Supplemental Table 1 Description of the 10 Completed DaTscan Clinical Trials

	Trial			
	CY95.FP.I[a]	**CY96.FP.II[b]**	**PDT02005[c]**	**DP008-003[d]**
Trial Design	• Phase 1 • Single-center • Open-label • Non-controlled • Non-randomized • Single-dose	• Phase 2 • Single-center • Open-label • Non-controlled • Non-randomized • Single-dose	• Phase 2 • Single-center • Open-label • Controlled • Non-randomized • Single-dose	• Phase 3 • Multi-center • Open-label • Controlled • Non-randomized • Single-dose
Population	• Healthy volunteers	• Healthy volunteers • Subjects with PD	Subjects with: • PD or • Cerebrovascular disease	• Healthy volunteers • Subjects with: • PD • MSA • PSP, or • ET
Type of Control	None	None	Healthy volunteers (historical control)	Healthy volunteers
DaTscan™ Doses	111 MBq	111 MBq	111-185 MBq	111-185 MBq
Clinical Conduct	25 Apr 1996 to 27 Jun 1996	01 Jan 1997 to 21 Mar 1997	31 Mar 1999 to 07 Nov 2000	25 Aug 1997 to 24 Feb 1998
No. of Subjects who Received DaTscan	12 (12 HV)	30 (10 HV; 20 PD)	51 (26 PS; 25 non-PS)	224 (35 HV; 160 PS; 29 ET)
No. of Subjects Evaluable for Safety	12	30	51	224
Age Range, Years (Mean)	32, 59 (42.3)	40, 69 • HV, male (67.0) • HV, female (51.2) • PD, male (57.2) • PD, female (54.7)	44.0, 83.1 (65.5)	40, 80 (62.7)
Gender (% M/F)	50/50	60/40	66/34	61/39
Race (% C/B/O)	92/8/0	97/0/3	100/0/0	98/1/<1

	Trial			
	PDT304[e]	**PDT03007**[f]	**PDT301**[g]	**PDT408**[h]
Trial Design	• Phase 3 • Multi-center • Open-label • Controlled • Non-randomized • Repeat administration (at 18-month intervals), up to 3 doses	• Phase 3 • Multi-center • Open-label • Controlled • Non-randomized • Single-dose	• Phase 3 • Multi-center • Open-label • Non-controlled • Non-randomized • Single-dose	• Phase 3b/4 • Multi-center • Open-label • Non-controlled • Non-randomized • Up to 2 doses

Population	• Healthy volunteers
	• Subjects with the clinical features of
	  • Early PD or
	  • Tremor (mainly ET)
		• Healthy volunteers
		• Subjects with:
		  • PS or
		  • ET
			• Subjects with dementia	• Subjects with clinically uncertain parkinsonian symptoms

Type of Control	Healthy volunteers	Healthy volunteers	None	None
DaTscan Doses	111-185 MBq (3 to 5 mCi)	111-185 MBq (3 to 5 mCi)	111-185 MBq (3 to 5 mCi)	111-185 MBq (3 to 5 mCi)
Clinical Conduct	18 Jan 1999 to 28 Jun 2005	18 Jan 2000 to 27 Oct 2000	21 Nov 2003 to 28 Jun 2006	21 Nov 2000 to 14 Nov 2003
No. of Subjects who Received DaTscan	179	31 (8 HV; 20 PS; 3 ET)	326 (326 dementia)	120 (61 PS, 34 other, 25 unknown)
No. of Subjects Evaluable for Safety	179	31	326	120
Age Range, Years (Mean)	33, 86 (61.6)	44.4, 76.7 • PS (63.1) • ET (64.4) • HV (61.5)	54, 90 (73.9)	25, 84 (65.1)
Gender (% M/F)	57/43	52/48	57/43	50/50
Race (% C/B/O)	100/0/0	94/3/3	100/0/0	98/1/1

