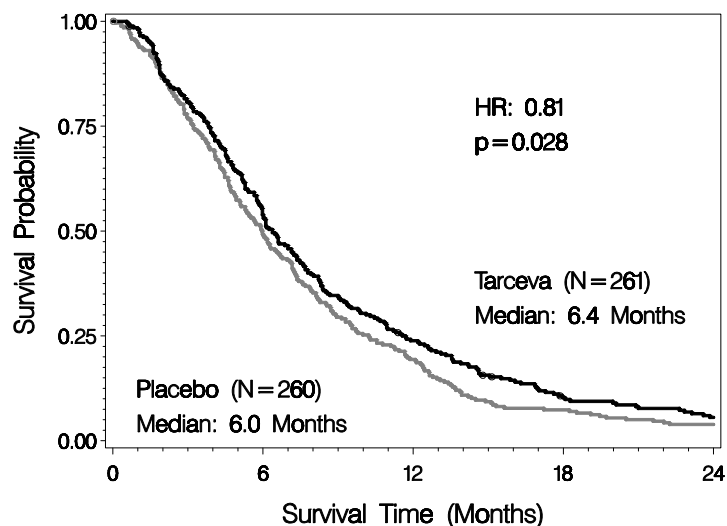


Figure 3: Kaplan–Meier Curve for Overall Survival: 100 mg Cohort



Note: HR is from Cox regression model with the following covariates: ECOG performance status and extent of disease. P-value is from two-sided Log-Rank test stratified by ECOG performance status and extent of disease.

16 HOW SUPPLIED/STORAGE AND HANDLING

25 mg Tablets

Round, biconvex face and straight sides, white film-coated, printed in orange with a “T” and “25” on one side and plain on the other side; supplied in: Bottles of 30: NDC 50242-062-01

100 mg Tablets

Round, biconvex face and straight sides, white film-coated, printed in gray with “T” and “100” on one side and plain on the other side; supplied in: Bottles of 30: NDC 50242-063-01

150 mg Tablets

Round, biconvex face and straight sides, white film-coated, printed in maroon with “T” and “150” on one side and plain on the other side; supplied in: Bottles of 30: NDC 50242-064-01

Store at 25°C (77°F); excursions permitted to 15° – 30°C (59° – 86°F). See USP Controlled Room Temperature.

17 PATIENT COUNSELING INFORMATION

If the following signs or symptoms occur, patients should be advised to seek medical advice promptly [*see Warnings and Precautions (5), Adverse Reactions (6) and Dosage and Administration (2.3)*].

- Onset or worsening of skin rash
- Severe or persistent diarrhea, nausea, anorexia, or vomiting
- Onset or worsening of unexplained shortness of breath or cough
- Eye irritation

Given that skin reactions are anticipated when taking TARCEVA, proactive intervention may include alcohol-free emollient cream and use of sunscreen or avoidance of sun exposure [*see Adverse Reactions (6.1)*]. The management of rash should be discussed with the patient. This may include topical

corticosteroids or antibiotics with anti-inflammatory properties. These approaches were used in the NSCLC and pancreatic pivotal clinical trials. Acne preparations with drying properties may aggravate the dry skin and erythema. Treatment of rash has not been formally studied and should be based on rash severity.

Women of childbearing potential should be advised to avoid becoming pregnant while taking TARCEVA [*see Warnings and Precautions (5.12) and Use in Specific Populations (8.1)*].

Smokers should be advised to stop smoking while taking TARCEVA as plasma concentrations of erlotinib are reduced due to the effect of cigarette smoking [*see Clinical Pharmacology (12.3)*].

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OSI Pharmaceuticals Inc., Melville, NY 11747

Manufactured by:

Schwarz Pharma Manufacturing, Seymour, IN 47274

Distributed by:

Genentech USA, Inc. 1 DNA Way, South San Francisco, CA 94080-4990

For further information please call 1-877-TARCEVA (1-877-827-2382).

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