



Date: March 29, 2008

Refer to: Joedy Isert
Eli Lilly and Company
317-276-5592 (office)
317-997-8544 (cell)

Rich Salem
Daiichi Sankyo (U.S.A.)
973-695-8330 (office)
973-563-1086 (cell)

Shigemichi Kondo
Daiichi Sankyo (Tokyo)
81-3-6225-1126 (office)

Study Results Show Investigational Drug, Prasugrel, Cuts Risk of Stent-Related Clots by More than Half Versus Clopidogrel

*Reductions seen as soon as three days and out to 450 days
in patients who received either bare metal or drug-eluting stents*

CHICAGO, IL (March 29, 2008) – The investigational antiplatelet drug prasugrel plus aspirin produced a marked and highly statistically significant reduction in the risk of coronary stent thrombosis (ST) – a major concern for physicians and patients with potentially fatal consequences – in patients who received a stent as compared to standard therapy with clopidogrel (Plavix[®]) plus aspirin (1.13 percent vs. 2.35 percent, $p < 0.0001$), according to a stent analysis from the head-to-head TRITON-TIMI 38 trial.

The findings were presented today by Dr. Stephen Wiviott, an assistant professor of medicine at Harvard Medical School and investigator with the Thrombolysis in Myocardial Infarction (TIMI) Study Group, at the Society for Cardiovascular Angiography and Interventions Scientific Sessions with the American College of

Cardiology's Innovation in Intervention: i2 Summit, in Chicago. In addition, the manuscript was simultaneously published online by the British medical journal, *The Lancet*.

In the TRITON-TIMI 38 trial, whose overall results were previously published, 12,844 of the 13,608 enrolled patients received at least one intracoronary stent. Of those patients, 6,461 received a bare metal stent (BMS), 5,743 patients received a drug-eluting stent (DES), and 640 patients received both BMS and DES at the time of enrollment. Stent thrombosis was a pre-defined secondary endpoint in the trial.

Prasugrel reduced the relative risk of coronary stent thrombosis (a new clot at the implanted stent site) over clopidogrel by 52 percent (1.13 percent vs. 2.35 percent, $p < 0.0001$). In patients who received drug-eluting stents (DES), treatment with prasugrel reduced relative risk by 64 percent over clopidogrel (0.84 percent vs. 2.31 percent, $p < 0.0001$), and by 48 percent in patients who received bare metal stents (BMS) (1.27 percent vs. 2.41 percent, $p = 0.0009$).

In the analysis, prasugrel was consistent in reducing stent thrombosis, compared to clopidogrel, whether assessment occurred early or late (< 30 days and ≥ 30 days, out to 450 days, the median duration of therapy), regardless of the type of stent used (bare metal or drug-eluting), and regardless of which academic research consortium (ARC) definition of stent thrombosis was used – definite/confirmed stent thrombosis, definite/confirmed plus probable stent thrombosis, and definite/confirmed plus probable plus possible stent thrombosis. Definite/probable stent thrombosis was reduced by 59 percent in prasugrel-treated patients within 30 days of stent placement (0.64 percent vs. 1.56 percent, $p < 0.0001$), and by 40 percent after 30 days (out to 450 days, 0.49 percent vs. 0.82 percent, $p = 0.03$).

"Stent thrombosis is very serious, given the high risk of mortality. In TRITON, among 210 patients with definite or probable stent thrombosis, 186 (89 percent) either died or experienced an MI as a result of the event," said Francis Plat, M.D., vice president, clinical development, Daiichi Sankyo Company, Limited. "We were excited by the results of this study and the possibility that prasugrel may someday provide an alternative treatment for ACS patients undergoing PCI and receiving coronary stents."

A 19 percent reduction in risk was observed with prasugrel compared with clopidogrel among all patients receiving a stent (9.7 percent vs. 11.9 percent, $p=0.0001$) in TRITON's primary endpoint of cardiovascular death, non-fatal heart attack, or non-fatal stroke. A 20 percent relative reduction favoring prasugrel was observed in the primary endpoint in patients who received only a bare metal stent (10.0 percent vs. 12.2 percent, $p=0.003$), and in patients who received only a drug-eluting stent, results showed an 18 percent relative reduction in the primary endpoint favoring prasugrel (9.0 percent vs. 11.1 percent, $p=0.019$). Fatal stent thrombosis occurred in 18 (0.28 percent) patients treated with prasugrel and 29 (0.46 percent) patients treated with clopidogrel ($p=0.10$). Of note, of the 210 patients with stent thrombosis, 89 percent either died or had a myocardial infarction associated with the event.

The rate of major bleeding was higher in all patients receiving a stent treated with prasugrel vs. clopidogrel (2.4 percent vs. 1.9 percent, $p=0.06$). Major bleeding in both DES and BMS prasugrel-treated groups when compared to clopidogrel-treated patients was 3 percent vs. 2 percent ($p=0.34$ DES) and 2 percent vs. 2 percent ($p=0.09$ BMS).

In addition to a reduction in the primary endpoint (CV death, non-fatal heart attack, or non-fatal stroke), a significantly lower rate of the composite endpoint of cardiovascular death, heart attack or urgent target vessel revascularization (UTVR) was observed with prasugrel vs. clopidogrel for both bare metal stents (10 percent vs. 12 percent, $p=0.009$) and for drug-eluting stents (9 percent vs. 11 percent, $p=0.004$). A significant reduction was also seen in heart attack alone (8 percent vs. 10 percent, $p=0.003$, BMS and 7 percent vs. 9 percent, $p=.006$, DES). In DES-implanted patients, regardless of those receiving only sirolimus-eluting or paclitaxel-eluting stents, there was a similar magnitude of event reduction with prasugrel compared to clopidogrel.

