Bristol-Myers Squibb and ZymoGenetics Present Positive 4-week Results of PEG-Interferon lambda with Ribavirin in Hepatitis C

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PEG-Interferon lambda well tolerated in combination with Ribavirin

Mean maximum HCV RNA viral load decrease 3.0 logs or greater at all weekly dose levels

PRINCETON, N.J. & SEATTLE--(BUSINESS WIRE)--Bristol-Myers Squibb (NYSE: BMY) and ZymoGenetics, Inc. (NASDAQ: ZGEN) today reported that the administration of the investigational compound PEG-Interferon lambda in combination with ribavirin in 10 patients resulted in a significant reduction in hepatitis C virus (HCV) RNA and was well tolerated in patients with relapsed HCV in an ongoing Phase 1b clinical trial. Antiviral activity was observed at all dose levels tested either as single agent or in combination with ribavirin. Treatment was well-tolerated with reversible, dose-dependent increases in liver enzyme levels and bilirubin. There was no evidence for potentiation of ribavirin-induced toxicities in the combination groups. The interim results were presented at the European Association for the Study of the Liver (EASL) annual meeting in Copenhagen, Denmark.

“PEG-Interferon lambda showed antiviral effects as a single agent and also in combination with ribavirin. The lack of hematologic adverse effects in the trial is very encouraging,” said Mitchell Shiffman, M.D., Virginia Commonwealth Medical Center.

The Phase 1b clinical trial was designed to evaluate the safety and antiviral activity of PEG-Interferon lambda as a single agent or in combination with ribavirin in genotype 1 HCV patients with relapsed disease. The single agent part of the study, designed to assess PEG-Interferon lambda administered subcutaneously either with a weekly or every other week dose-escalation schedule at 1.5 mcg/kg and 3.0 mcg/kg for four weeks, is complete. In the combination part of the study, data are available for the first 10 subjects who have received weekly subcutaneous administration of PEG-Interferon lambda at doses of 0.75 mcg/kg (3 patients) or 1.5 mcg/kg (7 patients) with daily oral ribavirin administered per the package insert over a four-week period.

Antiviral activity was seen in all cohorts, with a mean maximum decrease in HCV RNA viral load of at least 3.0 log₁₀ in all single agent and combination cohorts receiving weekly dosing. Of the 22 patients dosed weekly, 86% showed a 2 log₁₀ or greater decrease in HCV RNA at Day 29 and 50% had less than 1,000 HCV RNA copies. Of the six patients treated weekly with 3.0 mcg/kg single agent, 50% achieved a rapid virologic response (RVR; undetectable HCV RNA copies at 4 weeks).

PEG-Interferon lambda was well tolerated over four weeks of treatment with minimal hematologic effects or constitutional symptoms. No fever was reported. The majority of adverse events were Grade 1 or 2, the most common of which were fatigue (18%) and nausea (18%). Reversible, dose-dependent increases in liver enzymes (ALT, AST) meeting the protocol criteria for dose-limiting toxicity were observed in four patients, of which three also experienced reversible increases in bilirubin. There were no clinically significant changes in serum chemistry or renal function. Decreases in mean hemoglobin values occurred only in ribavirin cohorts, and there was no neutropenia.

Presentations

Two poster presentations will be given at the EASL 2009 Annual Meeting:

Friday, April 24, 2009

Time: 02:00 a.m. - 12:00 p.m. EDT
Poster Board #: 643
Title: PEG-IFN-λ: Antiviral Activity And Safety Profile In A 4-Week Phase 1B Study In Relapsed Genotype 1 Hepatitis C Infection

Session Title: Category 5G: Viral Hepatitis - g) Hepatitis C - Clinical (Therapy)
PEG-Interferon lambda

PEG-Interferon lambda (IL-29) is a novel type 3 interferon currently in Phase 1b development for hepatitis C. The native human protein Interferon lambda is generated by the immune system in response to viral infection.

About Hepatitis C

Hepatitis C is a virus that infects the liver and is transmitted through direct contact with blood. An estimated 170 million people worldwide are infected with hepatitis C and, of these, 94.5 million people live in the Asia Pacific region. One to five percent of people with chronic infection will develop liver cancer. Although there is no vaccine to prevent hepatitis C, it is a curable disease.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to extend and enhance human life. For more information, visit www.bms.com.

About ZymoGenetics

ZymoGenetics creates novel protein drugs that help patients fight disease. ZymoGenetics developed and markets RECO THROM® Thrombin, topical (Recombinant). Other product candidates focus on cancer, autoimmune and viral diseases. ZymoGenetics intends to commercialize product candidates through internal development, collaborations with partners, and out-licensing of patents from its extensive patent portfolio. For further information, visit www.zymogenetics.com.

Bristol-Myers Squibb Forward-Looking Statements

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995, regarding the research, development and commercialization of pharmaceutical products. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among other risks, there can be no guarantee that the compound described in this release will move from early stage development into full product development, that clinical trials of this compound will support a regulatory filing, or that the compound will receive regulatory approval or become a commercially successful product. Forward-looking statements in the press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb's business, particularly those identified in the cautionary factors discussion in Bristol-Myers Squibb's Annual Report on Form 10-K for the year ended December 31, 2008, its Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K. Bristol-Myers Squibb undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise.

ZymoGenetics Forward Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on the current intent and expectations of the management of ZymoGenetics. These statements are not guarantees of future performance and involve risks and uncertainties that are difficult to predict. ZymoGenetics' actual results and the timing and outcome of events may differ materially from those expressed in or implied by the forward-looking statements because of risks associated with our unproven preclinical and clinical development and results, strategic partnering, including efforts by and results of collaborations, regulatory oversight and approvals, product sales and marketing abilities, discovery strategy, intellectual property claims and litigation and other risks detailed in the company's public filings with the Securities and Exchange Commission, including the company's Annual Report on Form 10-K for the year ended December 31, 2008. Except as required by law, ZymoGenetics undertakes no obligation to update any forward-looking or other statements in this press release, whether as a result of new information, future events or otherwise.

References


Language:

English

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