**SUPPLEMENTAL MATERIAL**

**METHODS**

Other exclusion criteria included the following: evidence or history of clinically significant hematological, renal, endocrine, pulmonary, gastrointestinal, oncologic, dermatologic, cardiovascular disease, or immunologic disease; significant neurological disorder or hepatic disorder; acquired immune deficiency syndrome (AIDS), human immunodeficiency virus (HIV) positive test; and history of either treatment-resistant schizophrenia according to Kane criteria,1 myeloproliferative disorder or clozapine-induced agranulocytosis or granulocytopenia, Neuroleptic Malignant Syndrome, clinically significant tardive dyskinesia, non-nicotine psychoactive substance dependence within 12 months of screening or substance abuse within 3 months prior to screening, or receipt of clozapine in the 6 months prior to randomization, depot antipsychotic medication in the 3 months prior to randomization, or electroconvulsive therapy within 6 months prior to randomization.

These criteria did not preclude adequately controlled hypothyroidism or hyperthyroidism, chronic bronchitis, mild emphysema, chronic obstructive pulmonary disease, controlled Type 2 diabetes, positive hepatitis C antibody with normal liver functions tests, controlled essential hypertension and nonclinically significant sinus bradycardia and sinus tachycardia.

Patients were additionally excluded for repeated demonstration of (Fridericia’s) corrected QT interval >450 msec on 12-lead ECG at screening or baseline and white blood cell (WBC) count <3500/mm3 or absolute neutrophil count (ANC) <2000/mm3 (thresholds for patients with benign ethnic neutropenia, WBC <3000/mm3, ANC <1500/mm3), positive urine drug screen for non-prescribed medications (unless the documented clinical history excluded a substance-induced etiology for the current episode of acute schizophrenia), use of prohibited medications that could not be discontinued during the study, inability to reduce daily benzodiazepine intake during hospitalization to a protocol-defined level, and clinically significant abnormal laboratory test results at screening. Screening aspartate aminotransferase (AST) and alanine aminotransferase (ALT) must have been ≤2 times the upper limit of the reference range, and total bilirubin, ≤1.5 times of the upper limit of the reference range.

Women of childbearing potential must have been sexually abstinent or agreed to use contraception from screening through 30 days after the last dose of study drug. Pregnant and breastfeeding women were excluded.

**TABLE S1.** Change From Baseline at Day 28 in PANSS-Derived Marder Factor Scores

|  |  |  |  |
| --- | --- | --- | --- |
| **Assessment** | **N** | **LS Mean (SE) Change From Baseline** | **Difference From Placebo** |
| **LS Mean (SE) Change** | **80% CI** | ***P*-Value** |
| **Marder Positive Factor Score** |
| PF-02545920 5 mg Q12H | 63 | –5.0 (0.6) | –0.7 (0.9) | (–1.8, 0.4) | NS |
| PF-02545920 15 mg Q12H | 58 | –4.7 (0.6) | –0.4 (0.9) | (–1.5, 0.8) | NS |
| Risperidone 3 mg Q12H | 26 | –6.9 (0.9) | –2.6 (1.1) | (–4.1, –1.2) | 0.010 |
| Placebo | 63 | –4.3 (0.6) | - | - | - |
| **Marder Negative Factor Score** |
| PF-02545920 5 mg Q12H | 63 | –2.8 (0.6) | –0.8 (0.8) | (–1.8, 0.2) | NS |
| PF-02545920 15 mg Q12H | 58 | –2.6 (0.6) | –0.6 (0.8) | (–1.6, 0.4) | NS |
| Risperidone 3 mg Q12H | 26 | –2.8 (0.8) | –0.8 (1.0) | (–2.1, 0.5) | NS |
| Placebo | 63 | –2.0 (0.6) | - | - | - |
| **Marder Disorganized Thought Score** |
| PF-02545920 5 mg Q12H | 63 | –2.1 (0.4) | –0.4 (0.6) | (–1.2, 0.4) | NS |
| PF-02545920 15 mg Q12H | 58 | –1.8 (0.5) | –0.1 (0.6) | (–0.9, 0.7) | NS |
| Risperidone 3 mg Q12H | 26 | –3.2 (0.7) | –1.5 (0.8) | (–2.5, –0.4) | 0.035 |
| Placebo | 63 | –1.7 (0.4) | - | - | - |
| **Marder Hostility / Excitement Score** |
| PF-02545920 5 mg Q12H | 63 | –0.8 (0.4) | –0.04 (0.5) | (–0.7, 0.6) | NS |
| PF-02545920 15 mg Q12H | 58 | –0.6 (0.4) | 0.2 (0.5) | (–0.5, 0.8) | NS |
| Risperidone 3 mg Q12H | 26 | –2.4 (0.5) | –1.7 (0.6) | (–2.5, 0.8) | 0.005 |
| Placebo | 63 | –0.7 (0.4) | - | - | - |
| **Marder Anxiety / Depression Score** |
| PF-02545920 5 mg Q12H | 63 | –2.5 (0.4) | 0.1 (0.5) | (–0.6, 0.8) | NS |
| PF-02545920 15 mg Q12H | 58 | –2.2 (0.4) | 0.5 (0.5) | (–0.2, 1.2) | NS |
| Risperidone 3 mg Q12H | 26 | –4.3 (0.6) | –1.7 (0.7) | (–2.6, 0.9) | 0.007 |
| Placebo | 63 | –2.6 (0.4) | - | - | - |
| Level of significance is 0.1.CI indicates confidence interval; LS, least squares; NS, not statistically significant; SE, standard error. |

