



Amgen, The Familial Hypercholesterolemia Foundation And Stanford Medicine Launch FIND FH™ Initiative To Improve Diagnosis And Care For People With Familial Hypercholesterolemia

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FIND FH Initiative Unites Industry, Advocacy Community and Academia in an Effort to Support People Affected by Familial Hypercholesterolemia (FH), a Serious Genetic Disorder

THOUSAND OAKS, Calif., SOUTH PASADENA, Calif. and PALO ALTO, Calif., Jan. 29, 2015 /PRNewswire/ -- Amgen (NASDAQ: AMGN), The Familial Hypercholesterolemia Foundation and Stanford Medicine today announced the launch of the *FIND (FLAG, IDENTIFY, NETWORK, DELIVER) FH™* initiative. With financial support from Amgen, the *FIND FH* initiative is a large-scale program to identify and engage individuals and families affected by familial hypercholesterolemia (FH). Familial hypercholesterolemia is an inherited condition caused by genetic mutations that leads to high levels of low-density lipoprotein cholesterol (LDL-C), or "bad" cholesterol, at an early age and premature cardiovascular disease.¹ Familial hypercholesterolemia occurs in all populations and ethnic groups² and affects 14 to 34 million people worldwide.³

"Over 600,000 people in the U.S. are estimated to have FH, though some research has shown this number could be approaching one and a half million. More than 90 percent of those living with FH are not accurately diagnosed,^{3,4} and therefore The FH Foundation is focused on addressing this major gap in care," said Katherine Wilemon, founder and president of The FH Foundation. "*FIND FH* is a forward-thinking and groundbreaking initiative to identify individuals who are at profound risk of early and aggressive heart disease because they have FH, through the use of innovative technologies. Correct diagnosis is the substrate of optimal care and in the case of FH can help reduce the consequences of this condition."

Through the application of cutting-edge algorithms developed in partnership with globally recognized academic research centers, including Stanford Medicine, the multidimensional *FIND FH* initiative is designed to help healthcare providers identify individuals who have FH but who are undiagnosed, untreated or undertreated.

"There are currently few systematic approaches to identify patients with FH in the U.S., and it is unrealistic to expect most patients to recognize FH on their own, as it is a condition largely unknown to the general public," said Joshua W. Knowles, M.D., Ph.D., FAHA, FACC, assistant professor of cardiovascular medicine at Stanford University School of Medicine and director of the FH clinic in Stanford's Center for Inherited Cardiovascular Disease. "We are hopeful that the *FIND FH* initiative can help identify and engage individuals and families affected by FH and potentially aid physicians."

Through the development of patient education materials, the *FIND FH* initiative aims to also educate patients about FH and provide guidance on how to screen their family members who may also be affected.

"The *FIND FH* initiative further demonstrates our commitment to reduce the global burden of cardiovascular disease as FH is one of the single largest genetic causes of atherosclerotic heart disease,⁵" said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "We believe the use of predictive modeling with objective clinical parameters can enhance the ability of healthcare providers to identify FH patients who are unaware of their condition."

FIND FH complements The FH Foundation's patient registry (CASCADE FH), the only established registry and database dedicated to the incidence of FH in the U.S. Patients identified by *FIND FH* will have an opportunity to join the CASCADE FH registry, helping to improve data and understanding related to FH. For more information about CASCADE FH, visit <http://thefhfoundation.org/registry>.

People can have one of two types of FH.¹ Heterozygous FH (HeFH) is the more common type and occurs in approximately one in 200 to 500 people in the general population.³ It can cause LDL-C levels twice as high as normal (e.g., >190 mg/dL).⁶ Individuals with HeFH have one altered copy of a cholesterol-regulating gene.⁶ Homozygous FH (HoFH) is the rare and more severe form, occurring in approximately one in a million individuals.⁷ It can cause LDL-C levels more than six times as high as normal (e.g., 500-1,000 mg/dL).^{4,8} An individual with HoFH has two altered copies of cholesterol-regulating genes (one from each parent).¹

About Amgen's Commitment to Cardiovascular Disease

Amgen is dedicated to addressing important scientific questions in order to advance care and improve the lives of patients with cardiovascular disease. Through its own research and development efforts and innovative partnerships, Amgen has built a robust cardiology pipeline consisting of several investigational molecules in an effort to address a number of today's important unmet patient needs, such as high cholesterol and heart failure.

