RGC's foundational collaboration with Geisinger Health System is gathering and sequencing genetic data from hundreds of thousands of people, and is already facilitating the return of validated health information to patients.

The UK Biobank exome sequencing project builds on previously completed genotyping that was conducted on the 500,000 samples and released publicly in mid-2017. Genotyping measures specific "letters" in DNA at select locations across the genome. Exome sequencing records every letter in the DNA of the exome, the 1-2 percent (30 to 40 million letters) of the genome that encodes all known proteins and that is believed to have the most relevance for therapeutic development and understanding of inherited disease. Sequencing of the entire genome of UK Biobank participants is also being planned, but it is anticipated that this will not be completed for several years after the completion of this exome sequencing effort.

Partner Statements
"We are excited to participate in this critically important initiative with Regeneron, the UK Biobank, and other industry partners," said **John Maraganore, Ph.D., Chief Executive Officer of Alnylam Pharmaceuticals**. "In our view, modern drug discovery and development must include human genetic data, and there's no current richer resource than that provided through this effort. Indeed, broad and ongoing access to detailed health and full exome sequencing data for the 500,000 UK Biobank participants will greatly enhance Alnylam's target identification and validation efforts, contributing to the sustainability of our RNAi therapeutics product engine."

"Discoveries derived from the study of the human genome have brought us advanced knowledge to treat disease," said **Michael Severino, M.D., executive vice president, research and development and chief scientific officer, AbbVie**. "AbbVie is proud to partner with this consortium to

create an unparalleled resource to fuel human genetics research. Our focus on developing new, cutting-edge treatments for some of the world's most complex medical conditions will be aided by the discoveries enabled by this collaborative effort."

"We are proud to contribute to the advancement of genetic research by joining this important initiative, which is poised to potentially provide new insights into human health and could help guide the research efforts of Pfizer and our consortium partners as we continually work toward our shared mission of bringing new therapies to patients in need," said **Morten Sogaard, Vice President, Genome Sciences and Technologies at Pfizer.**

"As pioneers in neuroscience, we are committed to developing therapies to treat debilitating CNS diseases with few treatment options," said **Michael Ehlers, M.D., Ph.D., Executive Vice President, Head of Research & Development of Biogen.** "We are excited about the formation of this consortium and look forward to working with other industry partners to better understand the impact of protein coding variants on human health and disease as we advance the discovery of novel therapeutics."

"At AstraZeneca we are discovering new medicines by analysing two million genomes, working with pioneering global partners and sequencing 500,000 samples from our own clinical trials. This exciting new partnership demonstrates our shared ambition to discover genetic drivers of disease, delivering innovative, impactful treatments to patients," said **Ruth March, Ph.D., Vice President and Head of Precision Medicine and Genomics at AstraZeneca.**

About UK Biobank
UK Biobank is the most comprehensive resource of its kind in the world. Its 500,000 participants have provided information about their health, well-being and lifestyle, as well as blood and other biological samples for long-term storage and analysis. In addition, they have agreed to have their health followed through medical records for many years. Scientists from around the world are able to use anonymized data from the resource for research intended to improve the prevention and treatment of a wide range of common disorders.

UK Biobank is funded primarily by the UK Medical Research Council and the Wellcome Trust. For more information about other funders visit www.ukbiobank.ac.uk

About the Regeneron Genetics Center
The Regeneron Genetics Center LLC (RGC) is a wholly-owned subsidiary of Regeneron Pharmaceuticals, Inc. The RGC is a fully integrated genomics program that spans early gene and target discovery, functional genomics, and genetics-guided drug development. The primary goal of the RGC is to improve patient outcomes by identifying new drug targets, genetically-validated clinical indications, and genomic markers for pharmacogenetic applications. The RGC utilizes various sequencing and analytical approaches and has established nearly 60 collaborations with leading human genetics researchers and biobanks around the world. To enable this large-scale sequencing and analysis program, the RGC uses fully-automated sample preparation and data processing, as well as cutting-edge cloud-based informatics and large-scale analytical approaches. The RGC has sequenced samples from more than 250,000 appropriately-consented individuals to date.

Regeneron Forward-Looking Statements and Use of Digital Media
This press release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of Regeneron's products, product candidates, and research and clinical programs now underway or planned, including without limitation the use of human genetics in Regeneron's research; the extent to which the results from research programs conducted by Regeneron or its collaborators (such as those conducted by the research consortium discussed in this news release) or preclinical testing may lead to advancement of product candidates to clinical trials or therapeutic applications; the likelihood and timing of achieving any of the anticipated milestones described in this news release; ongoing regulatory obligations and oversight impacting Regeneron's research and clinical programs, marketed products, and business, including those relating to patient privacy and genetic information; unforeseen safety issues resulting from the administration of products and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's product candidates in clinical trials; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for marketed products; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's products and product candidates; competing drugs and product candidates that may be superior to Regeneron's products and product candidates; uncertainty of market acceptance and commercial success of Regeneron's products and product candidates; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its sales or other financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare LLC (or their respective affiliated companies, as applicable), to be cancelled or terminated without any further product success; and risks associated with intellectual property of other parties and pending or future litigation relating thereto, including without limitation the patent litigation proceedings relating to Praluent® (alirocumab) Injection, the ultimate outcome of any such litigation proceedings, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission, including its Form 10-K for the fiscal year ended December 31, 2016 and its Form 10-Q for the quarterly period ended September 30, 2017. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update publicly any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (http://newsroom.regeneron.com) and its Twitter feed (http://twitter.com/regeneron).

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[1] Handler, J., & Crawford, M. (2016). Clinical trial failures and drug repositioning. In W. Loging (Ed.), Bioinformatics and Computational Biology in Drug Discovery and Development (pp. 171-181). Cambridge: Cambridge University Press. doi:10.1017/CBO9780511989421.010.

[2] Nelson MR, Tipney H, Painter JL *et al*. The support of human genetic evidence for approved drug indications. *Nature* 2015. doi:10.1038/ng.3314.