

Supplementary table 1. List of central independent ethics committees or institutional review boards used by all investigators except those who were required to use their local IRB.

Name of ethics committee or institutional review boards
National Agency for Medicines and Medical Devices, Romania
Comisia Națională de Bioetică a Medicamentului, Romania
Bioethics Committee at the Okręgowa Izba Lekarska in Łódź, Poland
Ethical Council at the MoH of RF, Russia
State Expert Center of the Ministry of Health of Ukraine, Ukraine

Supplementary table 2. List of ethics committees or institutional review boards used by the investigators indicated

Name of ethics committee or institutional review boards
Aichi Medical Association IRB, Japan
Jintokukai Sakayori Clinic IRB, Japan
Jisenkai Nanko Psychiatric Institute IRB Japan
Yoyogi Mental Clinic IRB, Japan
Dr.Mano Medical Clinic IRB, Japan
Sankeikai Nishigahara Hospital IRB, Japan
Asai Dermatology Clinic IRB, Japan
NHO Hizen Psychiatric Center IRB, Japan
Osaka Medical Association IRB, Japan
Asakayama General Hospital IRB
Fujita Health University Hospital IRB, Japan
Ekihigashi Hifuka Clinic IRB, Japan

Zenshukai Hospital IRB, Japan

Hakuseikai Aoki Hospital IRB, Japan

Shiosakikai Ino Hospital IRB, Japan

Sakurazaka Circulatory Clinic IRB, Japan

National Center of Neurology and Psychiatry IRB, Japan

Aichi Medical University Hospital IRB, Japan

LEC of SPB SHI "Psychiatric Hospital #1 n.a. P.P.Kaschenko", Russia

LEC at SPB SR Psychoneurological Inst. n.a.V.M.Bekhterev of MoH, Russia

LIEC at SBHI "Chelyabinsk Region Clinical Hospital", Russia

LEC at Msc Scientific Research Inst. of Psychiatry, Russia

EC at "Saratov Regional Psychiatry Hospital of St. Sofia", Russia

EC of the SBHI "Sverdlovsk Regional Clinical Psychiatric Hospital", Russia

LEC at SHI "Psychiatric hospital #1 n. a. N.A. Alexeev", Russia

LEC at JSC "Scientific Centre of Personalized Medicine", Russia

EC of BHIOR "Clinical Psychiatric Hospital n.a. N.N. Solodnikov", Russia

LEC Kyiv City Psychoneurological Hospital #2, Ukraine

LEC CI Cherkasy Reg.Psych.Hospital, Ukraine

LEC Kharkiv Reg.Clin.Psych.Hosp.#3, Ukraine

LEC State Institution Institute of Neurology, Psychiatry and Narcology of NAMSU, Ukraine

LEC Regional Psychoneurological Hospital #3, Ukraine

LEC CI Kherson Regional Psychiatric Hospital, Ukraine

LEC Regional Psychoneurological Hospital #1, Ukraine

LEC CI " Lviv Regional Clinical Psychiatric Hospital", Ukraine

LEC Communal Institution of Kyiv Regional Council: Regional Psychiatric-Narcolo, Ukraine

LEC TMA Psychiatry in Kyiv, Ukraine

LEC CI Odesa Regional Psychiatric Hospital №2, Ukraine

LEC Transcarpathian Regional Narcological Dispensary, Ukraine

Supplementary table 3. Adverse events by treatment period at the initial dose increase from 40 to 80mg/d in max dose 80mg group (safety population)

Adverse events [n (%)]	Max dose 80mg group (N=166)	Number of days after initial dose increase from 40 to 80mg/d				
		1-7	8-14	15-21	22-28	≥ 29
Any adverse events	82 (49.4)	31 (18.7)	9 (5.9)	12 (8.2)	15 (10.8)	15 (11.6)
Common adverse events^a						
Constipation	9 (5.4)	2 (1.2)	1 (0.7)	1 (0.7)	0 (0)	5 (3.9)
Nasopharyngitis	9 (5.4)	0 (0)	1 (0.7)	1 (0.7)	2 (1.4)	5 (3.9)
Akathisia	8 (4.8)	3 (1.8)	2 (1.3)	1 (0.7)	1 (0.7)	1 (0.8)
Headache	7 (4.2)	3 (1.8)	2 (1.3)	0 (0)	0 (0)	2 (1.6)
Anxiety	6 (3.6)	2 (1.2)	2 (1.3)	1 (0.7)	0 (0)	1 (0.8)
Blood prolactin increased	6 (3.6)	0 (0)	0 (0)	3 (2.1)	2 (1.4)	1 (0.8)
Insomnia	5 (3.0)	2 (1.2)	1 (0.7)	0 (0)	0 (0)	2 (1.6)
Nausea	4 (2.4)	2 (1.2)	0 (0)	1 (0.7)	0 (0)	1 (0.8)
Parkinsonism	4 (2.4)	0 (0)	1 (0.7)	1 (0.7)	0 (0)	2 (1.6)

^a ≥ 2.0% in max dose 80mg group