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TASIGNA for adult patients with newly diagnosed Ph+ CML in chronic phase

TASIGNA DOUBLED THE MAJOR MOLECULAR RESPONSE (MMR) RATE OF IMATINIB AT 12 MONTHS¹

2 TASIGNA PATIENTS (<1%) PROGRESSED TO ACCELERATED PHASE OR BLAST CRISIS* (AP/BC) VS 17 IMATINIB PATIENTS (6%)¹

**MMR rates at 12 months¹**

<table>
<thead>
<tr>
<th></th>
<th>TASIGNA 300 mg bid (n=282)</th>
<th>Imatinib 400 mg qd (n=283)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients (%)</td>
<td>44% (95% CI: 38.4%-50.3%)</td>
<td>22% (95% CI: 17.6%-27.6%)</td>
</tr>
</tbody>
</table>

**Progression to AP/BC¹**

<table>
<thead>
<tr>
<th></th>
<th>TASIGNA 300 mg bid (n=282)</th>
<th>Imatinib 400 mg qd (n=283)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>n=2 (0.7%)</td>
<td>n=17 (6%)</td>
</tr>
</tbody>
</table>

**ENESTnd study design:** A randomized, controlled, open-label, multicenter Phase III trial of 846 patients with newly diagnosed Ph+ CML in chronic phase. Patients were randomized to receive either TASIGNA 400 mg bid (n=281), TASIGNA 300 mg bid (n=282), or imatinib 400 mg qd (n=283). The daily dose of imatinib could be escalated to 800 mg (400 mg bid), but no dose escalation was permitted with TASIGNA. A centralized laboratory was used for PCR testing. The primary end point was MMR at 12 months. MMR was defined as ≤0.1% BCR-ABL/ABL by international scale measured by RQ-PCR, which corresponds to a ≥3-log reduction of BCR-ABL transcripts from standardized baseline.¹ ²

**The distinct safety profile of TASIGNA supports its use in adult patients with newly diagnosed Ph+ CML in chronic phase¹**

- Discontinuation for adverse events regardless of causality was observed in 7% of patients
- In ENESTnd, most side effects associated with TASIGNA did not lead to discontinuation in the first year

*Definition includes patients with clonal evolution and CML-related death. Time was censored at last assessment on treatment for patients without events.¹ ³

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080  ©2011 Novartis
Printed in USA  12/10 AM7-100030
TASIGNA (nilotinib) is indicated for the treatment of adult patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. The effectiveness of TASIGNA is based on major molecular response and cytogenetic response rates. The study is ongoing and further data will be required to determine long-term outcome.

**Boxed WARNING and Additional Important Safety Information**

TASIGNA prolongs the QT interval. ECGs should be obtained to monitor the QTc at baseline, 7 days after initiation, and periodically thereafter, as well as following any dose adjustments. Sudden deaths have been reported in patients receiving TASIGNA. 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. 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. The concomitant use of strong CYP3A4 inducers should be avoided (including, but not limited to, dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifapentin, and phenobarbital). Patients should avoid food 2 hours before and 1 hour after taking dose. A dose reduction is recommended in patients with hepatic impairment as nilotinib exposure is increased in patients with impaired hepatic function.

- Treatment with TASIGNA can cause Grade 3/4 thrombocytopenia, neutropenia, and anemia
- 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 exposure of nilotinib 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
- In chronic phase patients, the most commonly reported nonhematologic adverse drug reactions (>10%) were rash, pruritus, nausea, fatigue, myalgia, headache, constipation, diarrhea, and vomiting
- In accelerated phase patients, the most commonly reported nonhematologic adverse drug reactions (>10%) were rash, pruritus, and fatigue

**Greater efficacy vs imatinib on every end point at 12 months**

References:

Please see brief summary of Prescribing Information on the following pages.
WARNING: QT PROLONGATION AND SUDDEN DEATHS
Tasigna prolongs the QT interval (5.2). Sudden deaths have been reported in patients receiving nilotinib (5.3). Tasigna should not be used in patients with hypokalemia, hypomagnesemia, or long QT syndrome (4). Hypokalemia or hypomagnesemia must be corrected prior to Tasigna administration and should be periodically monitored (5.2). Drugs known to prolong the QT interval and strong CYP3A4 inhibitors should be avoided (5.7). Patients should avoid food 2 hours before and 1 hour after taking dose (5.8). A dose reduction is recommended in patients with hepatic impairment (5.9). ECGs should be obtained to monitor the QTc at baseline, seven days after initiation, and periodically thereafter, as well as following any dose adjustments. (5.2, 5.3, 5.6, 5.12)

1 INDICATIONS AND USAGE
1.1 Newly Diagnosed Ph+ CML-CP
Tasigna (nilotinib) is indicated for the treatment of adult patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. The effectiveness of Tasigna is based on major molecular response and cytogenetic response rates [see Clinical Studies (14.1) in the full prescribing information]. The study is ongoing and further data will be required to determine long-term outcome.

1.2 Resistant or Intolerant Ph+ CML-CP and CML-AP
Tasigna is indicated for the treatment of chronic phase and accelerated phase Philadelphia chromosome positive chronic myelogenous leukemia (Ph+ CML) in adult patients resistant or intolerant to prior therapy that included imatinib. The effectiveness of Tasigna is based on hematologic and cytogenetic response rates [see Clinical Studies (14.2) in the full prescribing information].

2 DOSAGE AND ADMINISTRATION
2.1 Recommended Dosing
Tasigna should be taken twice daily at approximately 12 hour intervals and must not be taken with food. The capsules should be swallowed whole with water. No food should be consumed for at least 2 hours before the dose is taken and no food should be consumed for at least one hour after the dose is taken [see Boxed Warning, Warnings and Precautions (5.8), Clinical Pharmacology (12.3) in the full prescribing information]. For patients who are unable to swallow capsules, the contents of each capsule may be dispersed in one teaspoon of applesauce (puréed apple). The mixture should be taken immediately (within 15 minutes) and should not be stored for future use [see Clinical Pharmacology (12.3) in the full prescribing information].

Tasigna may be given in combination with hematopoietic growth factors such as erythropoietin or G-CSF if clinically indicated. Tasigna may be given with hydroxyurea or anagrelide if clinically indicated.

