<Study number>

Table 14.1-2.1 (Page 1 of 2)

Number (percent) of subjects in the analysis sets

All subjects

ADBC AECB DCAB EBAC CBDA BCEA BACD CABE Total

N=7 N=7 N=7 N=7 N=7 N=7 N=7 N=7 N=56

Population

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Subjects 7 (100.0%) 7 (100.0%) 7 (100.0%) 7 (100.0%) 7 (100.0%) 7 (100.0%) 7 (100.0%) 7 (100.0%) 56 (100.0%)

randomized

Safety 7 (100.0%) 7 (100.0%) 7 (100.0%) 7 (100.0%) 7 (100.0%) 7 (100.0%) 7 (100.0%) 7 (100.0%) 56 (100.0%)

analysis set

PK analysis 7 (100.0%) 7 (100.0%) 7 (100.0%) 7 (100.0%) 7 (100.0%) 7 (100.0%) 7 (100.0%) 7 (100.0%) 56 (100.0%)

set

PD analysis 7 (100.0%) 7 (100.0%) 7 (100.0%) 7 (100.0%) 7 (100.0%) 7 (100.0%) 7 (100.0%) 7 (100.0%) 56 (100.0%)

set

Treatment: 150 mg AAA-XXXYYY

Safety analysis set: Subjects that received study drug

PK analysis set: Subjects with evaluable PK parameter data.

Program: C:\Users \Desktop\report (template)\pgm\_saf\p\_demosum3.r 16DEC2011:11:37

<Study number>

Table 14.1-2.1 (Page 2 of 2)

Number (percent) of subjects in the analysis sets

All subjects

ADBC AECB DCAB EBAC CBDA BCEA BACD CABE Total

N=7 N=7 N=7 N=7 N=7 N=7 N=7 N=7 N=56

Population

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Subjects 8 (100.0%) 8 (100.0%) 8 (100.0%) 8 (100.0%) 8 (100.0%) 8 (100.0%) 7 (100.0%) 7 (100.0%) 56 (100.0%)

randomized

Safety 8 (100.0%) 8 (100.0%) 8 (100.0%) 8 (100.0%) 8 (100.0%) 8 (100.0%) 7 (100.0%) 7 (100.0%) 56 (100.0%)

analysis set

PK analysis 8 (100.0%) 8 (100.0%) 8 (100.0%) 8 (100.0%) 8 (100.0%) 8 (100.0%) 7 (100.0%) 7 (100.0%) 56 (100.0%)

set

PD analysis 8 (100.0%) 8 (100.0%) 8 (100.0%) 8 (100.0%) 8 (100.0%) 8 (100.0%) 7 (100.0%) 7 (100.0%) 56 (100.0%)

set

Treatment: 150 mg AAA-XXXYYY

Safety analysis set: Subjects that received study drug

PK analysis set: Subjects with evaluable PK parameter data.

Program: C:\Users\Desktop\report (template)\pgm\_s\p\_demosum3.r 16DEC2011:11:37