Supplementary Table S4. Safety data in safety population at AFU1

≥10% in either arm	Abemaciclib+ ETN=2791, n (%)			ET alone N=2800, n (%)		
	Any grade	**Grade 3**	**Grade 4**	**Any grade**	**Grade 3**	**Grade 4**
Any adverse event	2745 (98.4%)	1284 (46.0%)	89 (3.2%)	2486 (88.8%)	424 (15.1%)	22 (0.8%)
Diarrhea	2331 (83.5%)	218 (7.8%)	0[a]	242 (8.6%)	6 (0.2%)	0
Neutropenia	1278 (45.8%)	527 (18.9%)	19 (0.7%)	157 (5.6%)	19 (0.7%)	4 (0.1%)
Fatigue	1133 (40.6%)	80 (2.9%)	NA[b]	499 (17.8%)	4 (0.1%)	NA[b]
Leukopenia	1049 (37.6%)	313 (11.2%)	4 (0.1%)	186 (6.6%)	11 (0.4%)	NA[b]
Abdominal pain	992 (35.5%)	39 (1.4%)	NA[b]	275 (9.8%)	9 (0.3%)	NA[b]
Nausea	824 (29.5%)	14 (0.5%)	NA[b]	252 (9.0%)	2 (0.1%)	NA[b]
Arthralgia	742 (26.6%)	9 (0.3%)	NA[b]	1060 (37.9%)	29 (1.0%)	NA[b]
Anemia	681 (24.4%)	56 (2.0%)	1 (0.0%)	104 (3.7%)	9 (0.3%)	1 (0.0%)
Headache	546 (19.6%)	8 (0.3%)	NA[b]	421 (15.0%)	5 (0.2%)	NA[b]
Vomiting	491 (17.6%)	15 (0.5%)	0	130 (4.6%)	3 (0.1%)	0
Hot flush	427 (15.3%)	4 (0.1%)	NA[b]	643 (23.0%)	10 (0.4%)	NA[b]
Lymphopenia	395 (14.2%)	148 (5.3%)	3 (0.1%)	96 (3.4%)	13 (0.5%)	0
Cough	391 (14.0%)	1 (0.0%)	NA[b]	222 (7.9%)	0	NA[b]
Thrombocytopenia	373 (13.4%)	28 (1.0%)	8 (0.3%)	52 (1.9%)	2 (0.1%)	2 (0.1%)
Lymphedema	347 (12.4%)	5 (0.2%)	NA[b]	250 (8.9%)	1 (0.0%)	NA[b]
Alanine aminotransferase increase	343 (12.3%)	72 (2.6%)	5 (0.2%)	157 (5.6%)	19 (0.7%)	0
Urinary tract infection	336 (12.0%)	16 (0.6%)	0	211 (7.5%)	6 (0.2%)	0
Constipation	333 (11.9%)	2 (0.1%)	0	168 (6.0%)	1 (0.0%)	0
Aspartate aminotransferase increased	330 (11.8%)	49 (1.8%)	3 (0.1%)	137 (4.9%)	15 (0.5%)	0
Decreased appetite	329 (11.8%)	16 (0.6%)	0	68 (2.4%)	2 (0.1%)	0
Alopecia	313 (11.2%)	NA[c]	NA[c]	75 (2.7%)	NA[c]	NA[c]
Rash	312 (11.2%)	11 (0.4%)	0	127 (4.5%)	0	0
Blood creatinine increased	311 (11.1%)	3 (0.1%)	0	23 (0.8%)	0	0
Dizziness	304 (10.9%)	4 (0.1%)	NA[b]	188 (6.7%)	1 (0.0%)	NA[b]
Upper respiratory tract infection	301 (10.8%)	6 (0.2%)	0	238 (8.5%)	0	0
Pain in extremity	286 (10.2%)	3 (0.1%)	NA[b]	325 (11.6%)	4 (0.1%)	NA[b]
Back pain	283 (10.1%)	10 (0.4%)	NA[b]	347 (12.4%)	9 (0.3%)	NA[b]
Pyrexia	279 (10.0%)	2 (0.1%)	0	127 (4.5%)	0	0
Additional adverse events of interest						
Venous thromboembolic event[d]	71 (2.5%)	32 (1.1%)	6 (0.2%)	17 (0.6%)	7 (0.3%)	0[a]
PE	28 (1.0%)	24 (0.9%)	3 (0.1%)	4 (0.1%)	3 (0.1%)	0[a]
Interstitial lung disease[e]	89 (3.2%)	10 (0.4%)	0[b]	37 (1.3%)	1 (0.0%)	0
Serious adverse events						
Any SAEs	424 (15.2%)			247 (8.8%)		

[a]One Grade 5 event occurred, [b]Max Grade 3 event (according to CTCAE v. 4),[c]Max Grade 2 event (according to CTCAE v. 4), [d]Identified by selected terms in Embolic and thrombotic events SMQ, [e]Identified by Interstitial lung disease SMQ

Abbreviations: ET=endocrine therapy; n=number of patients; N=number of patients in population; NA=not applicable; PE=pulmonary embolism