	Trial	
	PDT409[i]	**001-013**[j]
Trial Design	• Phase 4 • Multi-center • Open-label • Controlled • Randomized • Single-dose	• Phase 4 • Multi-center • Open-label • Controlled • Randomized • Single-dose
Population	• Subjects with clinically uncertain parkinsonism	• Subjects with a clinically uncertain diagnosis of DLB
Type of Control	No-imaging group	No-imaging group
DaTscan Doses	111-185 MBq (3 to 5 mCi)	111-185 MBq (3 to 5 mCi)
Clinical Conduct	02 Oct 2006 to 03 Jan 2011	14 Jan 2011 to 08 Oct 2012
No. of Subjects who Received DaTscan	122	116
No. of Subjects Evaluable for Safety	122	116
Age Range (Mean)	19, 87 (66.9)	54, 90 (75.3)
Gender (% M/F)	53/46	55/45
Race (% C/B/O)	98/1/1	100/0/0

% C/B/O = percent subjects by race: Caucasian/Black/Other races; DLB = dementia with Lewy bodies; ET = essential tremor; EudraCT = European Union Drug Regulatory Affairs Clinical Trials (database); F = female; HV = healthy volunteers; [^{123}I]FP-CIT = ^{123}I-2-β-carbomethoxy-3β-(4-iodophenyl)-*N*-(3-fluoropropyl)nortropane (DaTscan); M = male; MSA = multiple system atrophy; PD = Parkinson's disease; PS = parkinsonian syndrome(s); PSP = progressive supranuclear palsy; SPECT = single-photon emission computed tomography.

[a] A single centre open study of an intravenous dopamine transporter ligand, containing 111 MBq [^{123}I]FP-CIT, in healthy volunteers to examine biodistribution, safety, and tolerability.

[b] A single centre open study of an intravenous dopamine transporter ligand, containing 111 MBq [^{123}I]FP-CIT, in healthy volunteers and patients with Parkinson's disease to examine uptake kinetics in various brain regions and safety.

[c] An open, single centre, Phase 2, clinical and imaging study to assess the striatal uptake of an intravenous solution, DaTscan, containing a dopamine transporter radio-ligand in subjects with vascular parkinsonism compared to subjects with cerebrovascular disease.

[d] A multicentre, Phase 3, clinical study to compare the striatal uptake of an intravenous solution containing a dopamine transporter radio-ligand, [123I]FP-CIT, in patients diagnosed with Parkinson's disease, multiple system atrophy, progressive supranuclear palsy, and definite essential tremor.

[e] (Also known as PDT03004. Diagnosis at baseline, 18 and 36 months.) An open, Phase 3, clinical study to assess the striatal uptake of an intravenous solution containing the dopamine transporter radio-ligand, DaTscan, in patients with early parkinsonism.

[f] (Subjects in this trial were from "d.") A Phase 3, multicentre, open clinical study to assess the striatal uptake of intravenous DaTscan, to monitor progression, in healthy volunteers and subjects previously diagnosed with parkinsonian syndrome and essential tremor, by SPECT imaging.

[g] An open-label, Phase 3, clinical study to assess the striatal uptake of an intravenous solution containing the dopamine transporter radio-ligand, DaTscan, in subjects with dementia with Lewy bodies.

[h] A Phase 3b/4, multicentre, open-label, non-comparative clinical study to assess the striatal uptake of intravenous DaTscan ([123I]ioflupane injection) in subjects with clinically uncertain parkinsonian syndromes.

[i] A multicentre, randomized, open-label, comparative Phase 4 trial to assess changes in clinical management after DaTscan imaging of subjects with clinically uncertain parkinsonism.

[j] A multicentre, randomised, open-label, comparative Phase 4 trial to assess, changes in dementia diagnostic category and diagnostic confidence after, DaTscan imaging in subjects with an uncertain diagnosis of dementia with Lewy bodies (possible DLB).

