Prescription Copay Assistance for Patients taking Gleevec or Tasigna for Philadelphia chromosome-positive Chronic Myelogenous Leukemia (Ph+ CML)

Novartis Pharmaceuticals Corporation offers a prescription copay assistance program for Ph+ CML (Chronic Myelogenous Leukemia or Chronic Myeloid Leukemia) patients through the My CML Circle Copay Assistance Program (www.mycmlcircle.com).

East Hanover, NJ (PRWEB) February 27, 2009 -- Novartis Pharmaceuticals Corporation is helping patients save money on out of pocket costs for GLEEVEC® (imatinib mesylate) tablets and TASIGNA® (nilotinib) 200-mg capsules prescriptions with My CML Circle. The program provides GLEEVEC and TASIGNA patients being treated for Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) with prescription copay assistance. No matter where patients are in their Ph+ CML treatment journey, My CML Circle Copay Assistance Program is there for them. To participate, visit the My CML Circle Web site at www.mycmlcircle.com or call 1-888-625-2333.

Here's how it works:

- If patients are starting on, or currently taking, GLEEVEC ([http://www.mycmlcircle.com/patient/Gleevec-safety-information.jsp](http://www.mycmlcircle.com/patient/Gleevec-safety-information.jsp)) 400 mg, they can receive up to $15 per prescription refill for 12 refills. This is a total savings of up to $180 of prescription copay assistance.
- If patients are already taking a higher dose of GLEEVEC or their healthcare provider increases their dose of GLEEVEC, they can receive up to $25 per prescription refill for 12 refills. This is a total benefit of up to $300 of prescription copay assistance.
- If patients are currently taking TASIGNA ([http://www.mycmlcircle.com/patient/Tasigna-safety-information.jsp](http://www.mycmlcircle.com/patient/Tasigna-safety-information.jsp)) or should their healthcare provider transition them to TASIGNA, they can receive up to $50 per prescription refill for 12 refills. This is a total savings of up to $600 of prescription copay assistance.

How to Enroll and Activate The Card

To participate in My CML Circle Copay Assistance Program, all patients need to do is call 1-888-625-2333 to request a card. If they already have a copay card from their doctor, just call the number to enroll and activate it. Patients will provide their 12 digit member ID number, in addition to their name and mailing address to enroll in the program and activate the card.

After activating their copay assistance card, present the card--along with their GLEEVEC or TASIGNA prescription--at their retail pharmacy, specialty pharmacy, and/or mail order pharmacy. Patients will then get valuable savings on their next 12 refill copayments for that prescription.

All pharmacies are invited to process the My CML Circle copay card for GLEEVEC and TASIGNA prescriptions, and there are no network requirements.

Patients whose medications are paid for in whole or in part by federal or state healthcare programs may not obtain prescription copay assistance under this program. Examples of these programs are Medicare, Transitional Assistance Program, Tricare, Medicaid, CHAMPUS, VA and State Maternal.
Patients in the state of Massachusetts are not eligible for My CML Circle Copay Assistance Program. My CML Circle Copay Assistance Program is only available in the U.S. and Puerto Rico.

Additional Benefits

In addition to prescription copay assistance, patients will receive a number of important benefits by enrolling in My CML Circle Copay Assistance Program. These benefits include:

- Informative Ph+ CML brochures that cover topics including managing side effects and the best way to communicate with their healthcare provider
- Regular updates about staying on Ph+ CML treatment
- Healthy living tips
- My CML Circle Copay Assistance Program features

Frequently Asked Questions

- What if patients don't have insurance at all; can they still use the My CML Circle Card?

Yes. They can still use the My CML Circle copay card even if they don't have insurance.

- How long does the My CML Circle Prescription Copay Assistance Program run?

The enrollment period ends on 12/31/09. The program expires on 12/31/10. Novartis Pharmaceuticals Corporation reserves the right to rescind, revoke, or amend this program without notice.

- What are the call center hours of operation?

The call center is open Monday through Friday 8 AM to 10 PM EST, Saturday 8 AM to 5 PM EST, and closed on Sundays.

Please see the full list of frequently asked questions for answers to any additional questions.

For more information about My CML Circle Copay Assistance Program, visit the My CML Circle Web site: www.mycmlcircle.com

About Tasigna

Tasigna (nilotinib) capsules is indicated for the treatment of chronic phase and accelerated phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) in adult patients resistant or intolerant to prior therapy that included imatinib. Tasigna has been approved in more than 50 countries. The effectiveness of Tasigna is based on hematologic and cytogenetic response rates. There are no controlled trials demonstrating a clinical benefit, such as improvement in disease-related symptoms or increased survival. Please see Important Safety Information below.

