CORRECTION

Correction to: Safety and Effectiveness of Lenvatinib in 594 Patients with Unresectable Thyroid Cancer in an All-Case Post-Marketing Observational Study in Japan

Shunji Takahashi · Makoto Tahara · Koichi Ito · Masayuki Tori ·
Naomi Kiyota · Katsutoshi Yoshida · Yukinori Sakata ·
Akira Yoshida

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In the original article, there were errors published. Please see correct versions of Tables 2, 3, 4, S2 and S3 below.

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S. Takahashi (✉)
Department of Medical Oncology, Cancer Institute
Hospital of the Japanese Foundation for Cancer
Research, 3-8-31, Ariake, Koto-ku, Tokyo 135-8550,
Japan
e-mail: s.takahashi-chemotherapy@jfc.or.jp

M. Tahara
Department of Head and Neck Cancer Oncology,
National Cancer Center Hospital East, Kashiwa,
Chiba 277-8577, Japan

K. Ito
Ito Hospital, 4-3-6 Jingu-mae, Shibuya-ku, Tokyo
150-8308, Japan

M. Tori
Department of Endocrine Surgery, Osaka Police
Hospital, 10-31, Kitayamacho, Tennouji-ku, Osaka
543-0035, Japan

N. Kiyota
Oncology/Hematology, Kobe University Hospital
Cancer Center, 7-5-1, Kusunokicho, Chuo-ku, Kobe,
Hyogo 650-0017, Japan

K. Yoshida · Y. Sakata
Eisai Co. Ltd., 4-6-10 Koishikawa, Bunkyo-ku, Tokyo
112-8088, Japan

A. Yoshida
Kanagawa Health Service Association, Nihon-odori
bldg. 58 Nihon-odori, Naka-ku, Yokohama 231-
0021, Japan

Table 2 Administration dose of lenvatinib according to the histological subtypes

	DTC		MTC		ATC	
	(<i>n</i> = 442)		(<i>n</i> = 28)		(<i>n</i> = 124)	
Initial dose per day						
24 mg	337	(76.2)	22	(78.6)	87	(70.2)
20 mg	29	(6.6)	2	(7.1)	18	(14.5)
14 mg	29	(6.6)	0	(0.0)	9	(7.3)
10 mg	26	(5.9)	4	(14.3)	6	(4.8)
8 mg	15	(3.4)	0	(0.0)	2	(1.6)
4 mg	0	(0.0)	0	(0.0)	0	(0.0)
Others ^a	6	(1.4)	0	(0.0)	2	(1.6)
Mean dose, mg/day, $\pm$ SD ^b	11.86	$\pm$ 5.40	12.20	$\pm$ 5.81	15.70	$\pm$ 6.35

The total might not equal 100% owing to rounding. Data are expressed as the number and percentage unless specified
DTC differentiated thyroid cancer, *MTC* medullary thyroid cancer, *ATC* anaplastic thyroid cancer, *SD* standard deviation

^a Others include 18 mg, 16 mg, and 12 mg

^b The mean dose was calculated by cumulating the lenvatinib dose administered during the study period divided by the administration days

Table 3 Adverse drug reactions according to the histological subtypes

	DTC (<i>n</i> = 442)				MTC (<i>n</i> = 28)				ATC (<i>n</i> = 124)			
Any ADR, <i>n</i> (%)	436		(98.6)		28		(100.0)		115		(92.7)	
ADR, <i>n</i> (%)	Any grade		Grade $\geq$ 3		Any grade		Grade $\geq$ 3		Any grade		Grade $\geq$ 3	
Hypertension ^a	354	(80.1)	267	(60.4)	18	(64.3)	11	(39.3)	87	(70.2)	58	(46.8)
Proteinuria	192	(43.4)	76	(17.2)	11	(39.3)	4	(14.3)	37	(29.8)	9	(7.3)
Palmar-plantar erythrodysesthesia syndrome ^b	178	(40.3)	26	(5.9)	14	(50.0)	1	(3.6)	32	(25.8)	4	(3.2)
Decreased appetite	115	(26.0)	20	(4.5)	7	(25.0)	1	(3.6)	20	(16.1)	6	(4.8)
Platelet count decreased	97	(21.9)	20	(4.5)	4	(14.3)	1	(3.6)	28	(22.6)	16	(12.9)
Malaise	88	(19.9)	10	(2.3)	3	(10.7)	0	(0.0)	24	(19.4)	1	(0.8)
Diarrhea	85	(19.2)	17	(3.8)	8	(28.6)	3	(10.7)	15	(12.1)	1	(0.8)