**TABLE S2.** Change From Baseline at Day 28 in PANSS-Derived BPRS, CGI-S, and GAF Scores

|  |  |  |  |
| --- | --- | --- | --- |
| **Assessment** | **N** | **LS Mean (SE) Change From Baseline** | **Difference From Placebo** |
| **LS Mean (SE) Change** | **80% CI** | ***P*-Value** |
| **PANSS-Derived BPRS Score** |
| PF-02545920 5 mg Q12H | 63 | –3.4 (0.4) | –0.3 (0.6) | (–1.1, 0.4) | NS |
| PF-02545920 15 mg Q12H | 58 | –3.1 (0.4) | –0.04 (0.6) | (–0.8, 0.7) | NS |
| Risperidone 3 mg Q12H | 26 | –5.1 (0.6) | –2.0 (0.7) | (–2.9, –1.1) | 0.003 |
| Placebo | 63 | –3.1 (0.4) | - | - | - |
| **CGI-I Score** |
| PF-02545920 5 mg Q12H | 63 | 3.2 (0.1) | –0.1 (0.2) | (–0.3, 0.2) | NS |
| PF-02545920 15 mg Q12H | 58 | 3.4 (0.1) | 0.1 (0.2) | (–0.1, 0.4) | NS |
| Risperidone 3 mg Q12H | 26 | 2.5 (0.2) | –0.8 (0.3) | (–1.1, –0.4) | 0.002 |
| Placebo | 63 | 3.3 (0.1) |  |  |  |
| **CGI-S Score** |
| PF-02545920 5 mg Q12H | 63 | –0.7 (0.1) | –0.1 (0.2) | (–0.3, 0.1) | NS |
| PF-02545920 15 mg Q12H | 58 | –0.6 (0.1) | –0.1 (0.2) | (–0.2, 0.2) | NS |
| Risperidone 3 mg Q12H | 26 | –0.9 (0.2) | –0.4 (0.2) | (–0.6, –0.1) | 0.039 |
| Placebo | 63 | –0.6 (0.1) |  |  |  |
| **GAF Score** |
| PF-02545920 5 mg Q12H | 62 | 5.7 (1.0) | –0.2 (1.5) | (–2.1, 1.7) | NS |
| PF-02545920 15 mg Q12H | 57 | 6.1 (1.1) | 0.2 (1.5) | (–1.7, 2.2) | NS |
| Risperidone 3 mg Q12H | 26 | 8.4 (1.6) | 2.5 (1.9) | (0.1, 5.0) | NS |
| Placebo | 62 | 5.9 (1.0) | - | - | - |
| Level of significance is 0.1.BPRS indicates Brief Psychiatric Rating Scale; CGI-I, Clinical Global Impression of Improvement; CGI-S, Clinical Global Impression of Severity; CI, confidence interval; GAF, Global Assessment of Function; LS, least squares; NS, not statistically significant; PANSS, Positive and Negative Syndrome Scale; SE, standard error. |

**Figure S1.** Patient disposition.

Screened N = 368

Randomized N = 259

PF-02545920

15 mg Q12H

N = 74

Risperidone

3 mg Q12H

N = 37

Placebo

N = 74

PF-02545920

5 mg Q12H

N = 74

Completed n = 58

Completed n = 25

Completed n = 60

Completed n = 52

Discontinued n = 16

Death n = 1

Insufficient clinical

 response n = 4

Lost to follow-up

 n = 1

Wanted to withdraw

 n = 4

Protocol violation

 n = 1

Other n = 3

Drug-related AE
n = 0

Other AE n = 2

Discontinued n = 22

Death n = 0

Insufficient clinical

 response n = 5

Lost to follow-up

 n = 2

Wanted to withdraw

 n = 8

Protocol violation

 n = 1

Other n = 1

Drug-related AE
n = 3

Other AE n = 2

Discontinued n = 11

Death n = 0

Insufficient clinical

 response n = 0

Lost to follow-up

 n = 0

Wanted to withdraw

 n = 5

Protocol violation

 n = 0

Other n = 3

Drug-related AE
n = 1

Other AE n = 2

Treated n = 36

Withdrew for personal reasons
n = 1

Treated n = 74

Treated n = 74

Treated n = 74

Discontinued n = 14

Death n = 0

Insufficient clinical

 response n = 5

Lost to follow-up

 n = 0

Wanted to withdraw

 n = 5

Protocol violation

 n = 0

Other n = 0

Drug-related AE
n = 3

Other AE n = 1

**Table S3**

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