



# FORTE FBI02 PHASE I BVITILIGO DATA

JULY 9, 2026



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# LARGE UNMET NEED IN VITILIGO PRESENTS A SUBSTANTIAL MARKET OPPORTUNITY

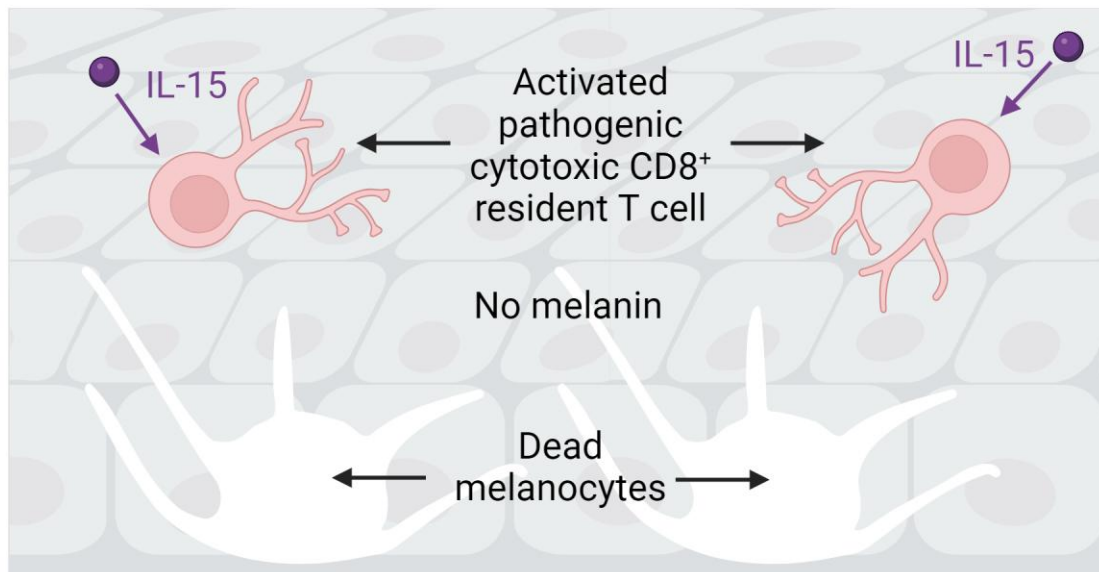
- Vitiligo is an autoimmune disease of the skin driven by pathogenic T cells that kill melanocytes and create white spots
- Vitiligo results in sensitive skin (increasing likelihood of sun burns), eye abnormalities, emotional challenges, and leads to a predisposition of other autoimmune conditions.
- Market Opportunity
  - Prevalent in 0.76% of population – 2 Million in US
  - While JAK inhibitors have demonstrated efficacy in vitiligo, regulatory scrutiny of the JAK class including black box warnings has dampened enthusiasm for this class and as a result there remains a significant unmet need for safe and effective therapies for treating AA and vitiligo



