# 2014. PURSUIT- SC

## Phase 2&3/GOLI/ UC/ Induction

## Subcutaneous Golimumab Induces Clinical Response And remission in Patients With Mod-to-Severe UC

Double blind phase 2 dose-finding and phase 3 dose-confirmation trials.
UC patients randomly assigned to GOLI 100 mg and then 50mg, 200mg and then 100mg, 400mg and then 200mg, 2 weeks apart.

**Phase 2**: dose-response of SC golimumab induction therapy assessed based on the change in Mayo score from baseline to w6.
Primary end point **phase 3:** clinical response at w6.
Secondary end points: clinical remission, mucosal healing, IBDQ change, all at week 6

Results:

- Phase 2, changes from baseline in the Mayo score were 1.0, 3.0, 2.0, and 3.0, in the placebo, 100 mg/50 mg, 200/100 mg, and 400/200 mg goli, respectively.
- Phase 3, clinical response at w6 were 51.0% and 54.9% among patients given 200 mg/ 100 mg and 400 mg/200 mg golimumab, respectively, vs 30.3% placebo (both, p .0001).

Conclusions:

Treatment with SC golimumab induces clinical response, remission, and mucosal healing, and increases quality of life in larger percentages of patients with active UC than placebo.

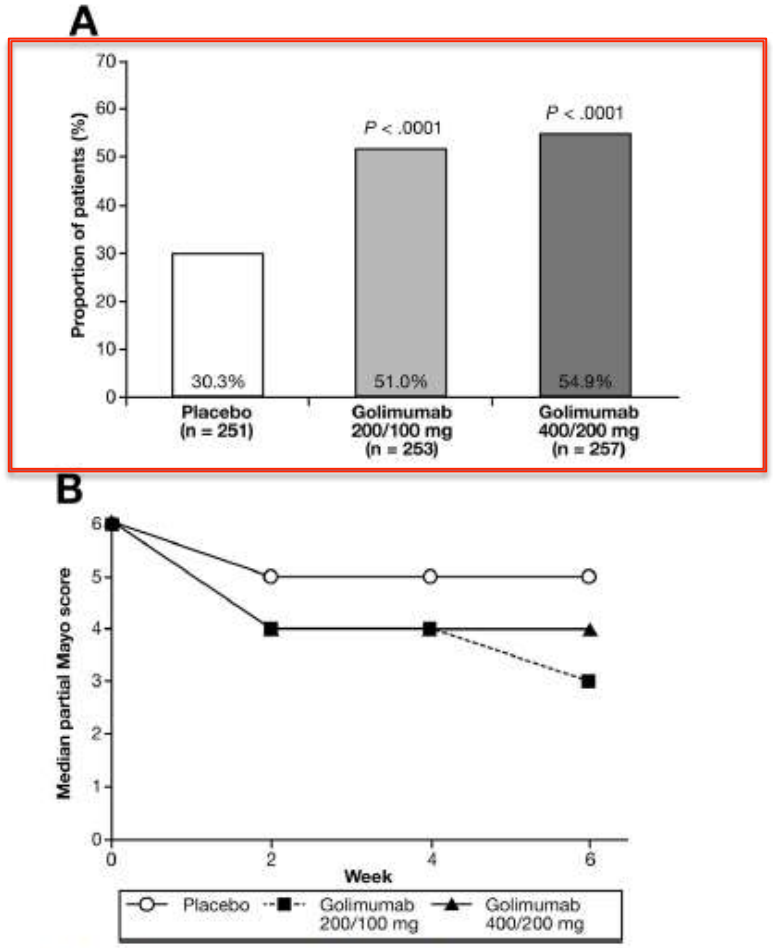


**Figure 3.** Efficacy at week 6 among the primary efficacy population (patients randomized in phase 3): (*A*) proportions of patients achieving clinical response[a,b] (primary efficacy end point) and (*B*) median partial Mayo scores.[a,c a]Patients who had

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