Supplemental Table 2 Key Criteria for Diagnoses of Patients Included in the 10 Completed DaTscan Clinical Trials

PS/PD	United Kingdom Parkinson's Disease Society Brain Bank criteria Steps 1 to 3 and Unified Parkinson's Disease Rating Scale Part III score pre-defined (as applicable to general PS, early or late PD)
CUPS	Signs/symptoms of PS but no specific clinical diagnosis was established yet, or PS with doubt whether diagnosis was PD, MSA, or PSP
MSA	Satisfaction of the Consensus Committee of the American Autonomic Society and the American Academy of Neurology diagnosis criteria[s-1]
PSP	Poor or non-response to levodopa and criteria of NINDS and the Society for PSP[s-2]
Dementias	Positive assessment for dementia according to the Diagnostic and Statistical Manual of Mental Disorder – Fourth Edition and at least one of the following: DLB as defined by the International Consensus Criteria or the independent expert committee's consensus for DLB, (dementia +1 core feature or 1 or more suggestive features), patients may or may not have also fulfilled criteria for AD, and no significant vascular pathology; the criteria of the National Institute of Neurological and Communicative Disorders and Stroke-AD and Related Disorders for AD; or the criteria of the NINDS-Association Internationale Pour la Recherché et l'Enseignement en Neurosciences for vascular dementia
ET	Satisfaction of Findley and Koller definitions and classifications for clinical diagnosis and long-standing condition (>5 years)[s-3]

AD = Alzheimer's disease; CUPS = clinically uncertain parkinsonian syndrome; DLB = dementia with Lewy bodies; MSA = multiple system atrophy;

NINDS = National Institute for Neurological Disorders and Stroke; PD = Parkinson's disease; PS = parkinsonian syndrome; PSP = progressive supranuclear palsy.

s-1. Consensus Committee of the American Autonomic Society and the American Academy of Neurology. Consensus statement on the definition of orthostatic hypotension, pure autonomic failure, and multiple system atrophy. *Neurology*. 1996;46:1470.

s-2. Litvan I, Agid Y, Calne D, et al. Clinical research criteria for the diagnosis of progressive supranuclear palsy (Steele-Richardson-Olszewski syndrome): report of the NINDS-SPSP international workshop. *Neurology*. 1996;47:1-9.

s-3. Findley LJ, Koller WC. Definitions and Behavioral Classifications. In: Findley LJ, editor. The Handbook of Tremor Disorders. New York: Marcel Dekker; 1994:1-5.

Supplemental Table 3 Safety Parameters Collected in the 10 Completed DaTscan Clinical Trials

Trial	Phase	AEs[a]	VS	EKG	Hem	Chem	U/A	Coag	PE	NE
CY95.FP.I[b]	1	X	X	X	X	X	X			
CY96.FP.II	2	X	X	X	X	X	X			
PDT02005	2	X	X	X	X	X	X	X	X	
DP008-003	3	X	X	X	X	X	X			
PDT304	3	X	X	X	X	X	X		X	
PDT03007	3	X	X	X	X	X	X	X	X	
PDT301	3	X	X	X	X	X	X		X	X
PDT408	3b/4	X								
GE-001-013[c]	4	X								X
PDT409	4	X								X

AEs = adverse events; Coag = coagulation; Chem = (serum) chemistry, EKG = electrocardiogram; Hem = hematology; NE = neurological examination; PE = physical examination; U/A = urinalysis; VS = vital signs.

[a] Included injection site reactions.

[b] Also included electroencephalogram.

Supplemental Table 4 Number (%) of Subjects in the 10 Completed DaTscan Clinical Trials by Final Diagnosis, Trial, and Overall (Safety Population)

		Trial, N									
		CY95.FP.I	CY96.FP.II	DP008-003	PDT02005	PDT304	PDT301	PDT408	PDT409	001-013	Total
		12	30	224[a]	51	179	326	120	122	116	1180
Dx	**SDD**	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**
PS	Yes	0 0	20 4	160 35	26 6	142 31	0 0	61 13	47 10	0 0	456 38.6
DLB		0 0	0 0	0 0	0 0	0 0	168 69	0 0	0 0	74 31	242 20.5
ET	No	0 0	0 0	29 59	0 0	0 0	0 0	0 0	20 41	0 0	49 4.2
HV		12 21	10 18	35 61	0 0	0 0	0 0	0 0	0 0	0 0	57 4.8
O[b]	-	0 0	0 0	0 0	25 8	37 11	158 48	34 10	35 11	41 12	330 28.0
U		0 0	0 0	0 0	0 0	0 0	0 0	25 54	20 43	1 2	46 3.9

DLB = dementia with Lewy bodies; Dx = baseline diagnosis; ET essential tremor; HV = healthy volunteers; MSA = multiple system atrophy; O = other; PD = Parkinson's disease; PS = parkinsonian syndrome (PD, PSP, MSA); PSP = progressive supranuclear palsy; SDD = striatal dopaminergic deficiency; U = unknown.

