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Two Additional Phase 3 Lipid-Lowering Studies of Bococizumab Deliver Positive Topline Results

Tuesday, June 28, 2016 - 04:30am

SPIRE-HR and SPIRE-FH trials met primary endpoints in patients at high and very high risk for cardiovascular events

Pfizer Inc. announced two additional Phase 3 bococizumab trials, SPIRE-HR (**H**igh**R**isk) and SPIRE-FH (**F**amilial **H**ypercholesterolemia), met their primary endpoint, demonstrating a significant reduction in the percent change from baseline in low-density lipoprotein cholesterol (LDL-C) at 12 weeks compared to placebo among adults at high and very high risk for cardiovascular events who were receiving a maximally tolerated dose of a highly effective statin.

SPIRE-HR and SPIRE-FH are the third and fourth of six SPIRE lipid-lowering Phase 3 studies to complete and show positive results. The two remaining SPIRE lipid-lowering studies are anticipated to complete later in 2016. Both SPIRE-HR and SPIRE-FH continued for 52 weeks to assess the longer-term efficacy and safety of bococizumab, an investigational Proprotein Convertase Subtilisin Kexin type 9 inhibitor (PCSK9i), in patients at high and very high risk for cardiovascular events.

“These positive results add to the growing body of scientific evidence in support of bococizumab for lowering LDL-cholesterol in patients at high risk for cardiovascular events,” said James M. Rusnak, MD, PhD, Chief Development Officer, Cardiovascular & Metabolic Disease, Pfizer Global Product Development. “The high burden of cardiovascular disease suggests that more treatment options are needed to help lower cholesterol and reduce cardiovascular risk in these patients. Our goal with the extensive SPIRE clinical program is to evaluate whether bococizumab not only reduces cholesterol, but also reduces the risk of cardiovascular events in a broad range of high-risk patients, including those without a history of heart disease.”

About SPIRE-HR study

The double-blind, randomized, placebo-controlled, parallel-group, multicenter, 52-week study evaluated the efficacy, safety and tolerability of bococizumab to lower LDL-C compared to placebo. The study included 711 adults with primary hyperlipidemia or mixed dyslipidemia at high and very high risk for cardiovascular events receiving a maximally tolerated dose of statin therapy whose LDL-C ?70 mg/dL.

Patients in the SPIRE-HR study were considered at high and very high risk for a future cardiovascular event if they had a known history of cardiovascular disease, including coronary heart disease or atherosclerotic diseases, diabetes or chronic kidney disease.

About SPIRE-FH study

The SPIRE-FH double-blind, randomized, placebo-controlled, parallel-group, multicenter, 52-week study evaluated the efficacy, safety and tolerability of bococizumab to lower LDL-C compared to placebo. The study included 370 adults with heterozygous familial hypercholesterolemia (HeFH) and at high and very high risk of cardiovascular events receiving a maximally tolerated dose of statin.

HeFH is a difficult-to-treat genetic condition that causes high LDL-C at birth putting patients at high risk for cardiovascular events at an early age.1,2

Patients with HeFH in the SPIRE-FH study were considered at high and very high risk for a future cardiovascular event if they had a known history of cardiovascular disease, diabetes or chronic kidney disease and an LDL-C ? 70 mg/dL or without a known history of cardiovascular disease, diabetes or chronic kidney disease with an LDL-C ?100 mg/dL; patients were required to be on the highest locally approved dose of an eligible statin or on the maximally tolerated dose.

Bococizumab was generally safe and well tolerated in both trials. Overall, the proportion of patients experiencing adverse events was similar among treatment groups, with one exception of a higher incidence of injection site reactions seen for patients on bococizumab compared to those on placebo in both trials. The majority of reported injection site reactions were mild.

Complete study results from the SPIRE-HR and SPIRE-FH trials will be presented at a future scientific forum and will be part of the potential future regulatory filing for bococizumab.