Newly Diagnosed Ph+ CML-CP
The recommended dose of Tasigna is 300 mg orally twice daily [see Clinical Pharmacology (12.3) in the full prescribing information].

Resistant or Intolerant Ph+ CML-CP and CML-AP
The recommended dose of Tasigna (nilotinib) is 400 mg orally twice daily [see Clinical Pharmacology (12.3) in the full prescribing information].

2.2 Dose Adjustments or Modifications
QT interval prolongation:

Table 1: Dose Adjustments for QT Prolongation

| ECGs with a QTc >480 msec | 1. Withhold Tasigna, and perform an analysis of serum potassium and magnesium, and if below lower limit of normal, correct with supplements to within normal limits. Concomitant medication use must be reviewed. |
| 2. Resume within 2 weeks at prior dose if QTcF returns to <450 msec and to within 20 msec of baseline. |
| 3. If QTcF is between 450 msec and 480 msec after 2 weeks, reduce the dose to 400 mg once daily. |
| 4. If, following dose-reduction to 400 mg once daily, QTcF returns to >480 msec, Tasigna should be discontinued. |
| 5. An ECG should be repeated approximately 7 days after any dose adjustment. |

Myelosuppression
Tasigna may need to be withheld and/or dose reduced for hematological toxicities (neutropenia, thrombocytopenia) that are not related to underlying leukemia (Table 2).

Table 2: Dose Adjustments for Neutropenia and Thrombocytopenia

| Newly diagnosed Ph+ CML in chronic phase at 300 mg twice daily | Resist or intolerant Ph+ CML in chronic phase or accelerated phase at 400 mg twice daily |
| ANC* <1.0 x 10^9/L and/or platelet counts <50 x 10^9/L | 1. Stop Tasigna, and monitor blood counts |
| 2. Resume within 2 weeks at prior dose if ANC >1.0 x 10^9/L and platelets >50 x 10^9/L |
| 3. If blood counts remain low for >2 weeks, reduce the dose to 400 mg once daily |

Table 3: Dose Adjustments for Selected Non-hematologic Laboratory Abnormalities

| Elevated serum lipase or amylase ≥ Grade 3 | 1. Withhold Tasigna, and monitor serum lipase or amylase |
| 2. Resume treatment at 400 mg once daily if serum lipase or amylase return to ≤ Grade 1 |
| Elevated bilirubin ≥ Grade 3 | 1. Withhold Tasigna, and monitor bilirubin |
| 2. Resume treatment at 400 mg once daily if bilirubin return to ≤ Grade 1 |
| Elevated hepatic transaminases ≥ Grade 3 | 1. Withhold Tasigna, and monitor hepatic transaminases |
| 2. Resume treatment at 400 mg once daily if hepatic transaminases return to ≤ Grade 1 |

Other Non-hematologic Toxicities
If other clinically significant moderate or severe non-hematologic toxicity develops, withhold dosing, and resume at 400 mg once daily when the toxicity has resolved. If clinically appropriate, escalation of the dose back to 300 mg (newly diagnosed Ph+ CML-CP) or 400 mg (resistant or intolerant Ph+ CML-CP and CML-AP) twice daily should be considered. For Grade 3 to 4 lipase elevations, dosing should be withheld, and may be resumed at 400 mg once daily. Test serum lipase levels monthly or as clinically indicated. For Grade 3 to 4 bilirubin or hepatic transaminase elevations, dosing should be withheld, and may be resumed at 400 mg once daily. Test bilirubin and hepatic transaminases levels monthly or as clinically indicated [see Warnings and Precautions (5.4, 5.5), Use in Specific Populations (8.7) in the full prescribing information].

Hepatic Impairment
If possible, consider alternative therapies. If Tasigna must be administered to patients with hepatic impairment, consider the following dose reduction:

Table 4: Dose Adjustments for Hepatic Impairment (At Baseline)

| Newly diagnosed Ph+ CML in chronic phase at 300 mg twice daily | Mild, Moderate or Severe* |
| 1. An initial dosing regimen of 200 mg twice daily followed by dose escalation to 300 mg twice daily based on tolerability |
| Resistant or intolerant Ph+ CML in chronic phase or accelerated phase at 400 mg twice daily | Mild or Moderate* |
| 1. An initial dosing regimen of 300 mg twice daily followed by dose escalation to 400 mg twice daily based on tolerability |

*Mild = mild hepatic impairment (Child-Pugh Class A); Moderate = moderate hepatic impairment (Child-Pugh Class B); Severe = severe hepatic impairment (Child-Pugh Class C) [see Boxed Warning, Warnings and Precautions (5.9), Use in Specific Populations (8.7) in the full prescribing information].

Concomitant Strong CYP3A4 Inhibitors
Avoid the concomitant use of strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin, atazanavir, saquinavir, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, voriconazole). Grapefruit products may also increase serum concentrations of nilotinib and should be avoided. Should treatment with any of these agents be required, it is recommended that therapy with Tasigna be interrupted. If patients must be co-administered a strong CYP3A4 inhibitor, based on pharmacokinetic studies, consider a

Tasigna® (nilotinib) Capsules
Initial U.S. Approval: 2007

BRIEF SUMMARY: Please see package insert for full prescribing information.

Tasigna® (nilotinib) Capsules
BRIEF SUMMARY: Please see package insert for full prescribing information.

Initial U.S. Approval: 2007
dose reduction to 300 mg once daily in patients with resistant or intolerable Ph+ CML or to 200 mg once daily in patients with newly diagnosed Ph+ CML-CP. However, there is no clinical data on treatment in patients receiving strong CYP3A4 inhibitors. If the strong inhibitor is discontinued, a washout period should be allowed before the Tasigna dose 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 [see Boxed Warning, Warnings and Precautions (5.2, 5.7), Drug Interactions (7.2) in the full prescribing information].

Concomitant Strong CYP3A4 Inducers Avoid the concomitant use of strong CYP3A4 inducers (e.g., dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital). Patients should also refrain from taking St. John’s Wort. Based on the non-linear pharmacokinetic profile of nilotinib, increasing the dose of Tasigna when co-administered with such agents is unlikely to compensate for the loss of exposure [see Drug Interactions (7.2) in the full prescribing information].

