**RESULTS**

### DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS

In the FAS population, the mean age of patients was 61.8 years with a majority of women (80.1%) having a diagnosed OA for a mean (SD) of 7.20 (7.269) years concerning the right knee (52.2%). The mean (SD) KL grading was 2.4 (0.5) and the mean (SD) BMI was 29.7 (5.09) kg/m². 93.3% of patients had an history of mean knee pain ≥ 40 in the last 3 months before inclusion and all of them suffered at inclusion of a mean (SD) knee pain in the last 24 hours of 62.09 (14.072). All these baseline characteristics were not significantly different between groups (Table 3).

### FLEXOFYTOL® DECREASED NSAIDS CONSUMPTION

The mean paracetamol of NSAIDs intake decreased with time in all groups but no significant difference was observed between groups at the different time points. While global analyses did not reveal any significant difference between groups at the different time points, complementary analyses on FAS population, covering within groups revealed that only subjects of the Flexofytol® high dose group showed a significant decrease in the intake frequency of paracetamol at the different time points (p=0.016; T1; p=0.016; T3) while no variation with time was observed in low dose and placebo group. For NSAIDs, a significant decrease of intake frequency was observed only in the low dose group (p=0.032; T1; p=0.027; T3).

### EFFECTS OF FLEXOFYTOL® ON KOOS SCORES

KOOS global score and subscales were significantly improved overtime in all groups (p<0.001) and the evolution was found comparable within the three groups in the FAS population (Table 3). Although KOOS global score and subscales changes to T1 and T3 tended to be more important in the BCL groups, no significant difference between groups was found.

### CONCLUSION

Flexofytol®, at a low dose, induced a rapid symptomatic relief of knee pain and a beneficial effect on the patient assessment of disease. Further, at low dose Flexofytol® reduced NSAIDs consumption and showed an excellent safety. This study suggests some beneficial effects of Flexofytol® in symptomatic knee OA over 1 and 3 months, and provides information on the dose to use and the design of a larger phase III clinical trial.