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Two Novartis Phase III Studies Show Twice as Many Ph+ CML Patients Achieve Deeper Levels of Response With Tasigna® Compared to Gleevec®

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- - ENESTcmr data show 23% of patients switched to Tasigna achieved undetectable levels of Bcr-Abl within 12 months compared to 11% who continued on Gleevec(1)
- - Three-year ENESTnd data show 32% of newly diagnosed patients on Tasigna reached deepest levels of molecular response measured versus 15% on Gleevec(2)
- - ENESTnd study also shows significantly fewer patients progressed to advanced stages of CML with Tasigna after three years, compared to Gleevec(2)

EAST HANOVER, N.J., Dec. 12, 2011 /PRNewswire/ -- Phase III clinical trial data presented today contribute to the growing evidence that adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase who are treated with Tasigna® (nilotinib) have deeper levels of response compared to those treated with Gleevec® (imatinib mesylate) tablets(*1,2).

The findings from the ENEST (Evaluating Nilotinib Efficacy and Safety in clinical Trials) clinical research program were presented at the 53rd Annual Meeting of the American Society of Hematology (ASH) in San Diego.

ENESTcmr is the first exploratory randomized trial to investigate the impact of switching adult patients with residual disease after a minimum of two years of treatment with Gleevec to Tasigna to determine if a deeper level of response could be achieved(1).

The study showed that twice as many patients switched to Tasigna 400 mg twice a day achieved undetectable Bcr-Abl levels by 12 months compared to Gleevec (23% taking Tasigna 400 mg twice daily and 11% taking Gleevec 400 mg or 600 mg once daily; p= 0.0202). The primary endpoint, which is more stringent than conventional measures, is undetectable Bcr-Abl level in two consecutive samples. Samples with any detectable level were not considered to be in complete molecular response (CMR). The lowest detected Bcr-Abl value was 0.00073%. This endpoint showed a two-fold difference in confirmed undetectable CMR for 13% of patients on Tasigna versus 6% of patients on Gleevec, although statistical significance was not achieved (p=0.108). The study has a planned follow-up of four years(1).

After 36 months of follow-up, data from the Phase III ENESTnd clinical trial in adult patients with newly diagnosed Ph+ CML in chronic phase continued to show significantly more patients achieved CMR, defined in this study as at least a 4.5 log reduction from baseline or a trace amount of 0.0032% or less of Bcr-Abl compared to Gleevec (32% taking Tasigna 300 mg twice daily and 15% taking Gleevec 400 mg once daily). The ENESTnd study also continued to show that first-line treatment with Tasigna resulted in significantly fewer patients progressing to advanced phase and blast crisis (AP/BC) stages of disease compared to Gleevec, leading to a significantly lower number of CML-related deaths in patients taking Tasigna versus Gleevec (p=0.0356)(2).

"Data from both ENESTnd and ENESTcmr reinforce that patients taking Tasigna have a greater chance of

achieving CMR, the deepest level of response measurable today, compared to those taking Gleevec," said Timothy P. Hughes, MD, ENEST study investigator and Clinical Professor at the University of Adelaide, Australia. "We are encouraged by what we saw in ENESTcmr and further follow-up on both trials should help to determine if more patients can reach undetectable levels of CML over time, which could have important implications for determining criteria for future studies on discontinuation of therapy."

CML is a disease in which the body produces cancerous white blood cells. Almost all patients with CML have an abnormality known as the Philadelphia chromosome, which is comprised of a protein called Bcr-Abl that causes malignant white blood cells to proliferate(3). The success of treatment for CML can be measured by a test called real-time quantitative polymerase chain reaction (RQ-PCR). A molecular response means RQ-PCR shows a reduction in Bcr-Abl in the blood; a CMR means no Bcr-Abl is detected(4,5).

"Data from the ENESTnd 36-month update and the ENESTcmr trial at ASH continue to reinforce the benefits of Tasigna over Gleevec, and support the use of Tasigna for adult patients with chronic-phase Ph+ CML," said Herve Hoppenot, President, Novartis Oncology. "We look forward to even more progress in the future as we observe the impact of achieving deep and sustained molecular response with Tasigna for people living with this cancer."

CML is responsible for approximately 10% to 15% of all adult cases of leukemia in the US, with an incidence of one to two cases per 100,000 people per year(6,7).