3 DOSAGE FORMS AND STRENGTHS

200 mg light yellow opaque hard gelatin capsules with a red axial imprint "NVR/TKI".

4 CONTRAINDICATIONS

Do not use in patients with hypokalemia, hypomagnesemia, or long QT syndrome [see Boxed Warning].

5 WARNINGS AND PRECAUTIONS

5.1 Myelosuppression

Treatment with Tasigna can cause Grade 3/4 thrombocytopenia, neutropenia, and anemia. Perform complete blood counts every two weeks for the first 2 months and then monthly thereafter, or as clinically indicated. Myelosuppression was generally reversible and usually managed by withholding Tasigna temporarily or dose reduction [see Dosage and Administration (2.2)].

5.2 QT Prolongation

Tasigna has been shown to prolong cardiac ventricular repolarization as measured by the QT interval on the surface ECG in a concentration-dependent manner [see Adverse Reactions (8.1), Clinical Pharmacology (12.4) in the full prescribing information]. Prolongation of the QT interval can result in a type of ventricular tachycardia called torsade de pointes, which may result in syncope, seizure, and/or death. ECGs should be performed at baseline, seven days after initiation, periodically as clinically indicated and following dose adjustments [see Warnings and Precautions (5.12)].

Tasigna should not be used in patients who have hypokalemia, hypomagnesemia or long QT syndrome. Hypokalemia or hypomagnesemia must be corrected prior to initiating Tasigna and these electrolytes should be monitored periodically during therapy [see Warnings and Precautions (5.2)].

Significant prolongation of the QT interval may occur when Tasigna is inappropriately taken with food or strong CYP3A4 inhibitors and/or medicinal products with a known potential to prolong QT. Therefore, co-administration with food must be avoided and concomitant use with strong CYP3A4 inhibitors and/or medicinal products with a known potential to prolong QT should be avoided [see Warnings and Precautions (5.2, 5.6)].

The presence of hypokalemia and hypomagnesemia may further enhance this effect [see Warnings and Precautions (5.6, 5.12)].

5.3 Sudden Deaths

Sudden deaths have been reported in patients with CML treated with nilotinib in clinical studies (n=5,661; 0.3%). The relative early occurrence of some of these deaths relative to the initiation of nilotinib suggests the possibility that ventricular repolarization abnormalities may have contributed to their occurrence.

5.4 Elevated Serum Lipase

The use of Tasigna can cause increases in serum lipase. Caution is recommended in patients with a previous history of pancreatitis. If lipase elevations are accompanied by abdominal symptoms, interrupt dosing and consider appropriate diagnostics to exclude pancreatitis. Test serum lipase levels monthly or as clinically indicated.

5.5 Hepatotoxicity

The use of Tasigna may result in elevations in bilirubin, AST/ALT, and alkaline phosphatase. Hepatic function tests should be checked monthly or as clinically indicated [see Warnings and Precautions (5.12)].

5.6 Electrolyte Abnormalities

The use of Tasigna can cause hypophosphatemia, hypokalemia, hyperkalemia, hypocalcemia, and hypernatremia. Electrolyte abnormalities must be corrected prior to initiating Tasigna and these electrolytes should be monitored periodically during therapy [see Warnings and Precautions (5.12)].

5.7 Drug Interactions

The administration of Tasigna with agents that are strong CYP3A4 inhibitors or anti-arrhythmic drugs (including, but not limited to amiodarone, disopyramide, procainamide, quinidine and sotalol) and other drugs that may prolong QT interval (including, but not limited to chloroquine, clarithromycin, haloperidol, methadone, moxifloxacin and pimozide) should be avoided. 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 [see Boxed Warning, Dosage and Administration (2.2), Drug Interactions (7.2) in the full prescribing information].

5.8 Food Effects

The bioavailability of nilotinib is increased with food. Tasigna must not be taken with food. No food should be taken at least 2 hours before and at least one hour after the dose is taken. Grapefruit products and other foods that are known to inhibit CYP3A4 should be avoided [see Boxed Warning, Drug Interactions (7.2) and Clinical Pharmacology (12.3) in the full prescribing information].

5.9 Hepatic Impairment

Nilotinib exposure is increased in patients with impaired hepatic function. A lower starting dose is recommended for patients with mild to severe hepatic impairment (at baseline) and QT interval should be monitored closely [see Boxed Warning, Dosage and Administration (2.2) and Use in Specific Populations (8.7) in the full prescribing information].

5.10 Total Gastrectomy

The exposure of nilotinib is reduced in patients with total gastrectomy. More frequent follow-up of these patients should be considered. Dose increase or alternative therapy may be considered in patients with total gastrectomy [see Clinical Pharmacology (12.3) in the full prescribing information].

5.11 Lactose

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.

5.12 Monitoring Laboratory Tests

Complete blood counts should be performed every two weeks for the first two months and then monthly thereafter. Chemistry panels, including the lipid profile, should be checked periodically. ECGs should be obtained at baseline, seven days after initiation and periodically thereafter, as well as following dose adjustments [see Warnings and Precautions (5.2)]. Laboratory monitoring for patients receiving Tasigna may need to be performed more or less frequently at the physician’s discretion.

5.13 Use in Pregnancy

There are no adequate and well controlled studies of Tasigna in pregnant women. However, Tasigna may cause fetal harm when administered to a pregnant woman. Nilotinib caused embryo-fetal toxicities in animals at maternal exposures that were lower than the expected human exposure at the recommended doses of nilotinib. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus. Women of child-bearing potential should avoid becoming pregnant while taking Tasigna [see Use in Specific Populations (8.1) in the full prescribing information].

6 ADVERSE REACTIONS

The following serious adverse reactions can occur with Tasigna and are discussed in greater detail in other sections of the package insert [see Boxed Warning, Warnings and Precautions (5.1)].

