

Supplementary material for Joensuu G, Joensuu T, Nupponen N, Ruutu M, Collan J, Pesonen S & Hemminki A. A phase II trial of gefitinib in patients with rising PSA following radical prostatectomy or radiotherapy Acta Oncologica, 2012;51:130–133.

Sequence analyses of *EGFR* and *KRAS* exons

As *EGFR* or *KRAS* mutations have been proposed to predict efficacy of gefitinib, *EGFR* exons 18, 19, 20 and 21 and *KRAS* exon 1 were screened for mutations in all of the available four samples (patients 2, 7, 10, 29) [1], but no activating mutations were found. Also it should be noted that having the samples from all patients would have been

valuable and thereby more reliable data for the whole population.

Reference

- [1] Pao W, Wang TY, Riely GJ, Miller VA, Pan Q, Ladanyi M, et al. *KRAS* mutations and primary resistance of lung adenocarcinomas to gefitinib or erlotinib. *PLoS Med* 2005;2:e17.101

Supplementary Table I. Patient population.

		Patients	N (%)
Demographic characteristics			
Sex	Male	30	(100.0)
Age (years)	Mean \pm SD	66.3 \pm 5.95	
	Median	67.0	
	Range	52–76	
Race	White	30	(100.0)
Baseline characteristics			
PSA before treatment (ng/ml)	Mean \pm SD	2.69 \pm 2.36	
	Range	0.2–8.5	
WHO performance status	0	24	(80.0)
	1	6	(20.0)
Previous cancer treatments			
Radical prostatectomy		18	(60)
Radiotherapy		11	(36.7)
Prostatectomy and radiotherapy		1	(3.3)

PSA, prostate-specific antigen, SD, standard deviation.

Supplementary Table II. Overall toxicity during three month study period*.

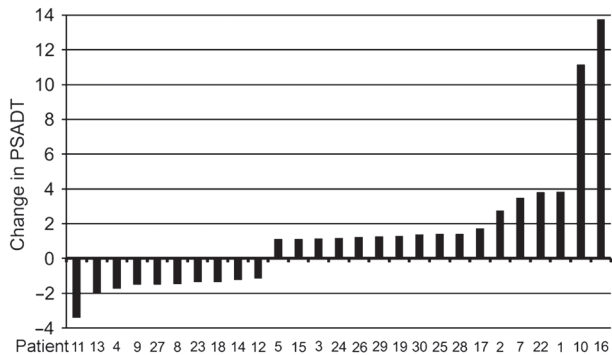
Toxicity	Grade (no. of patients)				% of Patients	
	1	2	3	4	Grade 1–2	Grade 3
Acne	15	4			63.3	
Diarrhea	12	3			50.0	
Nausea	3	1			13.3	
Constipation	3	1			13.3	
Elevated ALT		1	3		3.3	10.0
Elevated AST	2	2	1		13.3	3.3
Proctitis	1	3			13.3	
Flu	3	1			13.3	
Dry skin	4				13.3	
Erythema	2	1			10.0	
Tiredness	3	1			13.3	
Conjunctivitis	2	1			10.0	
Flatulence	3				10.0	
Worsening of onychomycosis	1	2			10.0	
Syncope			1			3.3

*Adverse events (AE) were collected for three months and classified according to Common Terminology Criteria for Adverse Events (CTCAE) version 2.0. Grade 1–2 toxicities occurring in only one or two patients are not listed. No grade 4–5 side effects were seen.

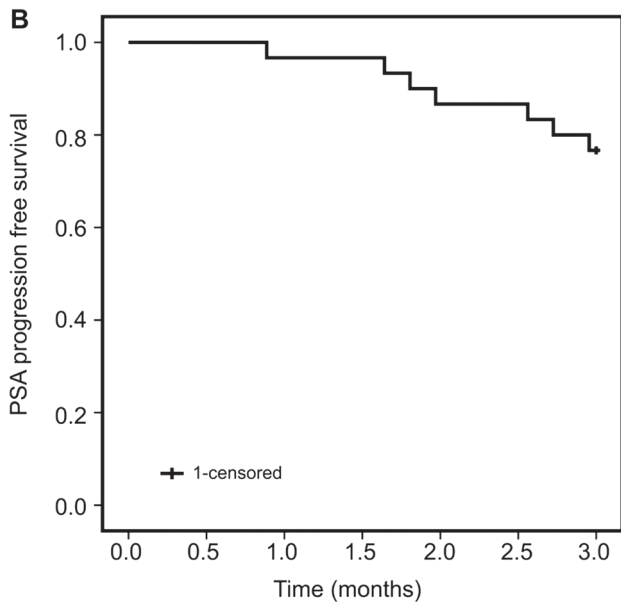
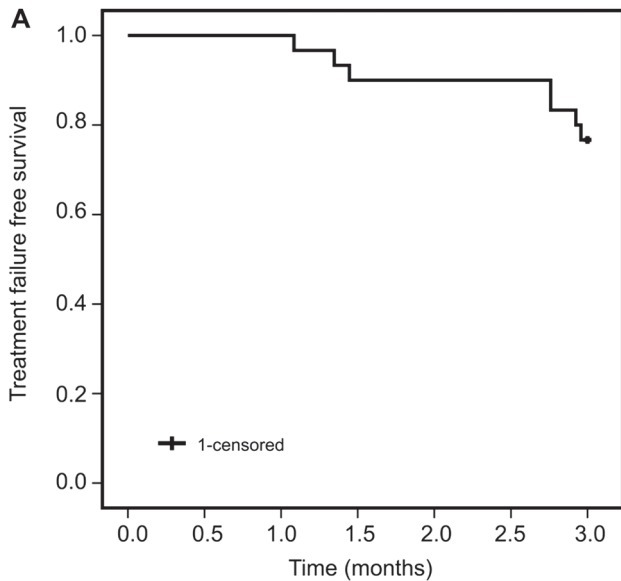
Supplementary Table III. Patient status at three months.

Patient status at three months (n = 30)	Number	(%)
Completed 3 months of trial medication	23	(76.7)
Discontinued because of AE	2	(6.7)
Discontinued because of PSA progression	5	(16.7)
Free from PSA progression	23	(76.7)
Free from PSA progression and on gefitinib	20	(66.7)
Free from PSA progression but withdrew due to AE	3	(10.0)
PSA progression	7	(23.3)

AE, adverse events; PSA, prostate-specific antigen.



Supplementary Figure 2.



Supplementary Figure 1.