ADRs were categorized on the basis of the preferred terms of the Medical Dictionary for Regulatory Activities (MedDRA), ver. 20.1

An ADR was counted as one event when the identical ADR was reported multiple times in 1 patient

DTC differentiated thyroid cancer, *MTC* medullary thyroid cancer, *ATC* anaplastic thyroid cancer, *ADR* adverse drug reactions

^a Hypertension included the MedDRA-preferred terms of blood pressure diastolic increased, blood pressure increased, diastolic hypertension, hypertension, systolic hypertension, and prehypertension

^b Palmar-plantar erythrodysesthesia included the MedDRA-preferred terms of erythema multiforme, palmar-plantar erythrodysesthesia syndrome, palmar erythema, rash erythematous, skin reaction, and hand dermatitis

Table 4 Assessment of the effectiveness of lenvatinib according to the histological subtypes

	DTC		MTC		ATC	
<i>N</i>	442	–	28	–	124	–
Overall survival, days, median (95% CI)	–		–		101.0	(80.0–130.0)
12-month overall survival rate, % (95% CI)	75.7	(71.3–79.5)	83.0	(60.7–93.3)	15.6	(9.6–22.9)
Time-to-treatment failure, days, median (95% CI)	413.0	(375.0 to –)	405.0	(252.0–405.0)	74.5	(57.0–108.0)
12-month treatment continuation, % (95% CI)	57.0	(52.2–61.5)	57.1	(35.8–73.6)	9.4	(4.9–15.7)
<i>N</i>	368	–	20	–	105	–
Best overall response ^a , <i>n</i> (%)						
Complete response	10	(2.7)	1	(5.0)	3	(2.9)
Partial response	208	(56.5)	8	(40.0)	43	(41.0)
Stable disease	122	(33.2)	11	(55.0)	34	(32.4)
Progressive disease	25	(6.8)	0	(0.0)	25	(23.8)
Not evaluable	3	(0.8)	0	(0.0)	0	(0.0)
Overall response rate ^b , % (95% CI)	59.2	(54.03–64.30)	45.0	(23.06–68.47)	43.8	(34.14–53.83)
Disease control rate ^c , % (95% CI)	92.4	(89.19–94.88)	100.0	(83.16–100.00)	76.2	(66.89–83.96)

DTC differentiated thyroid cancer, *MTC* medullary thyroid cancer, *ATC* anaplastic thyroid cancer, *CI* confidence interval

^a Tumor responses for the single largest tumor were evaluated using imaging data including computed tomography (CT), and the best response during 12 months after the first administration of lenvatinib was recorded as best overall response. The responses were classified into complete response (CR), which indicated a disappearance of the tumor; partial response (PR), which indicated a $\geq 30\%$ decrease in the tumor diameters, taking as reference the baseline diameter; stable disease (SD); progressive disease (PD), which indicated a $\geq 20\%$ increase in the diameters, taking as reference the baseline diameter; and not evaluable (NE). Unlike the Response Evaluation Criteria in Solid Tumors (RECIST) guidelines, tumors in the current study did not need to show CR and PR at ≥ 4 weeks to be indicators of those responses. Tumor responses were recorded at the discretion of the attending physician and were not reviewed by an independent central review board

^b The overall response rate indicates the sum of the proportion of patients with CR and those with PR

^c The disease control rate indicates the sum of the proportion of patients with CR, PR, and SD

Table S2 Adverse drug reactions of interest according to the histological subtypes

