

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