SUPPLEMENTARY FILE

Efficacy and safety of pregabalin for fibromyalgia in a population of Chinese subjects

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Supplementary Table S1 Description of major protocol deviations for patients in the FAS excluded from the PPAS[a]

Criteria	Description of violation	n[a]
1. Drug compliance	a. Subject's overall compliance with study medication (including titration and fixed-dose phases) <80%; or b. Subject's overall compliance with study medication (including titration and fixed-dose phases) >120% • Both criteria a and b were based on programming-derived compliance, text comment considered a. greater than 3 consecutive days of dosing missed in Week 10–Week 14 if the subject had not previously discontinued • If subject terminated early, before Week 14, this condition did not apply • If text comment stated >3 days with dose missing but dates were unknown, the dates were assumed to be consecutive days • Unknown dosing was imputed as 0	45

2. Prohibited drug	a. Prohibited medications for pain relief of fibromyalgia not washed out prior to study entry; or	
	b. Used prohibited medications for pain relief of fibromyalgia during the study	28
3. Did not meet fibromyalgia diagnostic criteria	a. Widespread pain present <3 months; or	
	b. <11 of 18 specific tender point sites	0
4. Pain criteria	a. At randomization, pain diaries available for <4 days, or average pain score <4	
	b. At screening and randomization, VAS <40 mm or ≥30% decrease in VAS at randomization compared with screening	4
5. Creatinine clearance	a. Subjects randomized when baseline serum creatinine clearance ≤60 mL/min.	5

[a] 261 subjects (131 pregabalin, 130 placebo) were included in the PPAS. The PPAS was a subset of the FAS and was defined as subjects who did not have any major protocol deviations that would have the potential to affect their efficacy assessments. Subjects violating listed criteria were excluded from the PPAS. Patients could have been listed in more than one category, and therefore n does not add up to 73 subjects.

Abbreviations: FAS, full analysis set; PPAS, per-protocol analysis set; VAS, visual analog scale.

Supplementary Figure S1 Study design. FU, follow-up; V, visit.