Myelosuppression [see Warnings and Precautions (5.1)]

QT prolongation [see Boxed Warning, Warnings and Precautions (5.2)]

Sudden deaths [see Boxed Warning, Warnings and Precautions (5.3)]

Elevated serum lipase [see Warnings and Precautions (5.4)]

Hepatotoxicity [see Warnings and Precautions (5.5)]

Electrolyte abnormalities [see Boxed Warning, Warnings and Precautions (5.6)]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Newly diagnosed Ph+ CML-CP

The data below reflect exposure to Tasigna from a randomized trial in newly diagnosed patients with Ph+ CML in chronic phase treated at the recommended dose of 300 mg twice daily (n=279). The median time on treatment in the nilotinib 300 mg twice daily group was 18.6 months. The median actual dose intensity was 593 mg/day in the nilotinib 300 mg twice daily group. The most common (>10%) non-hematologic adverse drug reactions were rash, pruritus, headache, nausea, fatigue and myalgia. Upper abdominal pain, alopecia, constipation, diarrhea, dry skin, muscle spasms, arthralgia, abdominal pain, peripheral edema and asthenia were observed less commonly.
(≤10% and >5%) and have been of mild to moderate severity, manageable and generally did not require dose reduction. Pleural and pericardial effusions occurred in 1% of patients. Gastrointestinal hemorrhage was reported in 0.4% of patients.

Increase in QTcF >60 msec from baseline was observed in 1 patient (0.4%) in the 300 mg twice daily treatment group. No patient had an absolute QTcF of >500 msec.

The most common hematologic adverse drug reactions (all grades) were myelosuppression including: thrombocytopenia (17%), neutropenia (15%) and anemia (7%) (see Table 7 for Grade 3/4 laboratory abnormalities).

Discontinuation due to adverse events regardless of causality was observed in 7% of patients.

**Resistant or intolerant Ph+ CML-CP and CML-AP**

In the single open-label multicenter clinical trial, a total of 458 patients with Ph+ CML-CP and CML-AP resistant to or intolerant to at least one prior therapy including imatinib were treated (CML-CP = 321; CML-AP = 137) at the recommended dose of 400 mg twice daily.

The median duration of exposure in days for CML-CP and CML-AP patients was 561 (range 1-1096) and 264 (range 2-1160), respectively. The median dose intensity for patients with CML-CP and CML-AP is 789 mg/day (range 151-1110) and 780 mg/day (range 150-1149), respectively and corresponded to the planned 400 mg twice daily dosing.

The median cumulative duration in days of dose interruptions for the CML-CP patients was 20 (range 1-346), and the median duration in days of dose interruptions for the CML-AP patients was 23 (range 1-234).

In patients with CML-CP, the most commonly reported non-hematologic adverse drug reactions (≥10%) were rash, pruritus, nausea, fatigue, headache, constipation, diarrhea, vomiting and myalgia. The common serious drug-related adverse reactions (≥1%) were thrombocytopenia, neutropenia and anemia.

In patients with CML-AP, the most commonly reported non-hematologic adverse drug reactions (≥10%) were rash, pruritus and fatigue. The common serious adverse drug reactions (>1%) were thrombocytopenia, neutropenia, febrile neutropenia, pneumonia, leukopenia, intracranial hemorrhage, elevated lipase and pyrexia.

Sudden deaths and QT prolongation were reported. The maximum mean QTcF change from baseline at steady-state was 10 msec. Increase in QTcF >60 msec from baseline was observed in 4.1% of the patients and QTcF change from baseline at steady-state was 10 msec. Increase in QTcF >60 msec from baseline was observed in 1 patient (0.4%)

Discontinuation due to drug-related adverse reactions was observed in 16% of CML-CP and 10% of CML-AP patients.

### Most Frequently Reported Adverse Reactions

Tables 5 and 6 show the percentage of patients experiencing treatment-emergent adverse reactions (excluding laboratory abnormalities) regardless of relationship to study drug. Adverse reactions reported in greater than 10% of patients who received at least one dose of Tasigna are listed.

#### Table 5: Most Frequently Reported Non-hematologic Adverse Reactions (Regardless of Relationship to Study Drug) in Patients with Newly Diagnosed Ph+ CML-CP (≥10% in Tasigna 300 mg twice daily or Gleevec 400 mg once daily groups)

<table>
<thead>
<tr>
<th>Body System and Preferred Term</th>
<th>All Grades (%)</th>
<th>CTC Grades 3 / 4 (%)</th>
</tr>
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<tbody>
<tr>
<td><strong>Skin and subcutaneous tissue disorders</strong></td>
<td></td>
<td></td>
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<tr>
<td>Rash</td>
<td>36</td>
<td>16</td>
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<tr>
<td>Pruritus</td>
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<td>7</td>
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<tr>
<td>Alopecia</td>
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<td>5</td>
</tr>
<tr>
<td><strong>Gastro-intestinal disorders</strong></td>
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</tr>
<tr>
<td>Nausea</td>
<td>19</td>
<td>38</td>
</tr>
<tr>
<td>Constipation</td>
<td>15</td>
<td>4</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>14</td>
<td>37</td>
</tr>
<tr>
<td>Vomiting</td>
<td>9</td>
<td>22</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>15</td>
<td>10</td>
</tr>
<tr>
<td><strong>Nervous system disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>28</td>
<td>16</td>
</tr>
</tbody>
</table>

#### Table 6: Most Frequently Reported Non-hematologic Adverse Reactions in Patients with Resistant or Intolerant Ph+ CML Receiving Tasigna 400 mg Twice Daily (Regardless of Relationship to Study Drug) (>10% in any Group)

<table>
<thead>
<tr>
<th>Body System and Preferred Term</th>
<th>All Grades (%)</th>
<th>CTC Grades 3 / 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Skin and subcutaneous tissue disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rash</td>
<td>36</td>
<td>2</td>
</tr>
<tr>
<td>Pruritus</td>
<td>32</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Night sweat</td>
<td>12</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Alopecia</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td><strong>Gastro-intestinal disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>37</td>
<td>2</td>
</tr>
<tr>
<td>Constipation</td>
<td>26</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>13</td>
<td>3</td>
</tr>
<tr>
<td>Vomiting</td>
<td>16</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>15</td>
<td>2</td>
</tr>
<tr>
<td>Abdominal pain upper</td>
<td>14</td>
<td>1</td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>10</td>
<td>&lt;1</td>
</tr>
<tr>
<td><strong>Nervous system disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>35</td>
<td>2</td>
</tr>
</tbody>
</table>

