Screening and Treatment
(cetuximab + irinotecan/FA/5-FU)

Follow-up

Screening
EGFR-typing
Screening visit
0-3 weeks

Treatment
Phase A of part I (up to 24 subjects, low or high dose 5-FU)
6 weeks

Treatment
Phase B of part I (treatment continuation)
until PD or unacceptable toxicity

EOS visit ≥6 weeks after study termination

Follow-up for survival status every 3 months after EOS visit

Screening
EGFR-typing
Screening visit
0-3 weeks

Treatment
Part II (27 subjects with dose of 5-FU selected in phase A of part I)
until PD or unacceptable toxicity

SD, stable disease; PD, disease progression; EOS, end of study visit

* Patients benefitting from combination therapy, but with unacceptable secondary intolerance to irinotecan and/or 5-FU/FA, could receive single-agent cetuximab until unacceptable toxicity or PD.