**Supplementary Table 1**

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| **Worst toxicities (NCI CTC v.03)** | **Lapatinib (%)**  **N=94** | **Placebo (%)**  **N=27** | **P value** |
| Fatigue  Grade 1/2 | 41% | 28% | NS |
| Rash  Grade 1/2  Grade 3 | 64%  6% | 12%  0% | p=0.001 |
| Nausea  Grade 1 | 21% | 17% | NS |
| Mucositis  Grade 1/2 | 15% | 4% | NS |
| Diarrhoea  Grade 1/2 | 56% | 8% | p=0.001 |
| Infection  Grade 1/2  Grade 3 | 6%  1% | 20%  0% | NS |