Tasigna important safety information

WARNING: QT PROLONGATION AND SUDDEN DEATHS
TASIGNA prolongs the QT interval. Sudden deaths have been reported in patients receiving nilotinib. TASIGNA should not be used in patients with hypokalemia, hypomagnesemia, or long QT syndrome. Hypokalemia or hypomagnesemia must be corrected prior to TASIGNA administration and should be periodically monitored. Drugs known to prolong the QT interval and strong CYP3A4 inhibitors should be avoided. Patients should avoid food 2 hours before and 1 hour after taking dose. Use with caution in patients with hepatic impairment. ECGs should be obtained to monitor the QTc at baseline, seven days after initiation, and periodically thereafter, as well as following any dose adjustments.

Myelosuppression
Treatment with Tasigna is associated with Grade 3/4 neutropenia, thrombocytopenia, and anemia. Complete blood counts should be performed every 2 weeks for the first 2 months, then monthly thereafter as clinically indicated. Myelosuppression with Tasigna was generally reversible and usually managed by withholding Tasigna temporarily or dose reduction.

QT prolongation
Tasigna prolongs the QT interval. Correct hypokalemia or hypomagnesemia prior to administration and monitor periodically. Avoid drugs known to prolong the QT interval and strong CYP3A4 inhibitors. Use caution in patients with hepatic impairment. Obtain ECGs at baseline, seven days after initiation, and periodically thereafter, as well as following any dose adjustments.

Sudden deaths
There were sudden deaths reported in the safety population and the expanded access program. Ventricular repolarization abnormalities may have contributed to their occurrence.

Elevated serum lipase
Caution is recommended in patients with history of pancreatitis. Check serum lipase periodically.

Liver function abnormality
Serum bilirubin and hepatic transaminases
The use of Tasigna may result in elevations in bilirubin, AST/ALT, and alkaline phosphatase. Check hepatic function tests periodically.

 Electrolyte abnormalities
Tasigna can cause hypophosphatemia, hypokalemia, hyperkalemia, hyponatremia and hypocalcemia. Correct electrolyte abnormalities prior to initiating Tasigna and monitor periodically during therapy.

Hepatic impairment
Metabolism of Tasigna is mainly hepatic. Tasigna has not been investigated in patients with hepatic impairment. Caution is recommended in these patients and QT interval should be monitored closely.

Drug interactions
The concomitant use of QT prolonging drugs and strong inhibitors or inducers of CYP3A4 should be avoided as they may affect serum concentration of Tasigna.

Concomitant strong CYP3A4 inhibitors
The concomitant use of strong CYP3A4 inhibitors should be avoided (including, but not limited to,
ketoconazole, itraconazole, clarithromycin, atazanavir, indinavir, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, voriconazole). Should treatment with any of these agents be required, it is recommended that therapy with Tasigna be interrupted. If interruption of treatment with Tasigna is not possible, patients who require treatment with a drug that prolongs QT or strongly inhibits CYP3A4 should be closely monitored for prolongation of the QT interval, and a dose reduction to ½ the daily dose is recommended (400 mg once daily). If the strong inhibitor is discontinued, a washout period should be allowed before Tasigna is adjusted upward to the indicated dose. Close monitoring for prolongation of the QT interval is indicated for patients who cannot avoid strong CYP3A4 inhibitors. Grapefruit products and other foods that are known to inhibit CYP3A4 should also be avoided.

Concomitant strong CYP3A4 inducers
The concomitant use of strong CYP3A4 inducers should be avoided (including, but not limited to, dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifapentin, phenobarbital). Patients should also refrain from taking St John's Wort. If patients must be co-administered a strong CYP3A4 inducer, the dose of Tasigna may need to be increased, depending on patient tolerability. If the strong inducer is discontinued, the Tasigna dose should be reduced to the indicated dose. Tasigna is a competitive inhibitor of CYP3A4, CYP2C8, CYP2C9, CYP2D6, and UGT1A1. Since warfarin is metabolized by CYP2C9 and CYP3A4, it should be avoided if possible. Tasigna inhibits human P-glycoprotein. If Tasigna is administered with drugs that are substrates of Pgp, increased concentrations of the substrate are likely and caution should be exercised. Tasigna may also induce CYP2B6, CYP2C8, and CYP2C9. Therefore, Tasigna may alter serum concentration of other drugs.

Food effects
Food increases blood levels of Tasigna. Patients should avoid food 2 hours before and 1 hour after taking dose.

Lactose
Since the capsules contain lactose, Tasigna is not recommended for patients with rare hereditary problems of galactose intolerance, severe lactase deficiency, or of glucose-galactose malabsorption.

Pregnancy
Fetal harm can occur when Tasigna is administered to a pregnant woman. Women should be advised not to become pregnant when taking Tasigna.

Adverse reactions
In chronic phase patients, the most commonly reported adverse reactions (>10%) were rash (33%), pruritus (29%), nausea (31%), fatigue (28%), headache (31%), constipation (21%), diarrhea (22%), and vomiting (21%). The most common (>10%) Grade 3/4 adverse reactions were thrombocytopenia (28%), neutropenia (28%), elevated lipase (15%), and hyperglycemia (11%). In accelerated phase patients, the most commonly reported adverse reactions (>10%) were rash (28%), pruritus (20%), and constipation (18%). The most common (>10%) Grade 3/4 adverse reactions were thrombocytopenia (37%), neutropenia (37%), anemia (23%), and elevated lipase (17%). Other serious adverse reactions included pneumonia, febrile neutropenia, leukopenia, intracranial hemorrhage, and pyrexia (Grade 3/4: 2%).