(continued)
Table 6: Most Frequently Reported Non-hematologic Adverse Reactions in Patients with Resistant or Intolerant Ph+ CML Receiving Tasigna 400 mg Twice Daily (Regardless of Relationship to Study Drug) (>10% in any Group)\(^a\)

<table>
<thead>
<tr>
<th>Body System and Preferred Term</th>
<th>CML-CP</th>
<th>CML-AP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Grades (%)</td>
<td>CTC Grades(^b) N=321</td>
</tr>
<tr>
<td>Musculo-skeletal and connective tissue disorders</td>
<td>Arthralgia</td>
<td>26</td>
</tr>
<tr>
<td></td>
<td>Muscle spasms</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Bone pain</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>Pain in extremity</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>Back pain</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Musculo-skeletal pain</td>
<td>11</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>Cough</td>
<td>27</td>
</tr>
<tr>
<td></td>
<td>Dyspnea</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>Oropharyngeal pain</td>
<td>11</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td>Nasopharyngitis</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td>Upper respiratory tract infection</td>
<td>12</td>
</tr>
<tr>
<td>Metabolism and nutritional disorders</td>
<td>Anorexia</td>
<td>12</td>
</tr>
<tr>
<td>Psychiatric disorders</td>
<td>Insomnia</td>
<td>12</td>
</tr>
<tr>
<td>Vascular disorders</td>
<td>Hypertension</td>
<td>10</td>
</tr>
</tbody>
</table>

\(^a\)Excluding laboratory abnormalities

\(^b\)NCI Common Terminology Criteria for Adverse Events, Version 3.0

Table 7: Percent Incidence of Clinically Relevant Grade 3/4 Laboratory Abnormalities

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Newly Diagnosed Ph+ CML-CP</th>
<th>Resistant or Intolerant Ph+</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TASIGNA 300 mg twice daily</td>
<td>GLEEVEC 400 mg once daily</td>
</tr>
<tr>
<td></td>
<td>N=279 (%)</td>
<td>N=280 (%)</td>
</tr>
<tr>
<td>Biochemistry Parameters</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypocalcemia</td>
<td>&lt;1</td>
<td>0</td>
</tr>
<tr>
<td>Elevated alkaline phosphatase</td>
<td>0</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Elevated creatinine</td>
<td>0</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>

*NCI Common Terminology Criteria for Adverse Events, version 3.0

6.2 Additional Data from Clinical Trials

The following adverse drug reactions were reported in patients in the Tasigna clinical studies at the recommended doses. These adverse drug reactions are ranked under a heading of frequency, the most frequent first using the following convention: common (1%-10%), uncommon (0.1%-1%), and unknown frequency (single events). For adverse drug reactions listed under “Investigations”, very common events (≥10%), which were not included in Tables 5 and 6, are also reported. These adverse reactions are included based on clinical relevance and ranked in order of decreasing seriousness within each category.


Neoplasms Benign, Malignant and Unspecified: Common: Skin papilloma. Unknown frequency: papilloma.


Metabolism and Nutrition Disorders: Common: electrolyte imbalance (including hypomagnesemia, hyperkalemia, hypocalcemia, hyperglycemia, hyperlipidemia). Unknown frequency: dehydration, increased appetite, increased appetite, unknown frequency: hyperuricemia, goit, hyg, hyperlipidemia, dyslipidemia.


Eye Disorders: Common: eye hemorrhage, periorbital edema, eye pruritus, conjunctivitis, dry eye. Uncommon: vision impairment, vision blurred, visual acuity reduced, photophobia, eye irritation. Unknown frequency: papilloedema, diplopia, photophobia, eye swelling, blepharitis, eye pain, choriorétinopathy, conjunctival hemorrhage, conjunctivitis allergic, conjunctival hyperemia, ocular hyperemia, ocular surface disease, scleral hyperemia.

Ear and Labyrinth Disorders: Common: vertigo. Unknown frequency: hearing impaired, ear pain, tinnitus.

Cardiac Disorders: Common: angina pectoris, arrhythmia (including atrioventricular block, cardiac flutter, extrasystoles, atrial fibrillation, bradycardia), palpitations, electrocardiogram QT prolonged. Uncommon: cardiac failure, pericardial effusion, coronary artery disease, cyanosis, cardiac murmur. Unknown frequency: myocardial infarction, ventricular dysfunction, pericarditis, ejection fraction decrease.


Skin and Subcutaneous Tissue Disorders: Common: night sweats, eczema, urticaria, erythema, hyperhidrosis, contusion, acne, dermatitis, dry skin. Uncommon: exfoliative rash, drug eruption, pain of skin, ecchymosis, swelling of face. Unknown frequency: erythema nodosum, skin ulcer, palmar-plantar erythrodysaesthesia syndrome, petechiae, photosensitivity, blister, dermal cyst, sebaceous hyperplasia, skin atrophy, skin discoloration, skin exfoliation, skin hyperpigmentation, skin hypertrophy.


Investigations: Common: blood amylase increased, gamma-glutamyltransferase increased, blood creatinine phosphokinase increased, weight decreased, weight increased. Uncommon: hemoglobin decreased, blood lactate dehydrogenase increased, blood urea increased. Unknown frequency: blood insulin increased, very low density lipoprotein increased, blood parathyroid hormone increased, blood pressure increased.

6.3 Postmarketing Experience

The following additional adverse reactions have been reported during post approval use of Tasigna. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Cases of tumor lysis syndrome have been reported in Tasigna treated patients with resistant or intolerant CML. Malignant disease progression, high WBC counts and/or dehydration were present in the majority of these cases.

10 OVERDOSAGE

Overdose with nilotinib has been reported, where an unspecified number of Tasigna capsules were ingested in combination with alcohol and other drugs. Events included neutropenia, vomiting, and drowsiness. In the event of overdose, the patient should be observed and appropriate supportive treatment given.

16 HOW SUPPLIED/STORAGE AND HANDLING

Tasigna (nilotinib) 150 mg capsules are red opaque hard gelatin capsules, size 1 with black axial imprint “NVR/BCR”. Tasigna (nilotinib) 200 mg capsules are light yellow opaque hard gelatin capsules, size 0 with the red axial imprint “NVR/TKI.” Tasigna capsules are supplied in blister packs.

