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# Pfizer Discontinues Global Development of Bococizumab, Its Investigational PCSK9 Inhibitor

Tuesday, November 01, 2016 - 02:30am

Company will record a charge to GAAP and Adjusted earnings in the fourth quarter of 2016 estimated to be approximately $0.04 per share

Pfizer Inc. announced today the discontinuation of the global clinical development program for bococizumab, its investigational Proprotein Convertase Subtilisin Kexin type 9 inhibitor (PCSK9i). The totality of clinical information now available for bococizumab, taken together with the evolving treatment and market landscape for lipid-lowering agents, indicates that bococizumab is not likely to provide value to patients, physicians, or shareholders. As a result, Pfizer has decided to discontinue the development program, including the two ongoing cardiovascular outcome studies.

With the completion of six bococizumab lipid-lowering studies, Pfizer has observed an emerging clinical profile that includes an unanticipated attenuation of low-density lipoprotein cholesterol (LDL-C) lowering over time, as well as a higher level of immunogenicity and higher rate of injection-site reactions with bococizumab than shown with the other agents in this class. The goal of treating elevated cholesterol is to reduce the occurrence of cardiovascular events such as heart attacks and stroke, which requires long-term effective and durable cholesterol-lowering.

“As a company, we understand that developing new and important medicines for patients is a critical, but difficult undertaking. Accordingly, we continually evaluate our development programs as data emerge to support prudent decisions that provide value both to the patients we serve and our shareholders,” said James Rusnak, MD, PhD, Chief Development Officer, Cardiovascular and Metabolic Diseases, Pfizer Global Product Development. “We are disappointed by this outcome, but remain committed to investing in innovation, concentrating our pipeline on areas where we can bring transformational therapies to address unmet needs, including in patients with cardiovascular and metabolic diseases. We thank the investigators, their patients, and support staff who have participated in this important research program.”

Pfizer is working to ensure that all regulatory authorities are informed, and that all trial investigators are informed and instructed on next steps. If patients have questions, they should speak with their study physician for more information.

“To honor the altruism of trial participants, and to maximize the clinical and scientific knowledge derived from the halted trials, Pfizer has committed to ensuring that the data will be made available to study leaders for independent analysis and prompt public presentation. We believe the available data will allow us to test the core scientific questions posed by the overall program which is in the best interest of patients who volunteered in these clinical trials, and for patients worldwide who suffer from heart disease,” stated Paul M. Ridker, MD, Co-chair Executive Committee, SPIRE clinical trials program and director for Cardiovascular Disease Prevention, Brigham and Women’s Hospital.

It is estimated that the discontinuation of the bococizumab development program will have a negative impact of approximately $0.04 per share on both a GAAP and adjusted basis. Pfizer will record this as a Research and Development charge in the fourth quarter of 2016 and is incorporating this estimated impact into its updated 2016 financial guidance, which will be provided in conjunction with its third quarter earnings release to be issued this morning.

Bococizumab is a PCSK9i that was studied for its potential to lower LDL-C and improve cardiovascular outcomes. It works by blocking the function of the PCSK9 protein, which interferes with the clearance of LDL-C, a leading known risk factor for heart disease. Bococizumab has not received regulatory approval in any country.

The bococizumab SPIRE (**S**tudies of **P**CSK9 **I**nhibition and the **R**eduction of vascular **E**vents) Phase 3 global clinical development program included six lipid-lowering studies as well as two cardiovascular outcome studies. Pfizer previously announced that four of the lipid-lowering studies met their primary endpoints (SPIRE-SI, SPIRE-AI, SPIRE-HR, SPIRE-FH). Recent top-line results also showed the two remaining Phase 3 bococizumab lipid-lowering trials, SPIRE-LDL (**L**ow-**D**ensity **L**ipoproteins) and SPIRE-LL (**L**ipid **L**owering), met their primary endpoints, demonstrating a significant reduction in the percent change from baseline in LDL-C at 12 weeks compared to placebo among adults with primary hyperlipidemia or mixed dyslipidemia at high and very high risk for cardiovascular events who were receiving statin therapy. Bococizumab was generally safe and well tolerated in both trials.

An evaluation of cross-reactivity to other PCKS9i monoclonal antibodies was not suggestive of clinically important concerns.

With this decision to discontinue the bococizumab development program, Pfizer will now halt the two ongoing cardiovascular outcome studies, SPIRE-1 and SPIRE-2.

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At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @PfizerNews, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE: The information contained in this release is as of November 1, 2016. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer’s discontinuation of the global clinical development program for bococizumab, including the anticipated charge and impact on the Company’s GAAP and adjusted earnings for the fourth quarter and full year of 2016, which involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, continuing evaluation of the estimated costs

associated with discontinuation of the program as well as the potential impact of unanticipated costs, expenses or liabilities.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2015 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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