Dose adjustments or modifications
Tasigna may need to be temporarily withheld and/or dose reduced for QT prolongation, hematological toxicities that are not related to underlying leukemia, clinically significant moderate or severe nonhematologic toxicities, laboratory abnormalities, or concomitant use of strong CYP3A4 inhibitors. With concomitant use of strong
CYP3A4 inducers, the dose of Tasigna may need to be increased, depending on patient tolerability.

Other patients in whom Tasigna should be used with caution
Tasigna should not be used during pregnancy. Sexually active female patients should use effective contraception during treatment. Women should not breast feed while taking Tasigna. There are no data to support the use of Tasigna in pediatric patients. Use with caution in patients with hepatic impairment.

About Gleevec
Gleevec (imatinib mesylate) tablets are indicated for the treatment of newly diagnosed adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in the chronic phase. Follow-up is limited to 5 years. Gleevec is also indicated for patients with Ph+ CML in blast crisis (BC), accelerated phase (AP), or in the chronic phase (CP) after failure of interferon-alpha therapy.

Gleevec important safety information (1)
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.

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 severe fluid retention (e.g., pleural effusion, pulmonary edema, and ascites) and superficial edema (1.3%-11%), hemorrhage (1.8%-19%), 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.

Severe congestive heart failure and left ventricular dysfunction have occasionally been reported. Most of the patients with reported cardiac events have had other co-morbidities 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.

Dose adjustments may be necessary due to hepatotoxicity, other nonhematologic adverse reactions, or hematologic adverse reactions. Therapy with Gleevec was discontinued for drug-related adverse reactions in 2.4% to 5% of patients. 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).

A 25% decrease in the recommended dose should be used for patients with severe hepatic impairment. Patients with moderate renal impairment (CrCL = 20-39 mL/min) should receive a 50% decrease in the recommended starting dose and 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.

Patients should be weighed and monitored regularly for signs and symptoms of edema, which can be serious or life-threatening. There have also been reports, including fatalities, of cardiac tamponade, cerebral edema, acute respiratory failure, and GI perforation.

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Bullous dermatologic reactions (e.g., erythema multiforme and Stevens-Johnson syndrome) have also been reported. In some cases, the reaction recurred upon re-challenge. Several post marketing 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.

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

Gleevec is metabolized by the CYP3A4 isoenzyme and is an inhibitor of CYP3A4, CYP2D6, and CYP2C9. Dosage of Gleevec should increase by at least 50%, and clinical response should be carefully monitored, in patients receiving Gleevec with a potent CYP3A4 inducer such as rifampin or phenytoin. Examples of commonly used drugs that may significantly interact with Gleevec include ketoconazole, acetaminophen, warfarin, erythromycin, and phenytoin. (Please see full Prescribing Information for other potential drug interactions.)

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

Common side effects of Gleevec tablets
The majority of 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%), muscle cramps (28%-62%), vomiting (23%-58%), diarrhea (43%-57%), musculoskeletal pain (38%-49%), and rash and related terms (36%-47%)*†.

Supportive care may help management of some mild-to-moderate adverse reactions so that the prescribed dose can be maintained whenever possible. However, in some cases, either a dose reduction or interruption of treatment with Gleevec may be necessary.

Gleevec tablets should be taken with food and a large glass of water to minimize GI irritation. Gleevec tablets should not be taken with grapefruit juice and other foods known to inhibit CYP3A4.

Patients should be informed to take Gleevec exactly as prescribed, 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.

*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.

†For more detailed study information please see full Prescribing Information.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by terminology such as "suggesting," "may," "commitment," or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Tasigna, the long-term impact of a patient's use of Tasigna or regarding potential future revenues from Tasigna. 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 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 approved for any additional indications or labeling in any market. Nor can there be any guarantee regarding the long-term impact of a patient's use of Tasigna. Neither can there be any guarantee that Tasigna will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Tasigna 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 property protection; competition in general; government, industry and general public pricing pressures; 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 Pharmaceuticals Corporation

Novartis Pharmaceuticals Corporation researches, develops, manufactures and markets leading innovative prescription drugs used to treat a number of diseases and conditions, including those in the cardiovascular, metabolic, cancer, organ transplantation, central nervous system, dermatological, GI and respiratory areas. The Company's mission is to improve people's lives by pioneering novel healthcare solutions.

Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG, which provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2007, the Group's continuing operations (excluding divestments in 2007) achieved net sales of USD 38.1 billion and net income of USD 6.5 billion. Approximately USD 6.4 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 97,000 full-time associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

For more information


Reference


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