For the entire cohort, sub-acute stent thrombosis (24 hours to 30 days) was 0.36 percent in prasugrel-treated patients vs. 1.19 percent in clopidogrel-treated patients ($p<0.0001$). DES-implanted patients had lower rates of stent thrombosis compared to BMS-implanted patients, and prasugrel was shown to significantly reduce stent thrombosis in DES-implanted patients within the first three days compared to clopidogrel (0.14 percent vs. 0.63 percent, $p=0.003$) as well as for thromboses that occurred >30 days following the DES implantation (0.42 percent vs. 0.91 percent, $p=0.04$).

"The reduction in risk seen in patients in this analysis treated with prasugrel over patients treated with clopidogrel is encouraging for high-risk patients with acute coronary syndrome being managed with PCI," said J. Anthony Ware, M.D., Lilly vice president for cardiovascular/acute care.

About the TRITON-TIMI 38 stent analysis

TRITON-TIMI 38 was a Phase III, multi-center, randomized, double blind, parallel group, head-to-head clinical trial comparing the effects of prasugrel vs. clopidogrel in patients with acute coronary syndrome undergoing percutaneous coronary intervention (PCI). PCI is a procedure to open blockages in heart arteries including the use of coronary stenting. The study enrolled 13,608 patients at 707 trial sites in 30 countries.

The primary endpoint of the study was to compare the effects of prasugrel to clopidogrel on the composite incidence of cardiovascular death, non-fatal heart attack, or non-fatal stroke during a median period of 14.5 months following PCI. Key secondary objectives included rehospitalization for a cardiac ischemic event; the need for additional procedures to restore blood flow (urgent target vessel revascularization) at 30 days; and stent thrombosis. Key safety endpoints included non-CABG major, life threatening and minor bleeding as well as the overall safety and tolerability of prasugrel.

Patients were randomly assigned to one of two treatment groups and given a loading dose of either prasugrel 60 mg or the approved loading dose of clopidogrel 300 mg anytime between randomization and one hour after the completion of the PCI procedure, followed by a daily maintenance dose of either prasugrel 10 mg or clopidogrel 75 mg. All patients also received a daily low dose of aspirin.

Subjects enrolled in TRITON were included in the stent analysis if they received at least one coronary stent at randomization and were further subdivided based on the types of stents received. Clinical outcomes, including the primary study endpoint, stent thrombosis and net clinical benefit (all-cause death/MI/stroke/TIMI major bleeding) were assessed using survival analytic techniques.

Analyses that consider all 12,844 patients with stents include all three stent groups. Subjects were classified as having received bare metal stents (BMS), drug-eluting stents (DES), or a combination of stent types at the time of the index PCI. Analyses of DES and BMS individually include patients who received DES only or BMS only, respectively,

and patients with a mix of stents (<5 percent of the trial population) were excluded from the analysis of BMS or DES only subjects as they did not clearly fit into either group.

About prasugrel

Daiichi Sankyo Company, Limited (TSE: 4568), and Eli Lilly and Company (NYSE: LLY) are co-developing prasugrel, an investigational oral antiplatelet agent discovered by Daiichi Sankyo and its Japanese research partner, Ube Industries, Ltd., as a potential treatment, initially for patients with acute coronary syndrome who are managed with PCI. Prasugrel works by inhibiting platelet activation and subsequent aggregation by blocking the P2Y₁₂ adenosine diphosphate (ADP) receptor on the platelet surface. Antiplatelet agents prevent platelets from clumping or sticking together, which can result in clogged arteries and may lead to heart attack or stroke.

Lilly, on behalf of its alliance partner, Daiichi Sankyo, submitted a New Drug Application to the U.S. Food and Drug Administration for prasugrel in December 2007, and in February was granted priority review designation by the regulatory agency. Lilly, on behalf of the alliance, also submitted a Marketing Authorization Application for prasugrel to the European Medicines Agency in February.

About Daiichi Sankyo Company, Limited

Daiichi Sankyo Company, Limited, established in 2005 after the merger of two leading century-old Japanese pharmaceutical companies, is a global pharmaceutical innovator, continuously generating innovative drugs that enrich the quality of life for patients around the world. The company uses its cumulative knowledge and expertise in the fields of cardiovascular disease, cancer, metabolic disorders, and infection as a foundation for developing an abundant product lineup and R&D pipeline.

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of first in class and best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers – through medicines and information – for some of the world’s most urgent medical needs.

P-LLY

###

This press release contains certain forward-looking statements about the potential of the investigational compound prasugrel (CS-747, LY640315) and reflects Daiichi Sankyo's and Lilly's current beliefs. However, as with any pharmaceutical compound under development, there are substantial risks and uncertainties in the process of development and regulatory review. There is no guarantee that the compound will receive regulatory approval, that the regulatory approval will be for the indication(s) anticipated by the companies, or that later studies and patient experience will be consistent with study findings to date. There is also no guarantee that the compound will prove to be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's filing with the United States Securities and Exchange Commission and Daiichi Sankyo's filings with the Tokyo Stock Exchange. Daiichi Sankyo and Lilly undertake no duty to update forward-looking statements.