



**Karolinska
Institutet**

Date: 2021-09-27

Prematurely ended - statement

EudraCT number: 2014-002456-90

Full title of the study: Integrated Exposure-Based Therapy for Co-occurring Posttraumatic Stress Disorder and Alcohol Dependence: Effects of the FAAH inhibitor PF-04457845 on Extinction. A Randomized Controlled Trial

Sponsor: Karolinska Institutet

Contact person: Åsa Magnusson

Product: FAAH inhibitor PF-04457845

Date of the early termination of the trial: 2016/03/15

Statement on discontinuation of the study: Portuguese pharmaceutical company Bial conducted a phase I study, to test an FAAH inhibitor intended to affect the endocannabinoid system, in France. 108 subjects received the substance without any moderate or severe adverse reaction; however, another six subjects were hospitalized, with neurological symptoms.

The Swedish trial was a phase II study of another FAAH-inhibitor, previously administered to both healthy volunteers and patients without serious adverse events. However, both Pfizer and Janssen (<http://www.janssen.com/janssen-research-development-llc-voluntarilysuspends-dosing-phase-2-clinical-trials-experimental>) decided to suspend ongoing trials of FAAH inhibitors, until further information was available.

After a time of temporarily halt (2016/01/1), Pfizer decided to close the study (2016/03/15). Patients who participated in the trial were offered continued psychological treatment used in routine care, but no further tests specific to the trial was made. No serious adverse events, deemed to be related to the study drug, occurred in the Swedish trial.

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