[a] Eligible subjects from DP008-003 entered into PDT307 and are counted only once.

[b] For example Alzheimer's disease, vascular dementia.

Supplemental Table 5 All Adverse Events Occurring in >1 Subject in Descending Order of Frequency in the 10 Completed Clinical Trials

No. (%) of subjects experiencing each listed AE[a] (N = 1180)		Adverse event (AE)
n	(%)	Medical Dictionary for Regulatory Activities [MedDRA] preferred term[b]
42	(4)	Headache.
21	(2)	Nausea, dizziness.
16	(1)	Nasopharyngitis.
12	(1)	Injection site hematoma.
10	(<1)	Urinary tract infection, fall, arthralgia, back pain, neck pain.
9	(<1)	Hematoma, hypertension.
8	(<1)	Diarrhea, injection site erythema, pain in extremity.
7	(<1)	Tremor.
6	(<1)	Dry mouth, fatigue, influenza, balance disorder.
5	(<1)	Anemia, vertigo, constipation, chest pain, lower respiratory tract infection, hypercholesterolemia, depression, epistaxis.

4	(<1)	Angina pectoris, abdominal pain, vomiting, muscle spasms, musculoskeletal pain, myalgia, spinal osteoarthritis, cough.
3	(<1)	Myocardial infarction, hunger, vessel puncture site hematoma, pneumonia, femoral neck fracture, diabetes mellitus, arthritis, joint swelling, osteoarthritis, formication (i.e., paraesthesia), lethargy, somnolence, tension headache, anxiety, rash.
2	(<1)	Arrhythmia, atrial fibrillation, irritable bowel syndrome, asthenia, influenza-like illness, malaise, peripheral edema, ear infection, eye infection, infection, respiratory tract infection, contusion, joint dislocation, joint injury, blood bilirubin increased, EKG abnormal, hepatic enzyme increased, platelet count decreased, groin pain, intervertebral disc protrusion, limb discomfort, prostate cancer, akinesia, dementia, dysgeusia, epilepsy, mental impairment, paraesthesia, restless legs syndrome, stress, hematuria, nocturia, pollakiuria, renal pain, dyspnea, pharyngolaryngeal pain, flushing, orthostatic hypotension, Raynaud's phenomenon.

[a] The number (percentage) of subjects with each unique AE listed; e.g., 21/1180 subjects (2%) experienced nausea and 21/1180 subjects (2%) experienced dizziness; they were not necessarily the same 21 subjects. For any given subject, a unique AE is counted only once; e.g., a subject who experienced headache twice is counted only once. Hence, every unique AE is identified, and every subject is counted only once for each unique AE.

[b] The order of presentation for AEs is alphabetical (i) within System Organ Class (SOC), (ii) then by MedDRA preferred term for the AE. SOCs in which >1 subject had an AE include the following: Blood and lymphatic system disorders; Cardiac disorders; Ear and labyrinth disorders; Gastrointestinal disorders; General disorders and administration site conditions; Infections and infestations; Injury, poisoning and procedural complications; Investigations; Metabolism and nutrition disorders; Musculoskeletal and connective tissue disorders; Neoplasms benign, malignant and unspecified (including cysts and polyps); Nervous system disorders; Psychiatric system disorders; Renal and urinary disorders; Respiratory, thoracic and mediastinal disorders; Skin and subcutaneous system disorders; Vascular disorders.

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Supplemental Coinvestigator Appendix

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The affiliation of participating investigators is listed as that during the trial.

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