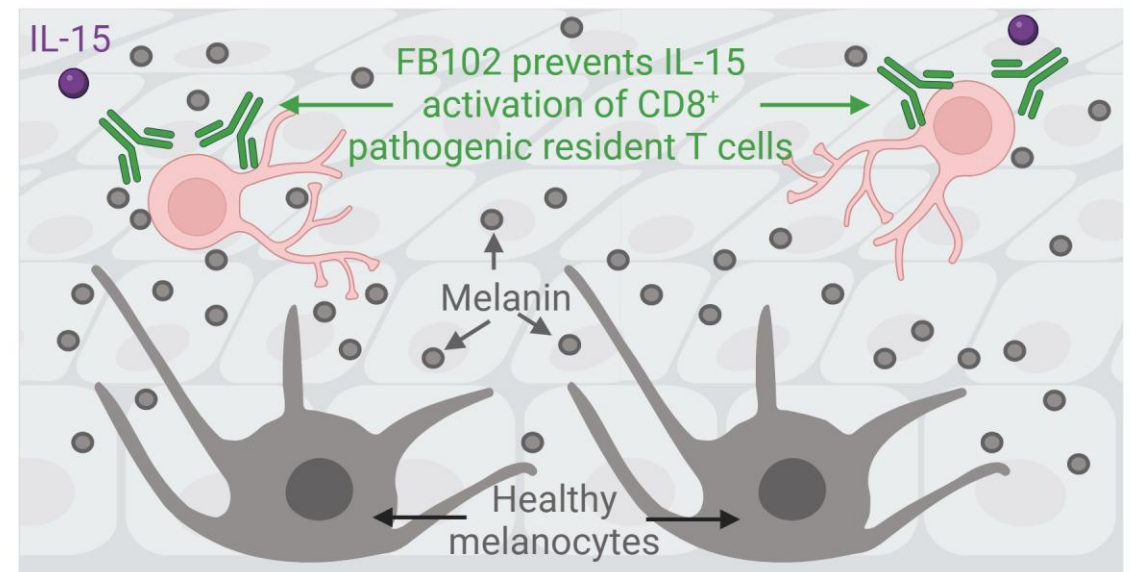
Amy Deanna / CoverGirl cosmetics

# IL-15 ACTIVATION OF PATHOGENIC CD8+ T CELLS IN SKIN

Vitiligo patients have unpigmented skin due activated pathogenic T cells killing melanocytes



FB102 blocks activation of pathogenic T cells, restoring melanocyte health and skin pigmentation



[Tokura Front Immunol. 2021 PMID 33633737](#)

# IL-2 THERAPY DRIVES VITILIGO

## Enhanced Survival Associated with Vitiligo Expression during Maintenance Biotherapy for Metastatic Melanoma<sup>(1)</sup>

Peter D. Boasberg<sup>1</sup>, Dave S.B. Hoon<sup>2</sup>, Lawrence D. Piro<sup>1</sup>, Maureen A. Martin<sup>1</sup>, Akhide Fujimoto<sup>2</sup>, Timothy S. Kristedja<sup>1</sup>, Sandeep Bhachu<sup>1</sup>, Xing Ye<sup>2</sup>, Regina R. Deck<sup>1</sup> and Steven J. O'Day<sup>1</sup>

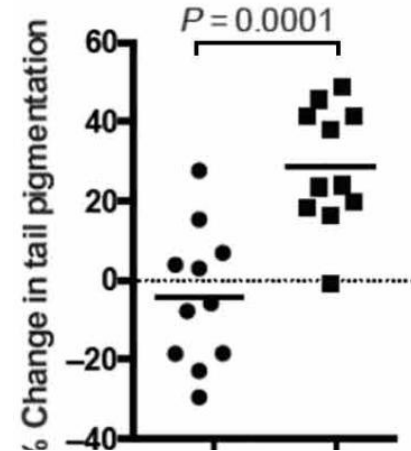
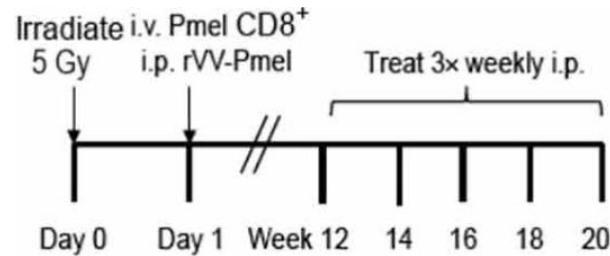
In a large retrospective analysis of 374 metastatic melanoma patients treated with high-dose IL-2, a total of 84 patients (22%) developed treatment-related vitiligo, although in patients with objective clinical responses the incidence of vitiligo was nearly 50% <sup>(2)</sup>

1) Journal of Investigative Derm. (2006) Vol 126

2) Journal of Clinical Oncology V19(15)

