

第2回検討会における
アストラゼネカ社への質問に対する回答

ISEL試験 患者背景 - 奏効しなかった患者 (東洋人及び東洋人以外)

| | Oriental | | Non-Oriental | |
|--------------------------------------|----------|----------|--------------|----------|
| | Geftinib | Placebo | Geftinib | Placebo |
| | N=209 | N=104 | N=839 | N=452 |
| Age (median) | 62 years | 61 years | 62 years | 61 years |
| Male | 61% | 59% | 71% | 69% |
| PS 0-1 | 73% | 71% | 63% | 68% |
| Never smoked | 39% | 42% | 15% | 18% |
| 2nd line | 55% | 64% | 47% | 45% |
| Refractory | 93% | 97% | 89% | 89% |
| Intolerant | 7% | 3% | 11% | 11% |
| Adenocarcinoma histology | 60% | 62% | 40% | 42% |
| Time from diagnosis to randomisation | | | | |
| <6 months | 25% | 32% | 27% | 23% |
| 6-12 months | 40% | 39% | 37% | 40% |
| > 12 months | 34% | 30% | 37% | 37% |
| Best response to prior chemotherapy | | | | |
| CR/PR | 21% | 21% | 17% | 19% |
| SD | 34% | 31% | 38% | 38% |
| PD/NE | 45% | 48% | 45% | 43% |

ISEL試験 患者背景 - 奏効しなかった非喫煙者 (東洋人及び東洋人以外)

| | Oriental | | Non-Oriental | |
|--------------------------------------|-------------------|-----------------|--------------------|-----------------|
| | Gefitinib N=82 | Placebo N=44 | Gefitinib N=128 | Placebo N=81 |
| Age (median) | 59 years | 55 years | 62 years | 63 years |
| Male | 21% | 27% | 34% | 37% |
| PS 0-1 | 76% | 71% | 66% | 64% |
| Never smoked | 100% | 100% | 100% | 100% |
| 2nd line | 54% | 64% | 48% | 52% |
| Refractory | 93% | 100% | 86% | 85% |
| Intolerant | 7% | 0% | 14% | 15% |
| Adenocarcinoma histology | 74% | 80% | 62% | 53% |
| Time from diagnosis to randomisation | | | | |
| <6 months | 23% | 41% | 38% | 21% |
| 6-12 months | 38% | 34% | 31% | 42% |
| > 12 months | 39% | 25% | 32% | 37% |
| Best response to prior chemotherapy | | | | |
| CR/PR | 20% | 16% | 12% | 22% |
| SD | 35% | 32% | 43% | 38% |
| PD/NE | 45% | 52% | 45% | 38% |