

Science Publication Highlights the Precision Medicine Approach of the Regeneron Genetics Center and Geisinger Health System

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TARRYTOWN, N.Y. and DANVILLE, Pa., Dec. 22, 2016 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Geisinger Health System (Geisinger) today announced that *Science* has published a paper describing how the DiscovEHR collaboration between the Regeneron Genetics Center (RGC) and Geisinger is using the combination of large-scale sequencing and de-identified electronic health records for genomic medicine implementation and precision medicine applications in genomics-guided therapeutic discovery.

The publication describes exome sequencing and analyses of the first 50,000 adult participants in the DiscovEHR study, one of the first and largest efforts of its kind. Genomic data from these patients, all members of the Geisinger MyCode Community Health Initiative, have been linked to corresponding de-identified electronic health records, enabling the discovery of clinical associations supporting new and existing therapeutic targets, including genes encoding drug targets for lipid lowering.

"In this study, we found 176,000 genetic variants predicted to result in partial or complete loss of gene function, affecting over 90 percent of the genes in the human genome. Paired with de-identified electronic health records, this provides one of the richest resources available to study the effects of gene inactivation in humans," said Rick Dewey, M.D., Senior Director of Translational Genetics at the RGC and co-author of the paper. "Integrating genetic research to increase the efficiency and speed of drug development is the primary goal of the RGC and supports Regeneron's long-time mission of using the power of science to bring new medicines to patients, over and over again."

In the DiscovEHR study, approximately 3.5 percent of individuals were found to have known or predicted deleterious genetic variants in one of 76 clinically actionable genes (56 as defined by the American College of Medical Genetics and Genomics plus an additional 20 recommended by Geisinger). While the data are completely de-identified to Regeneron, clinicians at Geisinger have begun returning this information to eligible patients as part of their clinical care, with nearly 200 patients already informed they carry one or more disease-causing genetic mutations with consequences that can be treated. These mutations are mainly related to cancer risk and cardiovascular illness.

"This is an important step forward for precision medicine," said David J. Carey, Ph.D., Professor and Chair of Molecular and Functional Genomics at Geisinger and co-author of the paper. "In addition to contributing to longer-term research that leads to new treatments, Geisinger aims to be on the forefront of integrating genetic data into patient care. Through this collaboration, individuals participating in the Geisinger MyCode Community Health Initiative may benefit in the near-term by receiving information about their personal health."

Another RGC-Geisinger *Science* publication in the December 23 issue provides a case study for how genomic medicine can be implemented in clinical care by qualified healthcare providers such as Geisinger. By the processes described above, for example, the collaborators assessed the prevalence and clinical impact of genomic variants associated with Familial Hypercholesterolemia (FH), a genetic disease that remains underdiagnosed despite widespread cholesterol screening.

About DiscovEHR

The DiscovEHR human genetics study population for this analysis includes 50,726 adult Geisinger Health System patients who consented to participate in the MyCode Community Health Initiative. More than 125,000 MyCode participants have consented into the program to date. MyCode volunteers have given informed consent to allow sharing of de-identified electronic health records, provide samples that can be linked to their health records for broad research, and permit re-contact for additional studies. Electronic health records for the group in this DiscovEHR study are available for a median of 14 years of clinical care.

For MyCode participants who are suspected to harbor a pathogenic variant in one of the 76 clinically actionable genes, Geisinger will confirm preliminary research findings in a lab facility that is certified to the Clinical Laboratory Improvement Amendments (CLIA) Act, the federal standard for clinical testing. Qualified Geisinger personnel will provide the results of confirmatory CLIA-certified testing to patients and their primary care providers along with genetic counseling and appropriate referrals to other specialists.

About Geisinger

Geisinger Health System is an integrated health services organization widely recognized for its innovative use of the electronic health record and the development of innovative care delivery models such as ProvenHealth Navigator® and ProvenCare®. As one of the nation's largest health service organizations, Geisinger serves more than 3 million residents throughout 45 counties in central, south-central and northeast Pennsylvania, and also in southern New Jersey with the addition of AtlantiCare, a National Malcolm Baldrige Award recipient. The physician-led system is comprised of approximately 30,000 employees, including nearly 1,600 employed physicians, 12 hospital campuses, two research centers and a 551,000-member health plan, all of which leverage an estimated \$10.5 billion positive impact on the Pennsylvania and New Jersey economy. Geisinger has repeatedly garnered national accolades for integration, quality and service. In addition to fulfilling its patient care mission, Geisinger has a long-standing commitment to medical education, research and community service. For more information, visit www.geisinger.org, or follow the latest Geisinger news and more on Twitter and Facebook.

About the Regeneron Genetics Center

The RGC is a fully integrated genomics program that spans early gene discovery and functional genomics and facilitates drug development. The primary goal of the RGC is to improve patient outcomes by identifying novel drug targets, clinical indications for development programs, and genomic biomarkers for pharmacogenomic applications. The RGC is tackling various sequencing (exomes, targeted sequencing, etc.) and analytical approaches and has established numerous collaborations with leading human genetics researchers. To enable this large-scale sequencing and analysis program, the RGC utilizes fully-automated sample preparation and data processing, as well as cutting-edge cloud-based informatics.

Including efforts with Geisinger, the RGC has sequenced de-identified DNA from more than 130,000 individuals to date and is now sequencing at a rate of 150,000 individuals per year.

About Regeneron Pharmaceuticals, Inc.

Regeneron (NASDAQ: REGN) is a leading science-based biopharmaceutical company that discovers, invents, develops, manufactures and commercializes medicines for the treatment of serious medical conditions. Regeneron commercializes medicines for eye diseases, high LDL cholesterol and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including rheumatoid arthritis, atopic dermatitis, asthma, pain, cancer and infectious diseases. For additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

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 process; the extent to which the results from Regeneron's research programs (such as the DiscovEHR collaboration between the Regeneron Genetics Center and Geisinger Health System discussed in this news release) or preclinical testing may lead to advancement of product candidates to clinical trials or therapeutic applications; 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; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs, and business, including those relating to patient privacy; 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 third party intellectual property and pending or future litigation relating thereto. 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, 2015 and its Form 10-Q for the quarterly period ended September 30, 2016. 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 (<u>http://newsroom.regeneron.com</u>) and its Twitter feed (<u>http://twitter.com/regeneron</u>).

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To view the original version on PR Newswire, visit: http://www.prnewswire.com/news-releases/science-publication-highlights-the-precision-medicineapproach-of-the-regeneron-genetics-center-and-geisinger-health-system-300382690.html

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