# Effects table: Criteria Definitions and Effects of Placebo and Efalizumab 1mg/kg/wk from the Wave 1 Case Study Report Efalizumab.

|  | **Name** | **Description** | **Source** | **Patient population** | **Fixed Lower†** | **Fixed Upper†** | **Units** | **Placebo**  **(pts number)** | **Efalizumab 1mg/kg/wk**  **(pts number)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Favourable effects** | PASI75\*  Percentage of patients achieving 75% reduction in baseline PASI **at week 12**  The PASI is a measure of the average redness, thickness, and scaliness of the lesions (each graded on a 0–4 scale), weighted by the area of involvement | | ACD2390g | Moderate to severe plaque psoriasis candidate for systemic treatment | 0 | 100 | % | 4.3  (175) | 26.6  (345) |
| ACD2058g | “ | 0 | 100 | % | 2.4  (151) | 38.9a  (149) |
| ACD2059g | “ | 0 | 100 | % | 4.9  (111) | 22.4 a  (211) |
| ACD2600g | “ | 0 | 100 | % | 3.0  (236) | 23.5 a  (450) |
| IMP24011 | Moderate to severe plaque psoriasis candidate for systemic treatment  + “high need” subgroup | 0 | 100 | % | 4.2  (264)  2.7(184) | 31.4 a  (529)  29.5(342) |
|  | |  |  |  |  |  |  |  |
| PGA  Percentage of patients achieving Physician’s Global Assessment clear/almost clear at week 12  This is a seven point scale with 7 being clear and 6 almost clear, 5 mild, 4 mild to moderate, 3 moderate, 2 moderately severe and 1 being severe psoriasis. | | ACD2390g | Moderate to severe plaque psoriasis candidate for systemic treatment | 0 | 100 | % | 5.3 | 33.1 a |
| ACD2058g | “ | 0 | 100 | % | 4.1 | 38.9 a |
| ACD2059g | “ | 0 | 100 | % | 4.1 | 22.4 a |
| IMP24011 | Moderate to severe plaque psoriasis candidate for systemic treatment  + “high need” subgroup | 0 | 100 | % | 7.5 c  2.7b | 29.9 c  25.7 b |
| OLS  Subjects with Overall Lesion Severity (OLS) rating of Minimal or Clear at FT Day 84) | | ACD2058g XOMA SC | Moderate to severe plaque psoriasis candidate for systemic treatment | 0 | 100 | % | 2.9 | 32.1 a |
| ACD2059g XOMA SC | “ | 0 | 100 | % | 4.4 | 24.2 |
| ACD2390g GNE SC | “ | 0 | 100 | % | 3.2 | 25.7 |
| IMP24011 | Moderate to severe plaque psoriasis candidate for systemic treatment  + “high need” subgroup | 0 | 100 | % | 5  2.7 | 34.8  21.3 |
|  | DLQI (Dermatology Life Quality Index) | | ACD 2058g | Moderate to severe plaque psoriasis candidate for systemic treatment | 0 | 100 | % | 2.1 | 5.3 |
|  | | ACD 2059g | Moderate to severe plaque psoriasis candidate for systemic treatment | 0 | 100 | % | 1.7 | 5.5 |
|  |  | ACD 2390g | Moderate to severe plaque psoriasis candidate for systemic treatment | 0 | 100 | % | 1.6 | 5.6 |
| IMP 24011 | Moderate to severe plaque psoriasis candidate for systemic treatment  + “high need” subgroup | 0 | 100 | % | 2.5  2.3 | 6.2  5.4 |
| PASI 50  Percentage of patients achieving 50% reduction in baseline PASI **at week 12** | | IMP24011 | Moderate to severe plaque psoriasis candidate for systemic treatment  + “high need” subgroup | 0 | 100 | % | 20  12 | 56.7  52 |
| **Unfavourable effects** | ADRs | Mild to moderate dose related acute flu-like symptoms | ISS (all RCTs + open label trials)  3291 pts  EU SPC 4.8 | Moderate to severe plaque psoriasis candidate for systemic treatment  + “high need” subgroup |  |  | % | 24 | 41 |
| ADRs | Hypersensitivity reactions, psoriasis,  Arthralgia, psoriatic arthritis, (exacerb./flare)  Back pain, asthenia  ALT and Ph. Alk increase | ISS (RCTs and all open label trials  3,291 pts  EU SPC 4.8 | Moderate to severe plaque psoriasis candidate for systemic treatment  + “high need” subgroup |  |  | % |  | >1/100 <1/10 |
| Meningitis aseptic | Number of cases | PSUR 10 | Cumulative post-mkt data  47,000 pt/yrs |  |  | No |  | 29 |
| Serious infections including pneumonia, sepsis, cellulitis | Proportion of patients experiencing severe infections | ISS (RCTs and all open label trials  3,291 pts | Moderate to severe plaque psoriasis candidate for systemic treatment  + “high need” subgroup |  |  | %/100 pt-yrs | 1.4 | 2.8 |
| Opportunistic infections including fungal infections, tuberculosis, herpes virus infections, EBV, CMV | Number of cases | PSUR 10 | Cumulative post-mkt data  47,000 pt/yrs |  |  | No |  | 111 |
| Serious thrombo  cytopenia | Number of cases | PSUR 10 | Cumulative post-mkt data  47,000 pt/yrs |  |  | No |  | 70 |
| Immune haemolytic anemia | Number of cases | PSUR 10 | Cumulative post-mkt data  47,000 pt/yrs |  |  | No |  | 24 |
| Psoriasis severe forms  (erythrodermic, pustular) | Number of cases | ISS (RCTs and all open label trials  3,291 pts | Moderate to severe plaque psoriasis candidate for systemic treatment  + “high need” subgroup |  |  | % | 1.4 | 3.2 |
| Nervous System disorders including Inflammatory polyradiculopathy, Facial Palsy, GBS, Fisher Miller Syndrome | Number of cases | PSUR 10 | Cumulative post-mkt data  47,000 pt/yrs |  |  | No |  | NA |
| Intersticial lung diseases including lung infiltration, pulmonary fibrosis | Number of cases | PSUR 10 | Cumulative post-mkt data  47,000 pt/yrs |  |  | No |  | 18 |
| Serious cases of psoriasis exacerbation or rebound |  | PSUR 10 | Cumulative post-mkt data  47,000 pt/yrs |  |  | No |  | 390  (0.8/100 pt-years) |
| Brain infections including Encephalitis and PML | Number of cases | PSUR 10 | Cumulative post-mkt data  47,000 pt/yrs  (5,900-8,900 >2 years) |  |  | No |  | 8  (4 PML) |