	DTC		MTC		ATC	
	(n = 442)		(n = 28)		(n = 124)	
Hypertension ^a	354	(80.1)	18	(64.3)	87	(70.2)
Renal disorders ^b	231	(52.3)	12	(42.9)	45	(36.3)
Proteinuria	192	(43.4)	11	(39.3)	37	(29.8)
Palmar-plantar erythrodysesthesia syndrome ^c	178	(40.3)	14	(50.0)	32	(25.8)
Hematological toxicity	126	(28.5)	8	(28.6)	42	(33.9)
Hemorrhagic events excluding carotid artery hemorrhage, venous hemorrhage, and tumor hemorrhage associated with tumor shrinkage or necrosis	111	(25.1)	7	(25.0)	25	(20.2)
Increased blood-thyroid-stimulating hormone level	81	(18.3)	7	(25.0)	33	(26.6)
Hepatic disorders	77	(17.4)	6	(21.4)	13	(10.5)
Infectious diseases	43	(9.7)	4	(14.3)	12	(9.7)
Hypocalcemia	26	(5.9)	2	(7.1)	9	(7.3)
Protracted wound healing	13	(2.9)	0	(0.0)	8	(6.5)
Carotid artery hemorrhage, venous hemorrhage, and tumor hemorrhage associated with tumor shrinkage or necrosis	7	(1.6)	0	(0.0)	10	(8.1)
Thromboembolic events	6	(1.4)	0	(0.0)	2	(1.6)
Perforation of the digestive tract and gastrointestinal fistula	5	(1.1)	0	(0.0)	4	(3.2)
Cardiac dysfunction	5	(1.1)	0	(0.0)	0	(0.0)
Arrhythmia	4	(0.9)	0	(0.0)	4	(3.2)
Reversible posterior leukoencephalopathy syndrome	1	(0.2)	0	(0.0)	0	(0.0)

DTC: differentiated thyroid cancer, MTC: medullary thyroid cancer, ATC: anaplastic thyroid cancer, ADR: adverse drug reactions.

Data are expressed as number and percentage. ADRs were categorized on the basis of the preferred terms used in the Medical Dictionary for Regulatory Activities (MedDRA), ver. 20.1.

^a Hypertension included the MedDRA-preferred terms of blood pressure diastolic increased, blood pressure increased, diastolic hypertension, hypertension, systolic hypertension, and prehypertension.

^b Renal disorders included the MedDRA-preferred terms of blood creatinine increased, blood urea increased, hemoglobinuria, nephrotic syndrome, protein urine, proteinuria, renal disorder, renal failure, protein urine present, renal impairment, chronic kidney disease, acute prerenal failure, renal tubular necrosis, hypercreatininemia, and renal ischemia.

^c Palmar-plantar erythrodysesthesia included the MedDRA-preferred terms of erythema multiforme, palmar-plantar erythrodysesthesia syndrome, palmar erythema, rash erythematous, skin reaction, and hand dermatitis.

Table S3 Adverse drug reactions according to previous treatments

	Patients with a history of RAI treatment		Patients without a history of RAI and sorafenib treatment		Patients without a history of RAI treatment but with sorafenib treatment	
	(n = 326)		(n = 91)		(n = 25)	
Any ADR, n (%)	323	(99.1)	89	(97.8)	24	(96.0)
ADR, n (%)						
Hypertension	262	(80.4)	68	(74.7)	22	(88.0)
Proteinuria	140	(42.9)	40	(44.0)	11	(44.0)
Palmar-plantar erythrodysesthesia syndrome	137	(42.0)	25	(27.5)	15	(60.0)
Decreased appetite	85	(26.1)	24	(26.4)	6	(24.0)
Platelet count decreased	76	(23.3)	17	(18.7)	4	(16.0)
Malaise	66	(20.2)	16	(17.6)	6	(24.0)
Diarrhea	69	(21.2)	12	(13.2)	3	(12.0)

RAI: radioactive iodine, ADR: adverse drug reactions.

ADRs were categorized on the basis of the preferred terms used in the Medical Dictionary for Regulatory Activities (MedDRA), ver. 20.1.

ADRs were counted as one event when the identical ADR was reported multiple times in one patient.