ENESTcmr study details

ENESTcmr is an open-label, randomized, prospective, multi-center Phase III study of Tasigna 400 mg twice daily versus standard-dose Gleevec (400 mg or 600 mg once daily) comparing kinetics of CMR for patients with Ph+ CML in chronic phase who had achieved complete cytogenetic response (CCyR) but were still Bcr-Abl positive (i.e., had evidence of residual leukemia) after at least two years of treatment with Gleevec. The study enrolled 207 patients. The patients were randomized into one of two treatment arms: Tasigna 400 mg twice daily versus continuing Gleevec 400 mg or 600 mg once daily (same dose as at study entry)(1).

The primary endpoint was the rate of confirmed best cumulative CMR by 12 months of study therapy with Tasigna or Gleevec. Samples with any detectable level were considered not to be in CMR. The lowest detected Bcr-Abl value was 0.00073%. Secondary objectives included the kinetics of CMR, duration of CMR, progression-free survival and overall survival in both arms. CMR was defined at three levels: CMR (CMR greater than or equal to 4.5-log, undetectable Bcr-Abl by RQ-PCR at a sensitivity of less than 0.0032%), CMR4 (CMR greater than or equal to 4-log, undetectable Bcr-Abl by RQ-PCR at a sensitivity of 0.01% or less) and CMR4.5 (CMR greater than or equal to 4.5-log, undetectable Bcr-Abl by RQ-PCR at a sensitivity of 0.0032% or less)(1).

These data showed that 23% of patients taking Tasigna achieved undetectable disease (24 patients) by 12 months, compared to 11% (11 patients) taking Gleevec(1).

A majority of patients in both treatment arms received prior Gleevec treatment for at least three years before entering the trial. Patients randomized to receive Tasigna were given a new treatment while the others continued to receive a therapy that they had been taking for a minimum of two years(1).

During this study, discontinuation due to adverse events (AEs) occurred in 8.9% and 1% for Tasigna- and Gleevec-treated patients, respectively. The majority of these were asymptomatic laboratory adverse events. The most commonly reported AEs in the Tasigna arm were headache (36.6%), rash (23.8%) and pruritus (23.8%), while in the Gleevec arm the most commonly reported AEs were diarrhea (12.6%) and headache (9.7%)(1).

ECGs were measured at baseline (both treatment arms), at day 8 (Tasigna arm only) and at early discontinuation from study treatment (both treatment arms). No patients in the Tasigna treatment arm were reported to have QTc prolongation intervals greater than 480 msec at baseline or at day 8; four patients (4.0%) had reported QTc prolongation intervals greater than 450 msec on day 8. No patients who discontinued early had QTc prolongation intervals greater than 450 msec(1).

ENESTnd study details

ENESTnd is a Phase III randomized, open-label, multicenter trial comparing the efficacy and safety of Tasigna versus Gleevec in adult patients with newly diagnosed Ph+ CML in chronic phase. It is the largest global randomized comparison of two oral therapies ever conducted in newly diagnosed Ph+ CML patients(2).

The study is being conducted at 217 global sites with 846 patients enrolled. Patients were randomized to receive Tasigna 300 mg twice daily (n=282), Tasigna 400 mg twice daily (n=281) or Gleevec 400 mg once daily (n=283). The primary endpoint was major molecular response (MMR) at 12 months; the key secondary endpoint was durable MMR at 24 months (patients having MMR when evaluated at both 12 and 24 months). MMR was defined in this study as 0.1% or less of Bcr-Abl as measured by RQ-PCR. Planned follow-up is for five years. Patients on the Gleevec treatment arm who had suboptimal response or treatment failure were allowed to escalate dose and/or switch to Tasigna in a separate extension study. These data, presented at ASH, were the 36-month minimum follow-up(2).

Results showed that fewer patients in the core treatment group progressed to accelerated phase or blast crisis while on treatment with Tasigna at 300 mg twice daily (n=2) and 400 mg twice daily (n=3) versus Gleevec at 400 mg once daily (n=12) with 36 months of minimum follow-up. Analysis of the broader study group, including patients followed after discontinuation of the study, showed 9 patients on Tasigna 300 mg twice daily, 6 patients on Tasigna 400 mg twice daily and 19 patients on Gleevec progressed(2).

Over the past three years a total of 38 patients (5%) died during the ENESTnd study (17 patients taking Gleevec, 13 taking Tasigna 300 mg twice daily and 8 taking Tasigna 400 mg twice daily). Tasigna treatment was also associated with significantly lower rates of CML-related deaths (5 patients taking Tasigna 300 mg twice daily, 4 patients taking Tasigna 400 mg twice daily and 14 patients taking Gleevec) consistent with the significant improvement observed with progression to AP/BC. Since the last data cut-off there were a total of five CML related deaths (4 with Gleevec 400 mg once daily and 1 with Tasigna 400 mg twice daily)(2).