150 mg
Carton of 4 blister packs of (4x28) .......................... NDC 0078-0592-87
Blisters of 28 capsules ........................................... NDC 0078-0592-51

200 mg
Carton of 4 blister packs of (4x28) .......................... NDC 0078-0526-87
Blisters of 28 capsules ........................................... NDC 0078-0526-51

Each blister pack contains one folded blister card of 28 capsules each, for dosing two in the morning and two in the evening at 12 hour intervals over a 7 day period.

Tasigna (nilotinib) capsules should be stored at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) [see USP Controlled Room Temperature].

T2010-104
Manufactured by: Novartis Pharma Stein AG
Stein, Switzerland
Distributed by: Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936
© Novartis
Check out
ASH’s VIDEO LIBRARY
for Useful Teaching Tools

ASH offers a number of FREE videos that are perfect for students. ASH’s video library includes films on a variety of topics including:

- Cancer Cells vs. Healthy Cells
- Hereditary Spherocytosis
- How Lymphoma Develops
- How a Clot Becomes a Pulmonary Embolism
- The Components of Blood
- The Problem With Sickled Cells
- The Role of Proteins in Blood Clotting
- The Role of Red Blood Cells in Anemia
- Von Willebrand Factor and ADAMTS13

Additionally, this library includes short videos about patients dealing with various hematologic disorders, excerpted from the film “Blood Detectives.”

www.hematology.org/videolibrary
Some see inhibitors as a lifetime of tests, bleeds, and complications.

Novo Nordisk helps them see a lifetime of possibilities.

We help provide the financial, educational, and community support he needs.

Through financial, educational, and community support programs offered by Novo Nordisk, people with hemophilia A or B with inhibitors have been able to live more normal lives.

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Hematology Web Focus is a new publication designed for clinicians. This resource highlights article content published by prominent experts in the field and selects the articles that enhances the clinicians’ ability to effectively treat diseases.

The first focus topic, Multiple Myeloma, provides an overview and the most timely and relevant articles in the following areas:

- Asymptomatic Myeloma/MGUS
- Induction Therapy
- Transplantation
- Relapsed/Refractory Disease
- Complete Multiple Myeloma Reading List

Future topics will include Acute Lymphocytic Leukemia, Chronic Lymphocytic Leukemia, and Von Willebrand Disease

Free to ASH Members and Blood subscribers, visit www.hematologywebfocus.org for more information and to begin using this resource today. If you have any questions, please call 866-828-1231. International callers dial +1-202-776-0544.

Not an ASH Member or subscriber of Blood? Create an account for a free trial subscription to Hematology Web Focus at www.hematologywebfocus.org

A randomized, double-blind, placebo-controlled, multicenter phase III trial to evaluate the efficacy and safety of the CD30-targeted antibody-drug conjugate brentuximab vedotin (SGN-35) and best supportive care (BSC) compared with placebo and BSC in treating residual Hodgkin lymphoma following autologous stem cell transplant (ASCT).

The primary end point is progression-free survival; secondary end points include overall survival, safety and tolerability.

**Key Inclusion Criteria:**
- Histologically confirmed HL
- ASCT after relapsed/refractory HL
- ECOG performance status of 0 or 1
- Adequate organ function

For full inclusion and exclusion criteria, please visit www.aetheratrial.com, contact Seattle Genetics at 866-333-7436 (US only) or e-mail clinicaltrials@seagen.com.

*Antibody-drug conjugate.

SGN-35 is an investigational drug; its efficacy and safety have not been established. There is no guarantee that SGN-35 will become commercially available.
With CancerCare, the difference comes from:

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- Free counseling
- Education and practical help
- Up-to-date information
- CancerCare for Kids®

For needs that go beyond medical care, refer your patients and their loved ones to CancerCare. CancerCare’s free services help people cope with the emotional and practical concerns arising from a cancer diagnosis and are integral to the standard of care for all cancer patients, as recommended by the Institute of Medicine.

1-800-813-HOPE (4673)

www.cancercare.org
A multicenter phase I trial to assess the safety profile of the CD30-directed antibody-drug conjugate brentuximab vedotin (SGN-35) in treatment-naïve systemic ALCL patients when administered sequentially and concurrently with multi-agent chemotherapy.

Key Inclusion Criteria

- Treatment-naïve systemic ALCL patients
- ALK negative disease, any IPI score
- ALK positive disease, IPI score ≥2
- Histologically confirmed diagnosis of CD30-positive systemic ALCL
- ECOG performance status of 0 to 2
- Adequate organ function

For key inclusion and exclusion criteria, please visit www.clinicaltrials.gov (NCT01309789); contact Seattle Genetics at 866-333-7436 (US only) or e-mail clinicaltrials@seagen.com.

Brentuximab vedotin is an investigational drug; its efficacy and safety have not been established. There is no guarantee that brentuximab vedotin will become commercially available.
RE- LAUNCHED, ENHANCED AND FREE Image Bank from ASH

The American Society of Hematology is pleased to announce its new and improved Image Bank. Images are still free and easy to download, but are now simpler to find and store. Featuring high quality digital photos and art, Image Bank is an ideal resource for professors, teachers, researchers, students, and anyone with an interest in hematology.

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At Bayer, scientific innovation in hemophilia has a simple mission: Help people live the lives they choose. Which is why we’re excited about potential treatments currently in development. Look to us for innovative research and see what opportunities develop in your patients’ lives.

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At Bayer, scientific innovation in hemophilia has a simple mission: Help people live the lives they choose.

Which is why we’re excited about potential treatments currently in development, including recombinant proteins, to provide long-acting rFVIII therapy and to treat patients who develop inhibitors to FVIII or FIX.

Look to us for innovative research and see what opportunities develop in your patients’ lives.

BAYER—HEMOPHILIA CARE
Never losing sight of the human factor
For the ninth year, ASH will host its annual State-of-the-Art Symposium (SAS) meeting in Chicago, which will present the most current developments in key areas of hematology giving attendees the opportunity to explore the impact of new data on current practice.

Some of the topics that will be featured at this year’s SAS meeting include:
- Acute Myeloid Leukemia
- Amyloidosis
- Hematopoietic Growth Factors
- Hodgkin Lymphoma
- Large Granular Lymphocyte Disorders (LGL)
- Monoclonal B-Cell Lymphocytosis
- Monoclonal Gammapathy Consults
- Relapsed Myeloma

Don’t miss out. Join us in Chicago this September!