# AN ANTI-CD122 ANTIBODY IS EFFECTIVE IN A MOUSE VITILIGO MODEL WITH ESTABLISHED DISEASE

## Repigmentation study



Melanin-reactive T cells eliminated pigment in tail

Vehicle (control) treatment did not restore pigment



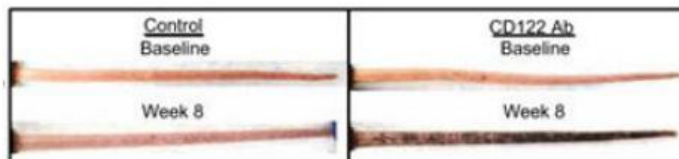
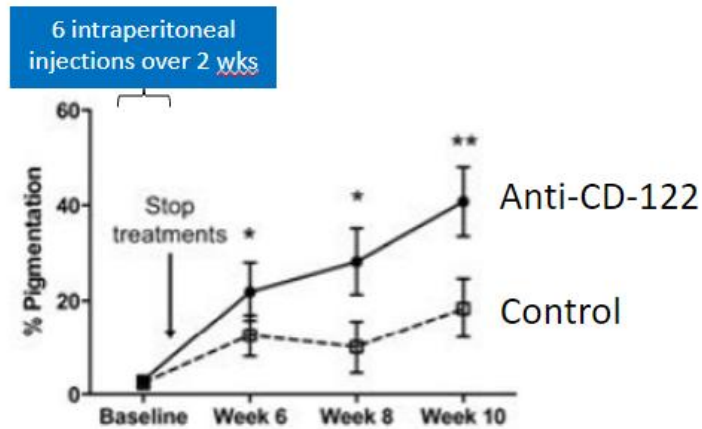
Melanin-reactive T cells eliminated pigment in tail

Anti-CD122 treatment restored pigmentation

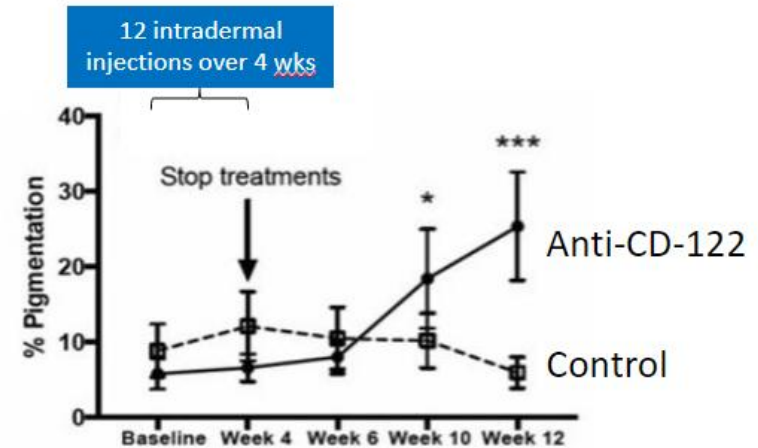
Richmond, 2012. Sci Transl Med. 2018 PMID 30021889

# ANTI-CD122 IN A MOUSE MODEL OF VITILIGO: POTENTIAL OF DURABLE RESPONSE WITH INFREQUENT DOSING REGIMEN

## Systemic



## Local



Richmond JM et al, *Sci Transl Med*. 2018;10(450): eaam7710.

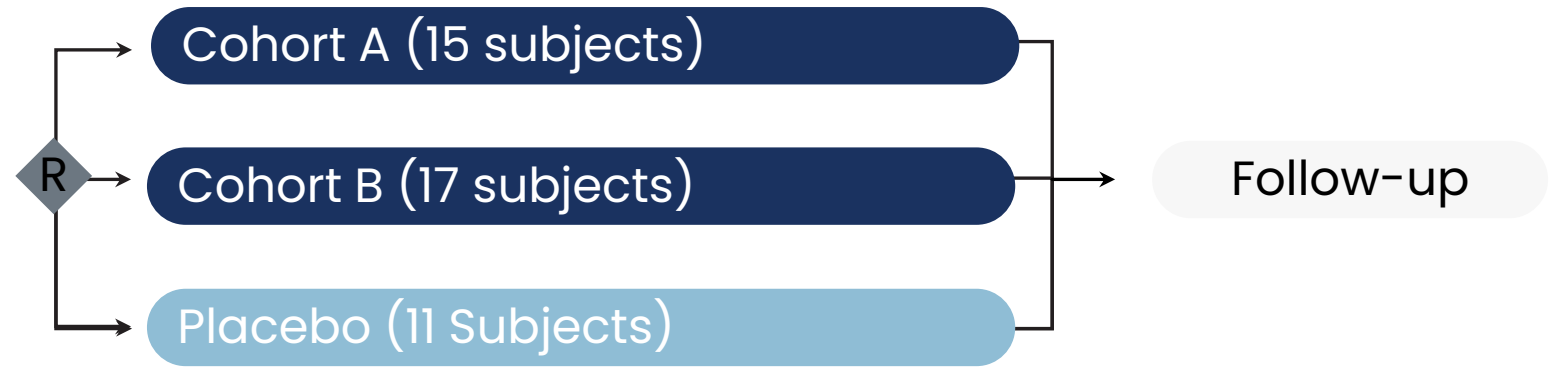
Note: anti-mouse CD122 (surrogate molecule) was used in these studies.



