1424 patients screened

652 patients randomized

772 patients withdrew prior to randomization

646 received treatment*

101 assigned to placebo

65 completed the study

36 discontinued placebo
21 lack of efficacy
13 exacerbation
1 patient withdrew
1 lost to follow-up

105 assigned to FF 200 mcg OD/AM

85 completed the study

20 discontinued FF 200 mcg OD/AM
10 lack of efficacy
2 exacerbation
4 patients withdrew
1 adverse event
1 other
1 non-compliance
1 LFT abnormality

103 assigned to FF 200 mcg OD/PM

82 completed the study

21 discontinued FF 200 mcg OD/PM
13 lack of efficacy
3 exacerbation
1 patient withdrew
1 adverse event
2 other
1 protocol violation

111 assigned to FF 400 mcg OD/AM

96 completed the study

15 discontinued FF 400 mcg OD/AM
9 lack of efficacy
2 exacerbation
1 patient withdrew
2 adverse event
1 non-compliance
1 lost to follow-up
1 protocol violation

113 assigned to FF 400 mcg OD/PM

96 completed the study

17 discontinued FF 400 mcg OD/PM
9 lack of efficacy
2 exacerbation
1 patient withdrew
3 adverse event
1 non-compliance
1 protocol violation

113 assigned to FF 200 mcg BD

96 completed the study

17 discontinued FF 200 mcg BD
13 lack of efficacy
2 patients withdrew
1 adverse event
1 other

103 assigned to FF 200 mcg OD/PM

82 completed the study

21 discontinued FF 200 mcg OD/PM
13 lack of efficacy
3 exacerbation
1 patient withdrew
1 adverse event
2 other
1 protocol violation

111 assigned to FF 400 mcg OD/AM

96 completed the study

15 discontinued FF 400 mcg OD/AM
9 lack of efficacy
2 exacerbation
1 patient withdrew
2 adverse event
1 non-compliance
1 lost to follow-up
1 protocol violation

113 assigned to FF 400 mcg OD/PM

96 completed the study

17 discontinued FF 400 mcg OD/PM
9 lack of efficacy
2 exacerbation
1 patient withdrew
3 adverse event
1 non-compliance
1 protocol violation

103 assigned to FF 200 mcg OD/PM

82 completed the study

21 discontinued FF 200 mcg OD/PM
13 lack of efficacy
3 exacerbation
1 patient withdrew
1 adverse event
2 other
1 protocol violation

111 assigned to FF 400 mcg OD/AM

96 completed the study

15 discontinued FF 400 mcg OD/AM
9 lack of efficacy
2 exacerbation
1 patient withdrew
2 adverse event
1 non-compliance
1 lost to follow-up
1 protocol violation

113 assigned to FF 400 mcg OD/PM

96 completed the study

17 discontinued FF 400 mcg OD/PM
9 lack of efficacy
2 exacerbation
1 patient withdrew
3 adverse event
1 non-compliance
1 protocol violation

*ITT population