Registration is now open. Visit www.hematology.org/sas for the most current information on this meeting and to register today.
Important Safety Information

Warnings and Precautions

FOLOTYN may suppress bone marrow function, manifested by thrombocytopenia, neutropenia, and anemia. Monitor blood counts and omit or modify dose for hematologic toxicities.

Mucositis may occur. If ≥Grade 2 mucositis is observed, omit or modify dose. Patients should be instructed to take folic acid and receive vitamin B₁₂ to potentially reduce treatment-related hematological toxicity and mucositis.

Fatal dermatologic reactions may occur. Dermatologic reactions may be progressive and increase in severity with further treatment. Patients with dermatologic reactions should be monitored closely, and if severe, FOLOTYN should be withheld or discontinued.

Tumor lysis syndrome may occur. Monitor patients and treat if needed.

FOLOTYN can cause fetal harm. Women should avoid becoming pregnant while being treated with FOLOTYN and pregnant women should be informed of the potential harm to the fetus.

Use caution and monitor patients when administering FOLOTYN to patients with moderate to severe renal function impairment.

Elevated liver function test abnormalities may occur and require monitoring. If liver function test abnormalities are ≥Grade 3, omit or modify dose.
FOLOTYN is indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma. The indication for FOLOTYN is based on overall response rate. Clinical benefit such as improvement in progression-free survival or overall survival has not been demonstrated.

**Adverse Reactions**
The most common adverse reactions were mucositis (70%), thrombocytopenia (41%), nausea (40%), and fatigue (36%). The most common serious adverse events were pyrexia, mucositis, sepsis, febrile neutropenia, dehydration, dyspnea, and thrombocytopenia.

**Use in Specific Patient Populations**
Nursing mothers should be advised to discontinue nursing or the drug, taking into consideration the importance of the drug to the mother.

**Drug Interactions**
Co-administration of drugs subject to renal clearance (e.g., probenecid, NSAIDs, and trimethoprim/sulfamethoxazole) may result in delayed renal clearance.

Please see FOLOTYN Full Prescribing Information.

**Demonstrated response in relapsed or refractory PTCL**

- **27%** overall response rate (CR+CRu+PR) by independent central review (95% CI, 19-36)*

  Of the responders,

  - **66%** responded within Cycle 1*
    - *Median time to first response was 45 days (range=37-349 days)

- **9.4-month** median duration of response by central review (range=1-503 days)*
  - *12% (95% CI, 7-20) of patients had responses lasting ≥14 weeks (range=98-503 days)


www.FOLOTYN.com
Brief summary of Full Prescribing Information for FOLOTYN® (pralatrexate injection)—Please consult Full Prescribing Information.

INDICATIONS AND USAGE
FOLOTYN is indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL). This indication is based on overall response rate. Clinical benefit such as improvement in progression-free survival or overall survival has not been demonstrated.

WARNINGS AND PRECAUTIONS
Bone Marrow Suppression
FOLOTYN can suppress bone marrow function, manifested by thrombocytopenia, neutropenia, and anemia. Dose modifications are based on ANC and platelet counts prior to each dose.

Mucositis
Treatment with FOLOTYN may cause mucositis. If ≥Grade 2 mucositis is observed, omit dose and follow guidelines in Table 1.

Dermatologic Reactions
FOLOTYN has been associated with severe dermatologic reactions, which may result in death. These dermatologic reactions have been reported in clinical studies (144/663 patients (2.1%) and post-marketing experience, and have included exfoliation, urticaria, and toxic epidermal necrolysis (TEN). These reactions may be progressive and increase in severity with further treatment, and may involve skin and subcutaneous sites of known lymphoma. Patients with dermatologic reactions should be monitored closely, and if severe, FOLOTYN should be withheld or discontinued.

Tumor Lysis Syndrome
Tumor lysis syndrome has been reported in patients with lymphoma receiving FOLOTYN. FOLOTYN patients receiving FOLOTYN should be monitored closely and treated for complications.

Folic Acid and Vitamin B12 Supplementation
Patients should be instructed to take folic acid and receive vitamin B12 to prevent complications.

Serious Adverse Events
Forty-four percent of patients (n=49) experienced a serious adverse event while on study. The most common serious adverse events (>5%) regardless of causality, were pneumonitis, mucositis, seizures, peripheral neuropathy, anemia, edema, dehydration, dyspnea, and thrombocytopenia. One death due to cardiac pulmonary arrest in a patient with mucositis and febrile neutropenia was reported in this trial. Deaths from febrile neutropenia, peripheral neuropathy, and pancytopenia occurred in 1.2% of patients treated on all FOLOTYN trials at doses ranging from 30 to 325 mg/m2.

Discontinuations
Twenty-three percent of patients (n=25) discontinued treatment with FOLOTYN due to adverse reactions. The adverse reactions reported most frequently as the reason for discontinuation of treatment were mucositis (6%, n=7), and thrombocytopenia (5%, n=5).

Dose Modifications
The target dose of FOLOTYN was 30 mg/m2 once weekly for 6 weeks in 7-week cycles. The majority of patients (69%, n=77) reached the target dose for the administration of pralatrexate. In all patients, 85% of scheduled doses were administered.

Post Marketing Experience
Toxic epidermal necrolysis has been identified during post approval use of FOLOTYN. Since these reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate reliably their frequency, or establish a causal relationship to drug exposure (see Warnings and Precautions).

DRUG INTERACTIONS
In vitro studies indicate that pralatrexate is not a substrate, inhibitor, or inducer of CYP450 isoenzymes and has low potential for drug-drug interactions at clinically relevant concentrations. No formal clinical pharmacokinetic studies of pharmacokinetic drug–drug interactions between FOLOTYN and other drugs have been conducted. The effect of co-administration of the uricosuric drug probenecid on pralatrexate was investigated in a Phase 1 clinical study. Co-administration of increasing doses of probenecid resulted in delayed clearance of pralatrexate and a commensurate increase in exposure.

Drug interactions due to the contribution of renal excretion (approximately 34%) to the overall clearance of pralatrexate, concomitant administration of drugs that are subject to substantial renal clearance (eg, NSAIDs, trimethoprim/sulfamethoxazole) may result in delayed clearance of pralatrexate.

