

Table 1. Treatment-Emergent Adverse Events (AE); Event Rate in E/100PYs		
	UPA 15 MG N=236 PYs=301.7 E/100PYs	UPA 30 MG N=240 PYs=290.7 E/100PYs
Any Adverse Event	353.3	435.8
Serious AE	17.9	29.2
AE Leading To Study Drug D/C	9.6	15.1
Serious Infection [§]	3.0	8.3
Herpes Zoster [†]	4.6	8.9
Hepatic disorder [‡]	4.6	8.3
Any Malignancy (exc NMSC) [¶]	1.7	1.0
MACE (adjudicated) [§]	1.0	0.3
VTE (adjudicated) [§]	2.3	0.7
Deaths [†]	0.7	1.0

E, events; PYs, patient-years; E/100PYs, events per 100 patient-years; NMSC, non-melanoma skin cancer; MACE, major adverse cardiovascular event (cardiovascular death, non-fatal myocardial infarction (MI), non-fatal stroke); VTE, venous thromboembolism (DVT, deep vein thrombosis; PE, pulmonary embolism).

[§]Most frequently reported serious infections were pneumonia, HZ, influenza, and respiratory tract infections.

[†]HZ: most involved 1 or 2 dermatomes. No meningoencephalopathic/noncutaneous involvement. Two HZ events were reported as ophthalmic.

[¶]Malignancy (excluding NMSC): UPA15: 1 malignant melanoma in situ, 1 bladder cancer, 1 pancreatic carcinoma Stage IV, 1 colon cancer, 1 non-small cell lung cancer metastatic; UPA30: 2 prostate cancers, 1 rectal cancer metastatic.

[§]MACE (adjudicated): UPA15: 1 CV death, 1 non-fatal MI, 1 non-fatal stroke; UPA30: 1 pt with 2 concurrent events (non-fatal MI and acute congestive heart failure) adjudicated to non-fatal MI

[§]VTE: UPA15: 3 pts with PE, 1 pt with DVT, 2 pts with PE and DVT, 1 pt with non-assessable thrombotic event; UPA30: 1 pt with PE, 1 pt with PE and DVT; no dose relationship in the rates of VTE or patterns in the time to onset of the events, were observed.

[†]Deaths: UPA15: 1 due to other CV causes, 1 due to cardiac arrest; UPA30: 1 pt with cardiac decompensation, 1 pt with presumed MI, 1 pt with rectal cancer metastasized to liver

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