The median follow-up for this study was 36 months. Overall, 90% and 88% of patients remained in the study on Tasigna 300 mg twice daily and Gleevec 400 mg once daily, respectively(2).

Rates of discontinuation due to adverse events or laboratory abnormalities continued to be lowest for Tasigna 300 mg twice daily (10%) compared to Tasigna 400 mg twice daily (14%) and Gleevec 400 mg once daily (11%). The most commonly reported adverse events in the Tasigna 300 mg arm were rash (38.0%), headache (30.5%) and increased alanine aminotransferase (24.7%), while the same adverse events for Tasigna 400 mg were 43.3%, 32.9% and 29.2% respectively. In the Gleevec arm, the most commonly reported AEs were diarrhea (43.6%), nausea (39.6%) and vomiting (25.0%)(2).

There were two new cases of QTc prolongation increases greater than 60 msec from baseline observed since the last data cut-off, one each in the Gleevec arm and the Tasigna 400 mg arm (total of 1, 1, and 3 patients in Gleevec, Tasigna 300 mg and Tasigna 400 mg arms, respectively). With the 36-month data cut-off, no patient in any treatment arm had a QTc prolongation greater than 500 msec(2).

*Known as Glivec® (imatinib) outside the US, Canada and Israel.

About Tasigna

TASIGNA® (nilotinib) is approved for the treatment of adult patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase. The effectiveness of TASIGNA for this indication is based on major molecular response and cytogenetic response rates at 12 months. The study is ongoing and further data will be required to determine long-term outcome.

TASIGNA is also approved in more than 90 countries for the treatment of chronic phase and accelerated phase Ph+ CML in adult patients resistant or intolerant to at least one prior therapy, including Gleevec. The effectiveness of TASIGNA for this indication is based on hematologic and cytogenetic response rates.

BOXED WARNING and Important Safety Information for TASIGNA (nilotinib):

WARNING: QT PROLONGATION AND SUDDEN DEATHS

TASIGNA prolongs the QT interval. Prior to TASIGNA administration and periodically, monitor for hypokalemia or hypomagnesemia and correct deficiencies. Obtain ECGs to monitor the QTc at baseline, seven days after initiation, and periodically thereafter, and follow any dose adjustments.

Sudden deaths have been reported in patients receiving nilotinib. Do not administer TASIGNA to patients with hypokalemia, hypomagnesemia, or long QT syndrome.

Avoid use of concomitant drugs known to prolong the QT interval and strong CYP3A4 inhibitors.

Patients should avoid food 2 hours before and 1 hour after taking dose.

Treatment with TASIGNA can cause Grade 3/4 thrombocytopenia, neutropenia, and anemia. Complete blood counts should be performed every 2 weeks for the first 2 months and then monthly thereafter.

Caution is recommended in patients with a history of pancreatitis.

The use of TASIGNA may result in elevations in bilirubin, AST/ALT, and alkaline phosphatase.

TASIGNA can cause hypophosphatemia, hypokalemia, hyperkalemia, hypocalcemia, and hyponatremia (see Boxed WARNING).

The concomitant use of strong CYP3A4 inhibitors or anti-arrhythmic drugs (including, but not limited to, amiodarone, disopyramide, procainamide, quinidine, and sotalol) and other drugs that may prolong the QT interval (including, but not limited to, chloroquine, clarithromycin, haloperidol, methadone, moxifloxacin, and

pimozide) should be avoided. Grapefruit products should also be avoided.

The concomitant use of strong CYP3A4 inducers should be avoided (including, but not limited to, dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifapentin, phenobarbital, and St. John's wort).

TASIGNA must not be taken with food.

TASIGNA exposure is increased in patients with impaired hepatic function.

Cases of tumor lysis syndrome have been reported in TASIGNA treated patients with resistant or intolerant CML. Due to potential for tumor lysis syndrome, maintain adequate hydration and correct uric acid levels prior to initiating therapy with TASIGNA.

The exposure of TASIGNA is reduced in patients with total gastrectomy.

Since the capsules contain lactose, TASIGNA is not recommended for patients with rare hereditary problems of galactose intolerance, severe lactase deficiency with a severe degree of intolerance to lactose-containing products, or of glucose-galactose malabsorption.

Women of childbearing potential should avoid becoming pregnant while taking TASIGNA and should be advised of the potential hazard to the fetus if they do. The safety and effectiveness of TASIGNA in pediatric patients have not been established.

In newly diagnosed Ph+ CML-chronic phase, the most commonly reported nonhematologic adverse drug reactions (>10%) were rash, pruritus, headache, nausea, fatigue, and myalgia.

