Japanese Subgroup Analysis of EV-301: An Open-Label, Randomized Phase 3 Study to Evaluate Enfortumab Vedotin vs Chemotherapy in Subjects With Previously Treated Locally Advanced or Metastatic Urothelial Carcinoma

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## **Supporting Information**

## **List of Investigators**

Country	Primary Investigator
JAPAN	Abe, Takashige; Ebara, Shin; Fukasawa, Satoshi; Hashimoto, Yasuhiro; Inokuchi, Junichi; Kanayama, Hiroomi; Kawasaki, Yoshihide; Kitamura, Hiroshi; Kobayashi, Takashi; Kondo, Yukihiro; Masumori, Naoya; Mizuno, Ryuichi; Nishimura, Kazuo; Obara, Wataru; Sugimoto, Mikio; Takamoto, Atsushi; Tomita, Yoshihiko; Uemura, Hiroji; Yokomizo, Akira; Yoshimura, Kazuhiro

Investigators are listed in alphabetical order by country and last name.

## **Supplemental Table**

Table S1. Treatment-Related Adverse Events of Special Interest<sup>†</sup> in the Japanese

## **Subgroup (Safety Population)**

Event, n (%)	Enfortumab Vedotin (N=36)	Standard Chemotherapy (N=48)
Skin reactions <sup>‡</sup>	21 (58.3)	12 (25.0)
Rash	20 (55.6)	6 (12.5)
Severe cutaneous adverse reaction§	11 (30.6)	7 (14.6)
Peripheral neuropathy	19 (52.8)	16 (33.3)
Sensory events¶	18 (50.0)	16 (33.3)
Motor events	1 (2.8)	0
Ocular disorders	2 (5.6)	2 (4.2)
Dry eye	2 (5.6)	1 (2.1)
Blurred vision	0	1 (2.1)
Corneal disorders	0	0
Infusion-related reactions	7 (19.4)	3 (6.3)
Systemic events	6 (16.7)	3 (6.3)
Local events	1 (2.8)	0
Infusion site reactions	1 (2.8)	0
Extravasation site reactions	1 (2.8)	0
Hyperglycemia	2 (5.6)	0

<sup>&</sup>lt;sup>†</sup>Events represent listings by Preferred Term and may include Sponsor Specific Query/Customized Medical Queries (SSQ/CMQ) or Standard MedDRA Queries.

<sup>‡</sup>Indicates rash or severe cutaneous adverse reactions.

<sup>§</sup>Composite Standard MedDRA Query High Level Term of severe cutaneous adverse reactions including: stomatitis, drug eruption, conjunctivitis, dermatitis bullous, skin

exfoliation, blister, erythema multiforme, exfoliative rash, fixed eruption, mouth ulceration, pemphigus, and toxic skin eruption.

Represents any peripheral neuropathy sensory events (SSQ/CMQ) including: peripheral sensory neuropathy, neuropathy peripheral, paresthesia, polyneuropathy,

 $hypoesthesia, neurotoxicity, dysesthesia, gait \ disturbance, burning \ sensation, \ neuralgia, \ and \ sensory \ loss.$