Enrolled N = 869

Entered Lean-in n = 394*

Not randomized n = 29

Randomized n = 366

Randomized and not treated n = 1

Patients randomized and treated n = 365

SAXA 2.5 mg q.A.M. n = 74

SAXA 5 mg q.A.M. n = 74

SAXA 2.5/5 mg q.A.M. n = 71

SAXA 5 mg q.P.M. n = 72

Placebo n = 74

Completed 24 wks n = 55†

Completed 24 wks n = 55†

Completed 24 wks n = 52

Completed 24 wks n = 55†

Completed 24 wks n = 53†

Completed 76 wks, n = 41
Completed and not rescued, n = 25

Completed 76 wks, n = 52
Completed and not rescued, n = 35

Completed 76 wks, n = 44
Completed and not rescued, n = 29

Completed 76 wks, n = 46
Completed and not rescued, n = 31

Completed 76 wks, n = 48
Completed and not rescued, n = 31