Letter to the Editor

Gefitinib versus Docetaxel for Previously Treated NSCLC—Letter

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We read with great interest the recent article by Lee and colleagues, reporting the final results of the ISTANA trial (1). The authors affirm that these results prove the superiority of gefitinib over chemotherapy in the treatment of advanced, pretreated non–small-cell lung cancer (NSCLC) in terms of survival, safety, and quality of life (see Translational Relevance). However, as a matter of fact, the results show uniquely the superiority of gefitinib in progression-free survival (PFS). These data, for the first time, show the superiority of a single, molecular, targeted agent in comparison with standard chemotherapy. Furthermore, they seem to clash with the main results of the INTEREST trial and the V-15-32 trial, which showed the "non inferiority" of gefitinib in comparison with docetaxel in terms of response rate or overall survival (the INTEREST trial) and in terms of symptoms control and quality of life (the INTEREST and V-15–32 trials; refs. 2–4). The ISTANA trial differs from these 2 trials for some substantial aspects in the study design and conduction:

• The ISTANA trial is a "superiority" trial, whereas the others are "noninferiority" trials.

• PFS was the primary endpoint in the ISTANA trial, whereas overall survival was the primary endpoint in the other trials.

• The ISTANA trial enrolled only Korean patients pretreated with just 1 line of treatment and a high percentage of them were never-smokers.

Moreover, some issues about the ISTANA trial need to be clarified for a correct, final interpretation of the results:

• Why the authors assumed an α error of 10% (instead of 5%) to show the superiority of gefitinib in PFS?

• Are the authors truly sure that the lack of any correlation between PFS and overall survival is due to a hypothetical role of third-line treatments?

• Why the 2 PFS curves differ only in their final part, suggesting equivalent outcomes for most patients in the 2 arms?

The authors of the ISTANA trial would aim at changing the actual perspective of second-line treatments of advanced NSCLC, but, unfortunately, the negligible entity of the final results and the lack of any significant effect on quality of life or symptoms control bring back the merit of the trial to its right perspective.

Further trials are probably needed to better understand the role of gefitinib in the second-line treatment of NSCLC.

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

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