

**Table 12.1** Objective response for subjects enrolled in the Maemondo study

Objective response	Gefitinib arm (% of subjects)	Carboplatin plus paclitaxel arm (% of subjects)
Complete response	4.4%	0%
Partial response	69.3	30.7
Stable disease	15.8	49.1
Progressive disease	9.6	14.0

### III. DATA ON OVERALL SURVIVAL AND PFS FROM CLINICAL TRIALS

#### a. Utilities of the endpoints of objective response, PFS, and overall survival

##### 1. *Data on PFS may be more significant than data on overall survival – the Maemondo study*

In a study on non-small cell lung cancer (NSCLC), Maemondo et al. (45) divided study subjects into two arms:

- **Arm A.** Gefitinib (study drug)
- **Arm B.** Carboplatin plus paclitaxel combination (standard treatment).

Chemotherapy was for 9 weeks and, in some cases longer, and following chemotherapy subjects were followed for about 42 months. During this follow-up period, the response of the tumors to chemotherapy was assessed by computed tomography at 2-month intervals. Analysis by computed tomography enabled the measurement of size and number of lung tumors, and comparison of the size and number with the RECIST criteria. In conducting this comparison, the researchers classified the objective response as partial response, complete response, stable disease, or progressive disease.

The endpoints in the Maemondo study included objective response, PFS, and overall survival. The results for objective response are shown in [Table 12.1](#). These results demonstrate that gefitinib worked better than the carboplatin–paclitaxel combination, in terms of all of the parameters. For example, the percent of subjects experiencing partial response was about twice as great in the gefitinib arm than in the carboplatin plus paclitaxel arm. The percent of subjects experiencing progressive disease was about 50% greater in the carboplatin plus paclitaxel arm than in the gefitinib arm.

Progression-free survival is shown in the Kaplan-Meier plot in [Fig. 12.1](#). Visual inspection of this plot reveals that the endpoint of PFS was triggered at earlier time points by subjects receiving carboplatin plus paclitaxel (standard treatment), and triggered at later time points in subjects receiving gefitinib. In other words, with standard treatment tumors progressed at an earlier time, and deaths occurred at an earlier time.

<sup>45</sup> Maemondo M, Inoue A, Kobayashi K, et al. Gefitinib or chemotherapy for non-small-cell lung cancer with mutated EGFR. *New Engl J Med*. 2010;362:2380–2388.