In resistant or intolerant Ph+ CML-chronic phase, the most commonly reported nonhematologic adverse drug reactions (greater than or equal to 10%) were rash, pruritus, nausea, fatigue, headache, constipation, diarrhea, vomiting, and myalgia.

In resistant or intolerant Ph+ CML-accelerated phase, the most commonly reported nonhematologic adverse drug reactions (greater than or equal to 10%) were rash, pruritus, and fatigue.

TASIGNA may need to be temporarily withheld and/or dose reduced for QT prolongation, hematologic toxicities that are not related to underlying leukemia, clinically significant moderate or severe nonhematologic toxicities, laboratory abnormalities, or concomitant use of strong CYP3A4 inhibitors.

Please see full Prescribing Information including Boxed Warning.

About Gleevec

Gleevec® (imatinib mesylate) tablets are indicated for newly diagnosed adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in the chronic phase (CP). Gleevec is also indicated for the treatment of patients with Ph+ CML in blast crisis (BC), accelerated phase (AP), or in CP after failure of interferon-alpha therapy.

GLEEVEC Important Safety Information

GLEEVEC is often associated with edema and occasionally serious fluid retention. Patients should be weighed and monitored regularly for signs and symptoms of fluid retention, which can be serious or life-threatening. Be advised to carefully investigate and provide appropriate management for unexpected weight gain. The probability of edema tended to be increased among older patients (>65 years) or those taking higher doses of GLEEVEC. If severe fluid retention occurs, GLEEVEC should be withheld until the event has resolved and

then resumed depending on the initial severity of the event.

Cytopenias have been reported. Complete blood counts should be performed weekly for the first month, biweekly for the second month, and periodically thereafter as clinically indicated (for example, every 2-3 months). Dose reduction or treatment interruption may be required for severe neutropenia or thrombocytopenia (see full Prescribing Information for dose adjustment recommendations).

Severe congestive heart failure and left ventricular dysfunction have occasionally been reported. Most patients with reported cardiac events have had other comorbidities and risk factors, including advanced age and previous medical history of cardiac disease. Patients with cardiac disease or risk factors for cardiac failure should be monitored carefully, and any patient with signs or symptoms consistent with cardiac failure should be evaluated and treated.

Hepatotoxicity, occasionally severe, may occur. Cases of fatal liver failure and severe liver injury requiring liver transplants have been reported with both short-term and long-term use of GLEEVEC. Assess liver function before initiation of treatment and monthly thereafter or as clinically indicated. Monitor liver function when combined with chemotherapy known to be associated with liver dysfunction. A 25% decrease in the recommended dose should be used for patients with severe hepatic impairment. If severe hepatotoxicity occurs, GLEEVEC should be withheld until the event has resolved and then resumed depending on the initial severity of the event.

In the newly diagnosed CML trial, 1.8% of patients had (NCI Grades 3/4) hemorrhage.

In patients with hypereosinophilic syndrome and cardiac involvement, cardiogenic shock and left ventricular dysfunction have been associated with initiation of GLEEVEC. The condition was reported to be reversible with the administration of systemic steroids, circulatory support measures, and temporarily withholding GLEEVEC.

Bullous dermatologic reactions (eg, erythema multiforme and Stevens-Johnson syndrome) have also been reported. In some cases, the reaction recurred upon rechallenge. Several postmarketing reports describe patients able to tolerate the reintroduction of GLEEVEC at a lower dose with or without concomitant corticosteroids or antihistamines following resolution or improvement of the bullous reaction.

Clinical cases of hypothyroidism have been reported in thyroidectomy patients undergoing levothyroxine replacement during treatment with GLEEVEC. TSH levels should be closely monitored in such patients.

Consider potential toxicities—specifically liver, kidney, and cardiac toxicity—and immunosuppression from long-term use.

Fetal harm can occur when administered to a pregnant woman; therefore, women of childbearing potential should be advised to not become pregnant while taking GLEEVEC tablets and to avoid breast-feeding while taking GLEEVEC tablets because of the potential for serious adverse reactions in nursing infants. Sexually active female patients taking GLEEVEC should use adequate contraception. If the patient does become pregnant while taking GLEEVEC, the patient should be advised of the potential hazard to the fetus.

Growth retardation has been reported in children and pre-adolescents receiving GLEEVEC. The long-term effects of prolonged treatment with GLEEVEC on growth in children are unknown; therefore, monitoring of growth in children taking GLEEVEC is recommended.

