Updated safety of erlotinib+bevacizumab in NSCLC: JO25567

Electronic Supplementary Material

Erlotinib Plus Bevacizumab Phase II Study in Patients with Advanced Non-Small-Cell Lung Cancer (JO25567): Updated Safety Results

Target journal: Drug Safety

Terufumi Kato¹ · Takashi Seto² · Makoto Nishio³ · Koichi Goto⁴ · Noboru Yamamoto⁵ · Isamu Okamoto⁶ · Liang Tao⁷ · Wei Yu⁸ · Tarik Khaznadar⁹ · Kosei Tajima¹⁰ · Masahiko Shibata¹⁰ · Akihiro Seki¹⁰ · Nobuyuki Yamamoto¹¹

¹Kanagawa Cancer Center, 2-3-2 Nakao, Asahi-ku, Yokohama, Kanagawa 241-8515, Japan.
²National Kyushu Cancer Center, Fukuoka, Japan.

³The Cancer Institute Hospital of the Japanese Foundation for Cancer Research, Tokyo, Japan.

⁴National Cancer Center Hospital East, Chiba, Japan.

⁵National Cancer Center Hospital, Tokyo, Japan.

⁶Research Institute for Diseases of the Chest, Graduate School of Medical Sciences, Kyushu University, Fukuoka, Japan.

⁷Roche (China) Holding Ltd, Building 11, 1100 Longdong Avenue, Shanghai 201203, China.

⁸Genentech Inc., 1 DNA Way, South San Francisco, CA 94080, USA.

⁹*F.* Hoffmann-La Roche Ltd, Grenzacherstrasse 124, Basel, CH-4070 Switzerland.

¹⁰Chugai Pharmaceutical Co. Ltd, Tokyo, Japan.

¹¹Wakayama Medical University, Wakayama, Japan.

Corresponding author:

Terufumi Kato, Department of Respiratory Medicine, Kanagawa Cancer Center, 2-3-2

Nakao, Asahi-ku, Yokohama, Kanagawa 241-8515, Yokohama, Japan.

Email: terufumikato@gmail.com

Supplementary Table S1. Criteria for interruption of administration, drug discontinuation, dose reduction, and discontinuation of administration of bevacizumab or erlotinib in JO25567

Adverse event		JO25567
Hypertension	Grade 3	Defer bevacizumab until controlled (use of anti-
		hypertensives possible).
	Grade 3	Continue erlotinib but can be withdrawn until
		recovery to grade ≤1 according to investigator
		judgement.
Proteinuria	Grade 2	If decreased albumin or edema is seen, defer
		administration until recovery to ≤grade 2. Continue if
		protein:urine ≤2g/24hr.
	Grade 3	Defer bevacizumab; restart if recovery to ≤grade 2
		and decreased albumin or edema is not seen or
		protein:urine ≤2g/24hr.
	Grade 3	Withdraw erlotinib until ≤grade 2, then restart at the
		same dose; dose reduction is also possible.
Hemorrhage	Grade 2	Defer until recovers to grade 0. If hemorrhage
(excluding		≥grade 2 after a restart, discontinue bevacizumab.
hemoptysis)	Grade 3	Discontinue bevacizumab.
	Grade 3	Erlotinib withdrawal until recovery to ≤grade 1.
Hemoptysis	Grade 1 and	Grade 1 and 2 that require treatment with an oral
(including bloody	Grade 2	hemostatic; defer until grade 0.
sputum)	Grade 2 and	Grade 2 and 3 that require treatment with an
	Grade 3	injectable hemostatic; discontinue bevacizumab.
	Grade 3	Erlotinib withdrawal until recovery to ≤grade 1.