

## Supplementary Online Content

Haas NB, Manolova J, Dutcher J, Flaherty KT, Uzzo RG, et al. Adjuvant treatment for high-risk clear cell kidney cancer: updated results from ASSURE (E2805), a randomized trial [published online March 9, 2017]. *JAMA Oncol*. doi:10.1001/jamaoncol.2017.0076

**eTable 1.** Baseline Characteristics of the Patients

**e Table 2.** Adverse Events

**eFigure.** OS by Quartile of Average Dose per 6-Week Cycle of Sunitinib

The full protocol is available at:

<http://ecog-acrin.org/resources/publications/e2805>

This supplementary material has been provided by the authors to give readers additional information about their work.

eTable 1. Baseline Characteristics of the Patients

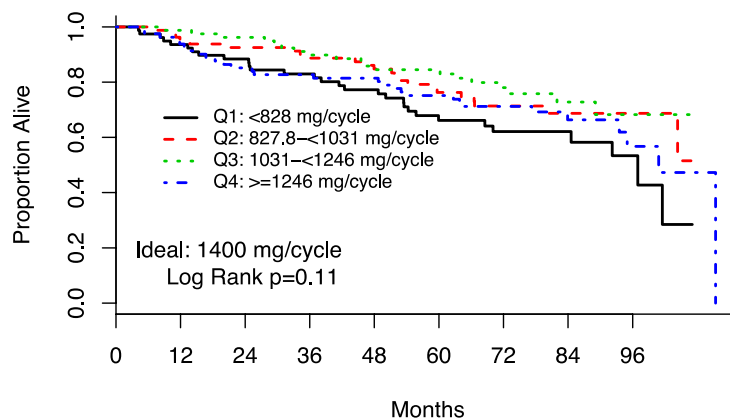
	<b>Sunitinib (N=358)</b>	<b>Sorafenib (N=355)</b>	<b>Placebo (N=356)</b>	<b>Total (N=1069)</b>
Gender – no. (%)				
Male	243 (67.9%)	248 (69.9%)	254 (71.3%)	745 (69.7%)
Female	115 (32.1%)	107 (30.1%)	102 (28.7%)	324 (30.3%)
Race – no. (%)				
White	339 (96.0%)	329 (93.7%)	321 (92.2%)	989 (94.0%)
African American	9 (2.5%)	9 (2.6%)	13 (3.7%)	31 (2.9%)
Asian	2 (0.6%)	10 (2.8%)	11 (3.2%)	23 (2.2%)
Other	3 (0.9%)	3 (0.9%)	3 (0.9%)	9 (0.9%)
Unknown	5	4	8	17
Age - years				
Median	59	56	58	58
Range	31 - 83	20 - 84	19 - 83	19 - 84
ECOG Performance Status – no. (%)				
0	274 (76.5%)	267 (75.2%)	279 (78.4%)	820 (76.7%)
1	84 (23.5%)	88 (24.8%)	77 (21.6%)	249 (23.3%)
Node-Positive – no. (%)				

pT1-2	3 (0.8%)	17 (4.8%)	15 (4.2%)	35 (3.3%)
pT3	19 (5.3%)	19 (5.4%)	25 (7.0%)	63 (5.9%)
pT4	1 (0.3%)	1 (0.3%)	0 (0.0%)	2 (0.2%)
Node-Negative – no. (%)				
pT3	330 (92.2%)	312 (87.9%)	315 (88.5%)	957 (89.5%)
pT4	5 (1.4%)	6 (1.7%)	1 (0.3%)	12 (1.1%)
Histology – no. (%)				
Clear Cell (Mixed, >25%)	12 (3.4%)	12 (3.4%)	17 (4.8%)	41 (3.8%)
“Pure” Clear Cell	346 (96.6%)	343 (96.6%)	339 (95.2%)	1028 (96.2%)

eTable 2. Grade 3 or higher adverse events as reported for any reason and occurring in more than 1% of patients on any arm

Toxicity Type	Treatment Arm								
	Sunitinib (n=344)			Sorafenib (n=342)			Placebo (n=347)		
	Grade			Grade			Grade		
	3	4	5	3	4	5	3	4	5
	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
Hypertension	17	<1	-	18	-	-	5	-	-
Fatigue	16	1	-	8	-	-	4	-	-
Pruritus/itching	-	-	-	2	-	-	<1	-	-
Rash/desquamation	3	-	-	14	-	-	1	-	-
Hand-foot reaction	15	-	-	33	-	-	1	-	-
Anorexia	2	-	-	1	-	-	-	-	-
Diarrhea w/o prior colostomy	10	-	-	10	-	-	<1	-	-
Dyspepsia	3	-	-	1	-	-	-	-	-
Mucositis/stomatitis	5	-	-	1	-	-	-	-	-
Nausea	4	-	-	1	-	-	-	-	-
Vomiting	3	-	-	1	-	-	<1	-	-
Infection Gr0-2 neut, lung	<1	-	-	1	<1	-	1	-	-
Depression	<1	-	-	1	<1	-	1	1	-
Chest/thoracic pain NOS	<1	-	-	2	-	-	<1	-	-
Joint, pain	1	-	-	2	-	-	1	-	-
Dyspnea	1	-	-	2	-	-	1	-	-
WORST DEGREE	60	5	1	68	3	-	24	4	-

### OS by Quartile of Average Dose per 6-Week Cycle of Sunitinib



Rank p=0.91

No. at Risk

Q1	83	75	73	66	63	51	32	18	6
Q2	84	79	69	67	62	57	36	23	12
Q3	83	81	80	73	63	54	35	16	6
Q4	84	84	79	72	69	60	47	24	11