# 1 STUDY SUMMARY

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| Title | **S**tandardized s**T**udy with **A**lmotriptan in ea**R**ly **T**reatment of migraine. |
| Short Title | START |
| Protocol Number | M/31416/51 |
| Phase | Clinical study phase 4 |
| Methodology | Open observational cohort study |
| Study Duration | *Actual study periods:*<br>Initiated (first screening): 15/April/2008<br>Finalized (last patient last visit): 23/March/2009 |
| Study Centres | Multi-center, international study: 63<br>France: 19<br>Italy: 24<br>Spain: 20 |
| Objectives | To describe the effectiveness of Almotriptan in treating acute migraine attacks when pain is mild and in the first hour of pain in everyday primary care clinical practice. |
| Number of Subjects | *Number of subjects (planned and analyzed):*<br>Planned: 800<br>Randomized: 501<br>Completed study: 436<br>Evaluated for safety: 456<br>Evaluated for ITT: 454<br>Evaluated PP: 303 |
| Diagnosis and Main Inclusion Criteria | Following SPC conditions and study requirements, male or female of 18 to 65 years old with a minimum of one year of migraine history (see **¡Error! No se encuentra el origen de la referencia.**) of moderate or severe intensity and with a frequency of 2 to 6 attacks per month for the past 3 months. |
| Study Product, Dose, Route, Regimen | Substance Name: Almotriptan (LAS31416)<br>Administration route: Oral<br>Dosage form: Tablets<br>Dose and regimen: 12.5 mg, 1 tablet during the migraine attack. |
| Duration of administration | Every patient could treat up to three (3) migraine attacks during the two months follow-up period. |
| Reference therapy | None |
| Criteria for evaluation | **Main effectiveness endpoint**:<br>▪ 2 h Pain Free<br><br>**Secondary effectiveness endpoints:**<br>▪ Sustained Pain Free<br>▪ SNAE (Sustained pain free and No Adverse Events)<br>▪ 24 h relapse<br>▪ Second tablet / rescue medication use<br>▪ Associated symptoms presence evolution: Nausea, Vomiting, Photophobia, Phonophobia. Basal - 2h - 24h<br>▪ Migraine attack duration<br>▪ Time loss (functional disability)<br><br>**Other secondary endpoints:**<br>▪ Patients' satisfaction: Basal – At each attack<br>▪ Consistency of response to treatment between attacks (2 h PF in 2/3 attacks)<br>▪ Reported AEs |

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| Statistical Methodology | Descriptive tables and listings were produced, showing the endpoint scores for the study population and the different pre-defined study sub-populations, differentiating patients depending on their medication history or concomitant medication, migraine triggers, stress degree and migraine functional impact. Data from both ITT and PP populations were displayed.<br><br>A comparison was performed to measure the possible influence of the secondary objective of a limited educational intervention on the early intake of the treatment. |