Additional file 1.

The constituent clinical studies were conducted in full compliance with Food and Drug Administration guidelines for good clinical practice and in accordance with the ethical principles that have their origins in the Declaration of Helsinki. The protocol of each study was approved by an institutional review board at sites in the United States or independent ethics committee at sites outside of the United States (Supplementary table). The studies were conducted in compliance with guidelines for good clinical practice; all patients gave informed written consent to participate.

### Table S1. Institutional Review Boards and Independent Ethics Committees

<table>
<thead>
<tr>
<th><strong>Institutional Review Board: United States</strong></th>
<th><strong>Independent Ethics Committee: Sites Outside the United States</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>The Copernicus Group IRB</td>
<td>Empresa Social del Estado Hospital Mental de Antioquia</td>
</tr>
<tr>
<td>Sharp HealthCare</td>
<td>C.E.I Campo Abierto Ltda</td>
</tr>
<tr>
<td>Western Institutional Review Board</td>
<td>Sistema Nervioso de Risaralda</td>
</tr>
<tr>
<td>University of Texas Health Science Center at Huston</td>
<td>Human Studies Committee</td>
</tr>
</tbody>
</table>

**Colombia**

- Empresa Social del Estado Hospital Mental de Antioquia
- C.E.I Campo Abierto Ltda
- Sistema Nervioso de Risaralda

**India**

- Shanti Nursing Home
- Mental Illness Treatment and Rehabilitation [MITR] Hospital
- Poona Hospital and Research Centre
- Sheth VS Hospital
- Spandana Ethics Committee
- VIMHANS Hospital
- DMHC Ethics Committee
- Kanpur Medical Ethics Committee
- SHASHVAT
- Jaslok Hospital and Research Centre
- Maharashtra Institute of Mental Health
- North Maharashtra Ethics Committee
- Andhra Medical College
- Nitte University
- Jagadguru Shi Shivarathreeshwaru Medical College
- Mallikatta Ethical Committee
- Lucknow Ethics Committee
- Brahmin Mitra Mandal Society
- Abhaya Hospital
- Mahendru Psychiatric Centre
- Kasturba Medical College
<table>
<thead>
<tr>
<th>Deenanath Mangeshkar Hospital &amp; Research Centre</th>
<th>Sri Venkateshwara Medical College</th>
<th>RK Yadav Memorial and Mental Health De-addiction Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Malaysia</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ministry of Health Malaysia c/o Institute for Health Management</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Romania</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comisia Nationala de Etica Pentru Studiul Clinic al Medicamentului</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Russia</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ministry of Social Health and Development of Russian Federation</td>
<td>St. Petersburg State Healthcare Institution</td>
<td>State Educational Institution of High Professional Education</td>
</tr>
<tr>
<td>St. Petersburg Scientific Research Psychoneurological Institute of Roszdrav</td>
<td>Russian Academy of Medical Science Institution Research Centre for Mental Health of RAMS</td>
<td>State Healthcare Institution of city of Moscow ‘Clinical Mental Hospital</td>
</tr>
<tr>
<td>Federal Body of Quality Control Drugs</td>
<td>Republican Ethic Committee</td>
<td>Federal Service on Surveillance in Healthcare and Social Development of Russian Federation</td>
</tr>
<tr>
<td><strong>Ukraine</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The Central Ethic Commission of the Ministry of Health of Ukraine</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>