About Amgen

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its biologics manufacturing expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

About The FH Foundation

The FH Foundation is a patient-led, patient-focused nonprofit (501c3) organization exclusively dedicated to education, advocacy and research of familial hypercholesterolemia. The FH Foundation's mission is to raise awareness of FH and save lives by increasing the rate of diagnosis and

encouraging proactive treatment of this disorder. If left untreated, FH leads to aggressive and premature cardiovascular disease in men, women, and children of all ethnic backgrounds. In execution of its mission The FH Foundation collaborates with patients, healthcare providers, researchers, government representatives, professional and patient advocacy organizations, and industry representatives to form a stronger and more effective FH community.

For more information, visit <http://thefhfoundation.org> and www.twitter.com/thefhfoundation.

About Stanford Medicine

The Stanford University School of Medicine consistently ranks among the nation's top medical schools, integrating research, medical education, patient care and community service. The medical school is part of Stanford Medicine, which includes Stanford Health Care and Lucile Packard Children's Hospital Stanford. For information about all three, please visit <http://med.stanford.edu>.

Forward-Looking Statements

This news release contains forward-looking statements that involve significant risks and uncertainties, including those discussed below and others that can be found in Amgen's Form 10-K for the year ended Dec. 31, 2013, and in any subsequent periodic reports on Form 10-Q and Form 8-K. Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those Amgen projects. Amgen's results may be affected by Amgen's ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments (domestic or foreign) involving current and future products, sales growth of recently launched products, competition from other products (domestic or foreign) and difficulties or delays in manufacturing its products. In addition, sales of Amgen products are affected by reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' regulations and reimbursement policies may affect the development, usage and pricing of Amgen products. Furthermore, Amgen's research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Amgen or others could identify safety, side effects or manufacturing problems with Amgen products after they are on the market. Amgen's business may be impacted by government investigations, litigation and product liability claims. If Amgen fails to meet the compliance obligations in the corporate integrity agreement between Amgen and the U.S. government, Amgen could become subject to significant sanctions. Further, while Amgen routinely obtains patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors. Amgen depends on third parties for a significant portion of its manufacturing capacity for the supply of certain of its current and future products and limits on supply may constrain sales of certain of its current products and product candidate development. In addition, Amgen competes with other companies with respect to some of its marketed products as well as for the discovery and development of new products. Discovery or identification of new product candidates cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product. Further, some raw materials, medical devices and component parts for Amgen products are supplied by sole third-party suppliers. Amgen's efforts to integrate the operations of companies it has acquired may not be successful. Cost saving initiatives may result in Amgen incurring impairment or other related charges on its assets. Amgen may experience difficulties, delays or unexpected costs and not achieve anticipated cost savings from its recently announced restructuring plans. Amgen's business performance could affect or limit the ability of its Board of Directors to declare a dividend or its ability to pay a dividend or repurchase its common stock.

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References

1. National Human Genome Research Institute. Learning About Familial Hypercholesterolemia. <http://www.genome.gov/25520184>. Accessed January 2015.
2. Austin MA, Hutter CM, Zimmern RL, et al. Genetic Causes of Monogenic Heterozygous Familial Hypercholesterolemia: a HuGE Prevalence Review. *Am J Epidemiol*. 2004;160(5):407-420.
3. Nordestgaard BG, Chapman JM, Humphries SE, et al. Familial hypercholesterolaemia is Underdiagnosed and Undertreated in the General Population: Guidance for Clinicians to Prevent Coronary Heart Disease. *Eur Heart J*. 2013;34:3478-3490.
4. Sjouke B, Kusters DM, Kindt I, et al. Homozygous autosomal dominant hypercholesterolaemia in the Netherlands: prevalence, genotype – phenotype relationship, and clinical outcome. *Eur Heart J*. 2014; Epub ahead of print. doi:10.1093/eurheartj/ehu058. Feb. 28, 2014.
5. Watts FG, Gidding S, Wierzbicki AS, et al. Integrated guidance on the care of familial hypercholesterolaemia from the International FH Foundation. *Int J Cardiol*. 2014; 171:309-325.
6. Hopkins PN, Toth PP, Ballantyne CM, et al. Familial Hypercholesterolemias: Prevalence, Genetics, Diagnosis and Screening Recommendations from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. *J Clin Lipidol*. 2011;5(3S):S9-S17.

7. Daniels SR, Samuel SG, de Ferranti SD. Pediatric Aspects of Familial Hypercholesterolemias: Recommendations from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. *J Clin Lipid*. 2011;5(3S):S30-S37.
8. Raal FJ and Santos RD. Homozygous familial hypercholesterolemia: Current perspectives on diagnosis and treatment. *Atherosclerosis*. 2012;223(2):262-268.



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