# FBI 02 PLACEBO CONTROLLED PHASE I B VITILIGO

# FBI02-401 DOUBLE-BLIND PLACEBO-CONTROLLED PHASE 1B VITILIGO STUDY DESIGN

## Treatment

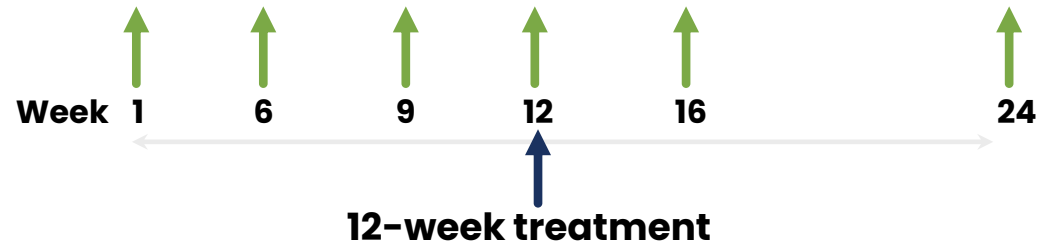


### Screening

*Includes Central Read FVASI*

### Randomization

*3:1 Ratio  
FBI02:PBO*



### Safety Follow-up

↑ Central Read FVASI

## SUMMARY OF FBI02 PHASE 1B VITILIGO STUDY

- The FBI02 phase 1b double-blind placebo-controlled vitiligo study enrolled 43 subjects 3:1 randomized with 11 on placebo and 32 on FBI02.
  - The primary endpoint of the study was mean percent FVASI improvement from baseline at week 24 as assessed by central-review
  - 12-week treatment with FBI02 or Placebo then observed through Week 24
  - Forte enrolled 2 FBI02 treatment cohorts in the trial including the 3 mg/kg maintenance cohort previously disclosed : FBI02 Cohort A (N=15) and FBI02 Cohort B (N=17)
  - 11 placebo subjects were in the ITT population
  - The protocol defined efficacy-evaluable population excluded one placebo subject (n=10) due to facial hair and that subject also experienced significant vitiligo progression during the study.
  - As a result, the protocol defined efficacy-evaluable placebo population (N=10) provides a more conservative assessment of the FBI02 activity.

# ITT: STATISTICALLY SIGNIFICANT PRIMARY ENDPOINT OF FVASI WEEK 24 PERCENT IMPROVEMENT FROM BASELINE: INTENT TO TREAT (ITT) POPULATION

<b>Week 24 Mean % Improvement</b>	<b>FB102</b>	<b>PBO (ITT: N=11)</b>	<b>PBO Adjusted</b>	<b>p-value</b>
<b>Cohort A (N=15)</b>	28.8%	-16.2%	+45.0 pts	0.013
<b>Cohort B (N=17)</b>	30.4%	-16.2%	+46.6pts	0.009
<b>FB102 (N=32)</b>	29.6%	-16.2%	+45.8 pts	0.005

Intent to Treat placebo population includes 1 placebo subject that was excluded from the efficacy evaluable population. (ITT PBO n=11). The protocol defined efficacy-evaluable (EE) population excluded this one placebo subject due to facial hair (EE PBO n=10). That placebo subject also had worsening vitiligo. As a result, the EE PBO group provides a more conservative assessment of the FB102 activity.

**EE: STATISTICALLY SIGNIFICANT PRIMARY ENDPOINT OF FVASI WEEK 24 PERCENT IMPROVEMENT FROM BASELINE: PROTOCOL-DEFINED EFFICACY EVALUABLE (EE) POPULATION**

<b>Week 24 Mean % Improvement</b>	<b>FB I02</b>	<b>PBO (EE: N=10)</b>	<b>PBO Adjusted</b>	<b>p-value</b>
<b>Cohort A (N=15)</b>	28.8%	7.9%	+20.9 pts	0.040
<b>Cohort B (N=17)</b>	30.4%	7.9%	+22.5pts	0.027
<b>FB I02 (N=32)</b>	29.6%	7.9%	+21.7 pts	0.020

The protocol defined efficacy-evaluable (EE) population excluded one placebo subject due to facial hair (EE PBO n=10). That placebo subject also had worsening vitiligo.