USE IN SPECIFIC POPULATIONS
Pregnancy
Pregnancy Category D (See Warnings and Precautions). FOLOTYN can cause fetal harm when administered to a pregnant woman. Pralatrexate was embryotoxic and fetotoxic in rats at IV doses of 0.06 mg/kg/late, early, and total resorptions. There was also a dose-dependent increase in fetal viability manifested as an increase in late, early, and total resorptions. There was also a dose-dependent increase in post-implantation loss. In rabbits, IV doses of 0.03 mg/kg/day (0.36 mg/m2/day) or greater on gestation days 8 through 20 resulted in delayed clearances of pralatrexate and a commensurate increase in exposure.

Due to the contribution of renal excretion (approximately 34%) to the overall clearance of pralatrexate, concomitant administration of drugs that are subject to substantial renal clearance (eg, NSAIDs, trimethoprim/sulfamethoxazole) may result in delayed clearance of pralatrexate.

USE IN SPECIFIC POPULATIONS
Pregnancy
Pregnancy Category D (See Warnings and Precautions). FOLOTYN can cause fetal harm when administered to a pregnant woman. Pralatrexate was embryotoxic and fetotoxic in rats at IV doses of 0.06 mg/kg/day (0.36 mg/m2/day or about 1.2% of the clinical dose on a mg/m2 basis) given on gestation days 7 through 20. Treatment with pralatrexate caused a dose-dependent decrease in fetal viability manifested as an increase in late, early, and total resorptions. There was also a dose-dependent increase in post-implantation loss. In rabbits, IV doses of 0.03 mg/kg/day (0.36 mg/m2/day) or greater on gestation days 8 through 21 also caused abortion and fetal resorption. This lethality was manifested as early and total resorptions, post-implantation loss, and a decrease in the total number of live fetuses. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

Nursing Mothers
It is not known whether pralatrexate is excreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from this drug, a decision should be made whether to discontinue nursing or to discontinue FOLOTYN, taking into account the importance of FOLOTYN to the mother.

Pediatric Use
Pediatric patients were not included in clinical studies with FOLOTYN. The safety and effectiveness of FOLOTYN in pediatric patients have not been established.

Geriatric Use
In the PTCL efficacy study, 36% of patients (n=40) were ≥65 years of age and over. No overall differences in efficacy and safety were observed in patients based on age ≥65 years compared to <65 years.

No dosage adjustment is required in elderly patients with normal renal function.

Hepatic Impairment
Formal studies have not been performed with FOLOTYN in patients with hepatic impairment. It is not known whether hepatic impairment will affect FOLOTYN pharmacokinetics.

OVERDOSAGE
No specific information is available on the overdosage of FOLOTYN. If an overdosage occurs, general supportive measures should be instituted as deemed necessary by the treating physician. Based on FOLOTYN’s mechanism of action the prompt administration of leucovorin should be considered.

PANCREATITIS
See Warnings and Precautions.

Table 1 FOLOTYN Dose Modifications for Mucositis

<table>
<thead>
<tr>
<th>Mucositis Grade</th>
<th>Dose on Day of Treatment</th>
<th>Dose over Recovery</th>
<th>Toxicity Grade</th>
<th>Preferred Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>0/1</td>
<td>1 week</td>
<td>20 mg/m2</td>
<td>1</td>
<td>Abdominal pain</td>
</tr>
<tr>
<td>2</td>
<td>1 week</td>
<td>20 mg/m2</td>
<td>1</td>
<td>Abdominal pain</td>
</tr>
<tr>
<td>3</td>
<td>1 week</td>
<td>20 mg/m2</td>
<td>2</td>
<td>abdominal pain</td>
</tr>
<tr>
<td>4</td>
<td>1 week</td>
<td>20 mg/m2</td>
<td>2</td>
<td>abdominal pain</td>
</tr>
</tbody>
</table>

Note: If the patient is ≥70 years of age and prior dose ≥Grade 3, consider ≤25% dose reduction.

Table 2 FOLOTYN Dose Modifications for Hematologic Toxicities

<table>
<thead>
<tr>
<th>Toxicity Grade</th>
<th>Dose on Day of Treatment</th>
<th>Dose on Day of Recovery</th>
<th>Toxicity Grade</th>
<th>Preferred Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1</td>
<td>1 week</td>
<td>20 mg/m2</td>
<td>1</td>
<td>Abdominal pain</td>
</tr>
<tr>
<td>Grade 2</td>
<td>2 weeks</td>
<td>20 mg/m2</td>
<td>1</td>
<td>Abdominal pain</td>
</tr>
<tr>
<td>Grade 3</td>
<td>3 weeks</td>
<td>20 mg/m2</td>
<td>2</td>
<td>abdominal pain</td>
</tr>
<tr>
<td>Grade 4</td>
<td>4 weeks</td>
<td>20 mg/m2</td>
<td>2</td>
<td>abdominal pain</td>
</tr>
</tbody>
</table>

Note: If the patient is ≥70 years of age and prior dose ≥Grade 3, consider ≤25% dose reduction.

Table 3 FOLOTYN Dose Modifications for All Other Treatment-Related Toxicities

<table>
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<tr>
<th>Toxicity Grade</th>
<th>Dose on Day of Treatment</th>
<th>Dose on Day of Recovery</th>
<th>Toxicity Grade</th>
<th>Preferred Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1</td>
<td>1 week</td>
<td>20 mg/m2</td>
<td>1</td>
<td>Abdominal pain</td>
</tr>
<tr>
<td>Grade 2</td>
<td>2 weeks</td>
<td>20 mg/m2</td>
<td>1</td>
<td>Abdominal pain</td>
</tr>
<tr>
<td>Grade 3</td>
<td>3 weeks</td>
<td>20 mg/m2</td>
<td>2</td>
<td>abdominal pain</td>
</tr>
<tr>
<td>Grade 4</td>
<td>4 weeks</td>
<td>20 mg/m2</td>
<td>2</td>
<td>abdominal pain</td>
</tr>
</tbody>
</table>

Note: If the patient is ≥70 years of age and prior dose ≥Grade 3, consider ≤25% dose reduction.

U.S. Patent: 6,028,071 and 7,622,470

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