Cases of tumor lysis syndrome (TLS), including fatal cases, have been reported. The patients at risk of TLS are those with tumors having a high proliferative rate or high tumor burden prior to treatment. These patients should be monitored closely and appropriate precautions taken.

In Ph+ CML trials**, severe (NCI Grades 3/4) lab abnormalities—including neutropenia (3.6%-48%), anemia (1%-42%), thrombocytopenia (<1%-33%), and hepatotoxicity (approx 5%)—and severe adverse experiences (NCI Grades 3/4), including hemorrhage (1.8%-19%), fluid retention (eg, pleural effusion, pulmonary edema, and ascites) (2.5%-11%) and superficial edema (1.5%-6%), and musculoskeletal pain (2%-9%), were reported among patients receiving GLEEVEC. Severe fluid retention appears to be dose-related, was more common in the advanced phase studies (where the dosage was 600 mg/day), and is more common in the elderly.

There have also been reports, including fatalities, of cardiac tamponade, cerebral edema, acute respiratory failure, and gastrointestinal (GI) perforation.

GLEEVEC is metabolized by the CYP3A4 isoenzyme and is an inhibitor of CYP3A4, CYP2D6, and CYP2C9. Significant reductions in imatinib concentrations may occur when GLEEVEC is administered concomitantly with agents that are strong CYP3A4 inducers such as rifampin, St. John's wort, and enzyme-inducing anti-epileptic drugs, eg, phenytoin. The use of concomitant strong CYP3A4 inducers should be avoided. If patients must be administered a strong CYP3A4 inducer, the dosage of GLEEVEC should be increased by at least 50% and clinical response should be carefully monitored. Caution is recommended when GLEEVEC is administered with CYP3A4 inhibitors such as ketoconazole, with CYP2D6 substrates that have a narrow therapeutic window, or with CYP3A4 substrates that have a narrow therapeutic window. Other examples of commonly used drugs that may significantly interact with GLEEVEC include acetaminophen, warfarin, erythromycin, and metoprolol. Grapefruit juice should also be avoided in patients taking GLEEVEC. (Please see full Prescribing Information for other potential drug interactions).

Patients with moderate renal impairment (CrCL = 20-39 mL/min) should receive a 50% decrease in the recommended starting dose and future doses can be increased as tolerated. Doses greater than 600 mg are not recommended in patients with mild renal impairment (CrCL = 40-59 mL/min). For patients with moderate renal impairment, doses greater than 400 mg are not recommended. GLEEVEC should be used with caution in patients with severe renal impairment.

Common Side Effects of GLEEVEC Tablets

Almost all adult Ph+ CML patients who received GLEEVEC in clinical studies experienced adverse reactions at some time, but most were mild to moderate in severity. The most frequently reported adverse reactions (all Grades) were superficial edema (60%-74%), nausea (50%-73%), diarrhea (43%-57%), musculoskeletal pain (38%-49%), rash and related terms (36%-47%), muscle cramps (28%-62%), and vomiting (23%-58%)(+).

Supportive care may help reduce the severity of some mild-to-moderate adverse reactions. However, in some cases, either a dose reduction or interruption of treatment with GLEEVEC may be necessary.

For daily dosing of 800 mg and above, dosing should be accomplished using the 400-mg tablet to reduce exposure to iron.

GLEEVEC tablets should be taken with food and a large glass of water to minimize GI irritation.

Patients should be informed to take GLEEVEC exactly as prescribed, and not to change their dose or stop taking GLEEVEC unless they are told to do so by their doctor. If patients miss a dose, they should be advised to take their dose as soon as possible unless it is almost time for their next dose, in which case the missed dose should not be taken. A double dose should not be taken to make up for any missed dose.

**For more detailed study information, please see full Prescribing Information.

+Numbers indicate the range of percentages in 4 studies among adult patients, with newly diagnosed Ph+ CML, patients in blast crisis, accelerated phase, and in the chronic phase after failure of interferon-alpha

therapy.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as "should," "could," "look forward to," or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Tasigna or regarding potential future revenues from Tasigna or Gleevec. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Tasigna or Gleevec to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Tasigna will be submitted or approved for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that Tasigna or Gleevec will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Tasigna or Gleevec could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; the company's ability to obtain or maintain patent or other proprietary intellectual protection; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; unexpected manufacturing issues; the impact that the foregoing factors could have on the values attributed to the Novartis Group's assets and liabilities as recorded in the Group's consolidated balance sheet, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis

Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG, which provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2010, the Group's continuing operations achieved net sales of USD 50.6 billion, while approximately USD 9.1 billion (USD 8.1 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately 121,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

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