About cardiovascular disease

Cardiovascular disease remains the leading cause of death worldwide.3 High LDL-C is a known modifiable risk factor for cardiovascular events such as heart attack and stroke.4,5,6,7 Despite the availability of highly effective lipid-lowering therapies such as statins, many patients remain at high risk for cardiovascular events.8,9,10,11 Of note, in the U.S., more than 70% of heart attacks occur in patients without a previous cardiovascular event.12

About SPIRE

Pfizer has created SPIRE (**S**tudies of **P**CSK9 **I**nhibition and the **R**eduction of vascular **E**vents), an extensive research program to study bococizumab, its investigational PCSK9i. The SPIRE Phase 3 global clinical development program will include approximately 32,000 patients and consists of six lipid-lowering studies (SPIRE-SI, SPIRE-AI, SPIRE-HR, SPIRE-FH, SPIRE-LL and SPIRE-LDL) as well as two cardiovascular outcome studies (SPIRE-1 and SPIRE-2).

The lipid-lowering studies are evaluating the LDL-C lowering efficacy, safety, and tolerability of bococizumab in adult patients at high risk for future cardiovascular events, while the two cardiovascular outcome studies are investigating the ability of bococizumab to reduce the risk of cardiovascular events in a broad range of high-risk primary and secondary prevention patients, including those with diabetes, chronic kidney disease, peripheral vascular disease or familial hypercholesterolemia, in addition to those with previous cardiovascular events such as heart attack, stroke, or cardiovascular revascularization procedures.

Pfizer’s Phase 3 program for bococizumab is the only PCSK9i research program with a dedicated CV outcomes study explicitly assessing cardiovascular outcomes in high-risk primary and secondary prevention patients with an LDL-C ?100 mg/dL, despite the use of highly effective statins or with documented partial or complete statin intolerance.

About bococizumab

Bococizumab is an investigational compound and has not received regulatory approval in any country.

Bococizumab is a PCSK9i being studied for its potential to lower LDL-C and improve cardiovascular outcomes in a broad range of high-risk primary and secondary prevention patients. 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.

More information about the bococizumab Phase 3 program can be found at www.clinicaltrials.gov.

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References:

1 Familial Hypercholesterolemia (FH) Foundation. About FH. What is Familial Hypercholesterolemia? http://thefhfoundation.org/about-fh/what-is-fh/. Accessed April 30, 2015.

2 Nordestgaard BG et al. Consensus Statement of the European Atherosclerosis Society. European Heart Journal. 2013 Dec; 34(45):3478-90a.

3 World Health Organization. Cardiovascular diseases (CVDs) Fact sheet N°317. Updated January 2015. http://www.who.int/mediacentre/factsheets/fs317/en/. Accessed April 8, 2016.

4 Grundy SM, Cleeman JI, Merz CN, et al. Circulation. 2004 Jul 13; 110(2): 227-239.

5 NCEP Adult Treatment Panel III. Circulation. 2002 Dec 17; 106(25): 3143-3421.

6 Prospective Studies Collaboration. Lancet. 2007 Dec 1; 370(9602): 1829-1839.

7 Iso H, Jacobs DR Jr, Wentworth D, et al. N Engl J Med. 1989 Apr 6; 320(14): 904-910.

8 Cholesterol Treatment Trialists' (CTT) Collaborators. Lancet. 2005 Oct 8; 366(9493): 1267-1278.

9 Cholesterol Treatment Trialists' (CTT) Collaboration. Lancet. 2010 Nov 13; 376(9753): 1670-1681.

10 Fruchart JC, Sacks FM, Hermans MP, et al. Diabetes Vasc Dis Res. 2008 Nov; 5(4): 319-335.

11 Sampson UK, Fazio S, Linton MF. Curr Atheroscler Rep. 2012 Feb; 14(1): 1-10.

12 Mozaffarian, Dariush, et al. Circulation. 2015 Jan 27; 131(4):e29-322.

DISCLOSURE NOTICE: The information contained in this release is as of June 28, 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 product candidate, bococizumab, including its potential benefits, that 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, the uncertainties inherent in research and development, including the ability to meet anticipated trial commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; whether and when any applications for bococizumab may be filed with regulatory authorities in any jurisdictions; whether and when regulatory authorities in any jurisdictions may approve such applications, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of bococizumab; and competitive developments. The competitive landscape for lipid-lowering therapies, including PCSK9 inhibitors, continues to evolve. The success of our bococizumab program is dependent on developments in that space.

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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