



**Figure, Supplemental Digital Content 1. CONSORT flow diagram**

<sup>a</sup>Patients who signed an ICF but did not qualify to enter the pretreatment period based on their screening evaluations. Patients who were rescreened and failed the second time were only counted once; <sup>b</sup>Patients who signed an ICF and entered the pretreatment period, but were not randomized into the study. Patients who were rescreened and failed the second time during the pretreatment period were counted in the screen failure category as well as in the pretreatment failure category. Patients who were rescreened and subsequently randomized were not counted in either of the failure categories.

AE. adverse event; ICF. informed consent form; RW. randomized withdrawal.