As a result, the EE PBO group provides a more conservative assessment of the FB I02 activity.

# STATISTICAL SIGNIFICANCE ACHIEVED BY DAY 64 AND CONTINUED THROUGH 24 WEEKS WITH 12-WEEK TREATMENT

	<b>FVASI mean % improvement</b>	<b>FBI02 (N=32)</b>	<b>PBO (N=10)</b>	<b>PBO-Adjusted</b>	<b>p-value</b>
	<b>Week 6</b>	5.6%	0.3%	+5.3 pts	0.059
	<b>Week 9 (Day 64)</b>	14.4%	1.9%	+12.5 pts	0.023
End of treatment →	<b>Week 12</b>	21.9%	5.4%	+16.5 pts	0.028
period	<b>Week 16</b>	28.6%	8.2%	+20.4 pts	0.023
	<b>Week 24</b>	29.6%	7.9%	+21.7 pts	0.020

FBI02 activity observed at day 64, with statistically significant 12.5 percentage point separation from placebo (p=0.023) and continued through week 24, after 12-week treatment period.

84% (27/32) FBI02 treated subjects improved from baseline to week 24 following the 12-week treatment period and 0% (0/32) worsened. 27% (3/11) of placebo subject worsened during the 24-week period.

## SUBJECTS WITH GREATER BASELINE VITILIGO INVOLVEMENT OUTPERFORMED ON FBI02 (BASELINE FVASI $\geq 0.75$ )

	FVASI mean % improvement	FB102 (N=17)	PBO (N=4)	PBO-Adjusted	p-value
End of treatment period →	<b>Week 6</b>	7.2%	0.5%	+6.7 pts	0.167
	<b>Week 9 (Day 64)</b>	19.4%	1.2%	+18.2 pts	0.058
	<b>Week 12</b>	29.6%	1.7%	+27.9 pts	0.033
	<b>Week 16</b>	40.2%	1.5%	+38.7 pts	0.010
	<b>Week 24</b>	43.2%	0.5%	+42.7 pts	0.006

FB102 demonstrated significant responses in subjects with more extensive disease with a 43% mean percent improvement from baseline at week 24 (P=0.006), underscoring robust FB102 disease activity.

- 0.75 baseline FVASI corresponds to 20-25% facial depigmentation.

# FVASI IMPROVEMENT AT WEEK 24 VS COMPETITORS (PHASE 2 DATA)

F-VASI Percent Improvement at Week 24		
Medication	Treatment	Placebo
Upadacitinib 22 mg	34.0%	14.4%
Upadacitinib 11 mg	35.6%	14.4%
Povorcitinib 75 mg	29.4%	5.1%
Povorcitinib 45 mg	36.4%	5.1%
Ritlecitinib 50 mg	18.5%	-2.1%
Ritlecitinib 100/50 mg	21.2%	-2.1%
<b>Oral JAK Range</b>	<b>21-36%</b>	<b>2-14%</b>
<b>FB102 (n=32)</b>	<b>29.6% (p=0.020)</b>	<b>7.9%</b>
<b>FB102 Baseline FVASI ≥ 0.75 (n=17)</b>	<b>43.2% (p=0.006)</b>	<b>0.5%</b>

## WEEK 24 FVASI50 AND FVASI75 DATA

<b>Population</b>	<b>FVASI50 FB102</b>	<b>FVASI50 PBO</b>	<b>FVASI75 FB102</b>	<b>FVASI75 PBO</b>
Protocol Defined Efficacy-evaluable	11/32 (34.4%)	1/10 (10.0%)	4/32 (12.5%)	1/10 (10.0%)
Baseline FVASI $\geq 0.75$	10/17 (58.8%)	0/4 (0.0%)	4/17 (23.5%)	0/4 (0.0%)

FB102 achieved FVASI50 of 58.8% in FVASI  $\geq 0.75$  subjects and 34.4% in overall FB102 treated subjects at week 24

FB102 achieved FVASI75 of 23.5% in FVASI  $\geq 0.75$  subjects and 12.5% of overall FB102 treated subjects at week 24

Responder endpoint was impacted by one placebo FVASI75 responder, reinforcing the importance of randomized controlled studies and baseline severity when interpreting vitiligo responder endpoints.

