



Pfizer Announces Positive Topline Results from Second Phase 3 Lipid-Lowering Study Evaluating Bococizumab

Friday, April 01, 2016 - 04:00am

SPIRE-AI study evaluating bococizumab administered with pre-filled pen (autoinjector) met co-primary endpoints

Pfizer Inc. announced that the Phase 3 SPIRE-AI (AutoInjector) trial of the investigational Proprotein Convertase Subtilisin Kexin type 9 inhibitor (PCSK9i) bococizumab administered with a pre-filled pen met its co-primary endpoints: percent change from baseline in low-density lipoprotein cholesterol (LDL-C) reduction at 12 weeks compared to placebo and proportion of patients successfully operating the pre-filled pen. The SPIRE-AI trial is the second study completed of the six SPIRE Phase 3 lipid-lowering studies, and we expect it will be part of the potential regulatory filing for bococizumab.

“We are encouraged by this second positive result from our ongoing SPIRE clinical trial program evaluating bococizumab,” said James M. Rusnak, MD, PhD, Therapeutic Area Clinical Head for Cardiovascular and Metabolism. “We believe the SPIRE program and bococizumab have the potential to play an important role in understanding and helping to address the unmet needs of patients at high risk for cardiovascular disease. We continue to maintain focus on delivering our Phase 3 program, including the two outcomes studies.”

The Phase 3 SPIRE-AI study – a 12-week, double-blind, placebo-controlled, randomized, parallel-group, multicenter, clinical trial in 299 patients with hyperlipidemia or mixed dyslipidemia receiving statin therapy and whose LDL-C ≥ 70 mg/dL – assessed the efficacy, safety, tolerability and subcutaneous administration of bococizumab 150mg and 75mg with a pre-filled pen. Co-primary endpoints included the percent change from baseline in fasting LDL-C at week 12 and the delivery system success rate, defined as the percent of patients whose attempts to operate the pre-filled pen met protocol-defined success.

Bococizumab was generally safe and well tolerated in this trial. Overall, the proportion of subjects experiencing treatment-related adverse events was similar among treatment groups. However, the trial was not designed to discern safety event differences among treatment groups. Complete study results of the SPIRE-AI trial will be presented at a future scientific forum.

About SPIRE

Pfizer has created SPIRE (Studies of PCSK9 Inhibition and the Reduction of vascular Events), an extensive research program to study bococizumab, its investigational PCSK9i. The SPIRE Phase 3 global clinical development program involves 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 outcomes studies (SPIRE-1 and SPIRE-2). The lipid-lowering studies are evaluating LDL-C lowering efficacy, safety, and tolerability of bococizumab in adult patients at risk of cardiovascular events, while the two cardiovascular outcomes studies are investigating the ability of bococizumab to reduce cardiovascular disease in a broad range of high-risk primary and secondary prevention patients. Pfizer's outcomes program for bococizumab is the only PCSK9i research program explicitly assessing cardiovascular outcomes in high-risk patients with an LDL-C ≥ 100 mg/dL, despite the use of highly effective statins.

SPIRE-SI (Statin Intolerance), the first of the six SPIRE Phase 3 lipid-lowering studies to be completed met its primary endpoint of lowering LDL-C in adult patients with hyperlipidemia who are intolerant to statins. No new or unexpected safety findings for bococizumab were observed in the study.

About bococizumab

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

Bococizumab is an investigational compound and has not received regulatory approval in any country. More information about the bococizumab Phase 3 program can be found at www.clinicaltrials.gov.

About Pfizer Inc.: Working together for a healthier world®

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 healthcare 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, Pfizer has worked to make a difference for all who rely on us. For more information, please visit us at www.pfizer.com. In addition, to learn more, follow us on Twitter @Pfizer and @Pfizer_News, LinkedIn, YouTube and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

DISCLOSURE NOTICE: The information contained in this release is as of April 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 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.

Pfizer Inc. Media Relations Steven Danehy, 212-733-1538 Steven.Danehy@pfizer.com or Investor Relations Ryan Crowe, 212-733-8160 Ryan.Crowe@pfizer.com