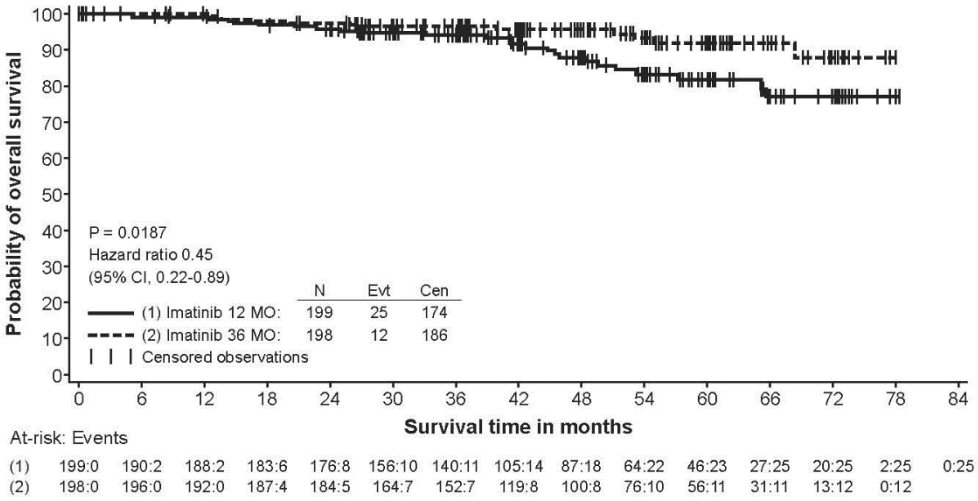
Figure 5: Study 2 Overall Survival (ITT Population)



15 REFERENCES

1. OSHA Hazardous Drugs. *OSHA.* [Accessed on 20-September- 2013, from http://www.osha.gov/SLTC/hazardousdrugs/index.html]

16 HOW SUPPLIED/STORAGE AND HANDLING

Each film-coated tablet contains 100 mg or 400 mg of imatinib free base.

100 mg Tablets

Very dark yellow to brownish orange, film-coated tablets, round, biconvex with bevelled edges, debossed with “NVR” on one side, and “SA” with score on the other side.

Bottles of 90 tablets…….NDC 0078-0401-34

400 mg Tablets

Very dark yellow to brownish orange, film-coated tablets, ovaloid, biconvex with bevelled edges, debossed with “400” on one side with score on the other side, and “SL” on each side of the score.

Bottles of 30 tablets…….NDC 0078-0438-15

400 mg Tablets

Very dark yellow to brownish orange, film-coated tablets, ovaloid, biconvex with bevelled edges, debossed with “gleevec” on one side and score on the other side.

Unit Dose (blister pack of 30) ……NDC 0078-0649-30

Storage and Handling

Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Protect from moisture.

Dispense in a tight container, USP.

Do not crush Gleevec tablets. Avoid direct contact of crushed tablets with the skin or mucous membranes. If such contact occurs, wash thoroughly as outlined in the references. Avoid exposure to crushed tablets.

17 PATIENT COUNSELING INFORMATION

Dosing and Administration

Advise patients to take Gleevec exactly as prescribed, not to change their dose or to stop taking Gleevec unless they are told to do so by their doctor. If the patient missed a dose of Gleevec, the patient should take the next scheduled dose at its regular time. The patient should not take two doses at the same time. Advise patients to take Gleevec with a meal and a large glass of water *[see Dosage and Administration (2.1)]*.

Fluid Retention and Edema

Inform patients of the possibility of developing edema and fluid retention. Advise patients to contact their health care provider if unexpected rapid weight gain occurs *[see Warnings and Precautions (5.1)]*.

Hepatotoxicity

Inform patients of the possibility of developing liver function abnormalities and serious hepatic toxicity. Advise patients to immediately contact their health care provider if signs of liver failure occur, including jaundice, anorexia, bleeding or bruising *[see Warnings and Precautions (5.4)]*.

Pregnancy and Breastfeeding

Advise patients to inform their doctor if they are or think they may be pregnant. Advise women of reproductive potential to avoid becoming pregnant while taking Gleevec. Female patients of reproductive potential taking Gleevec should use highly effective contraception during treatment and for fourteen days after stopping treatment with Gleevec *[see Use in Specific Populations (8.3)]*. Avoid breastfeeding during treatment and for 1 month after the last dose *[see Use in Specific Populations (8.2)]*.

Drug Interactions

Gleevec and certain other medicines such as warfarin, erythromycin, and phenytoin, including over-the-counter medications such as herbal products, can interact with each other. Advise patients to tell their doctor if they are taking or plan to take iron supplements. Avoid grapefruit juice and other foods known to inhibit CYP3A4 while taking Gleevec *[see Drug Interactions (7)]*.

Pediatric

Advise patients that 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, closely monitor growth in children under Gleevec treatment *[see Warnings and Precautions (5.11)]*.

Driving and Using Machines

Advise patients that they may experience side effects such as dizziness, blurred vision or somnolence during treatment with Gleevec. Therefore, caution patients about driving a car or operating machinery *[see Warnings and Precautions (5.13)]*.

Distributed by:
Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936

T2017-101