# FVASI50 AT WEEK 24 VS COMPETITORS (PHASE 2 DATA)

F-VASI50 at Week 24		
Medication	Treatment	Placebo
Upadacitinib 22 mg	39.5%	10.9%
Upadacitinib 11 mg	38.3%	10.9%
Povorcitinib 75 mg	23.8%	7.0%
Povorcitinib 45 mg	34.9%	7.0%
Ritlecitinib 50 mg	Not Reported	Not Reported
Ritlecitinib 100/50 mg	Not Reported	Not Reported
<b>Oral JAK Range</b>	<b>23.8-39.5%</b>	<b>7-10.9%</b>
<b>FB102 (n=32)</b>	<b>34.4%</b>	<b>10.0%</b>
<b>FB102 baseline FVASI <math>\geq</math> 0.75 (n=17)</b>	<b>58.8%</b>	<b>0.0%</b>

# FVASI75 AT WEEK 24 VS COMPETITORS (PHASE 2 DATA)

F-VASI75 at Week 24		
Medication	Treatment	Placebo
Upadacitinib 22 mg	14.0%	2.2%
Upadacitinib 11 mg	19.1%	2.2%
Povorcitinib 75 mg	11.9%	2.3%
Povorcitinib 45 mg	14.0%	2.3%
Ritlecitinib 50 mg	7.7%	0.0%
Ritlecitinib 100/50 mg	8.5%	0.0%
<b>Oral JAK Range</b>	<b>7.7-19.1%</b>	<b>0-2.3%</b>
FB102 (n=32)	12.5%	10.0%
FB102 Baseline FVASI $\geq$ 0.75 (n=17)	23.5%	0.0%

# FBI02 RE-PIGMENTATION



Baseline  
FVASI = 0.75



Week 12  
FVASI = 0.20  
73% improvement



Week 24  
FVASI = 0.10  
87% improvement

# FBI02-401 CONTINUES TO DEMONSTRATE STRONG SAFETY PROFILE

<b>Safety</b>	<b>FBI02</b>	<b>Placebo</b>
≥1 TEAE	25/32 (78.1%)	9/11 (81.8%)
Mild (Grade 1)	23/32 (71.9%)	9/11 (81.8%)
Moderate (Grade 2)	18/32 (56.3%)	6/11 (54.5%)
Severe (≥ Grade 3)	0	0

FBI02 continues to demonstrate a strong safety profile and compared favorably to placebo with only mild to moderate AEs.

# SUMMARY

**In double-blind placebo-controlled study, FB102 demonstrated robust activity, with statistically significant improvement in vitiligo from baseline to week 24, statistically significant responses occurring early (day 64), robust responder analysis, and continuing improvement through week 24 after 12-week treatment period and continuing strong safety profile:**

- FB102 achieved 29.6% mean FVASI improvement from baseline at week 24 (p-value = 0.020)
- Response to FB102 was observed early, with statistically significant improvements observed by the day 64 visit (p=0.023), continuing through week 24, after completion of the 12-week treatment period.
- FB102 achieved 43.2% mean FVASI improvement from baseline at week 24 (p-value = 0.006) in subjects with greater disease involvement having baseline FVASI  $\geq 0.75$  (approximately one-quarter of face fully depigmented), including:
  - FVASI50 = 58.8%
  - FVASI75 = 23.5%
- Responder endpoints in overall population achieved FVASI50 in 34.4% of FB102 treated subjects at week 24 with FVASI 75 achieved in 12.5% of FB102 treated subjects at week 24
  - Placebo responder reinforces the importance of randomized controlled studies and baseline severity when interpreting vitiligo responder endpoints.
- The majority of FB102 treated subjects continued to improve through week 24 after completion of the 12-week treatment period with an additional 8-14 percentage point FVASI improvement between week 12 and 24.
- 84% (27/32) of FB102 treated subjects improved from baseline to week 24 following the 12-week treatment period and 0% (0/32) worsened. 27% (3/11) of placebo subjects worsened during the 24 week period.
- FB102 continues to demonstrate a strong safety profile and compared favorably to placebo with only mild to moderate AEs.