Patients included N=316

Patients excluded N = 0

Safety population N = 316
  One intake N = 161
  Two intakes N = 155

Patients excluded N = 2*

ITT population N= 314 (99.4%)
  One intake N = 159
  Two intakes N = 155

Patients excluded
  N = 16**

PP population N= 298 (94.3%)
  One intake N = 148
  Two intakes N = 150