

Appendix 分析対象新医薬品一覧

消化器・代謝系

一般名 (INN)	ATC	適応症 [薬物特性・作用機序]	臨床的 重要度	オリジネーター 国籍	バイオ 医薬品	米国 承認年月日	EU 承認年月日	日本 承認年月日	日本承認 ラグ(日)	日本審査 期間(日)	現在の 日本の開発状況	世界初承認時の 日本の開発状況	日本の予測 患者数(人)	日本の予測 市場(億円)	米国 Priority	米国 FastTrack	日本 優先審査	日本 開発促進
repaglinide	A10B9	Diabetes mellitus [stimulator of insulin release]	H	Germany	No	22-Dec-97	29-Jan-01				Clinical pII	NA			Yes	No	No	No
infliximab	A7E	Crohn's disease [mAb to TNF alpha]	H	USA	Yes	24-Aug-98	13-Aug-99	17-Jan-02	1242	843		Clinical	5,700	88	No	No	Yes	No
orlistat	A8A	Obesity [pancreatic lipase inhibitor]	H	Switzerland	No	23-Apr-99	29-Jul-98				Discontinued	NA			Yes	No	No	No
rosiglitazone	A10B4	Diabetes mellitus [thiazolidinedione]	H	UK	No	25-May-99	11-Jul-00				Pre-registration	Clinical			Yes	No	No	No
pioglitazone	A10B4	Diabetes mellitus [thiazolidinedione]	H	Japan	No	15-Jul-99	13-Oct-00	22-Sep-99	69	1011		Pre-registration			Yes	No	No	No
alosetron	A3G	Irritable bowel syndrome [5HT3 receptor antagonist]	H	UK	No	9-Feb-00					Clinical pII	Clinical			Yes	No	No	No
aprepitant	A4A	Emesis [neurokinin 1a antagonist]	H	USA	No	26-Mar-03	12-Nov-03				Pre-registration	NA			Yes	No	No	No
glimepiride	A10B1	Diabetes mellitus	L	Germany	No	30-Nov-95	30-Nov-96	22-Sep-99	1392			Pre-registration			No	No	No	No
insulin lispro	A10C	Diabetes mellitus	L	USA	Yes	14-Jun-96	30-Apr-96	20-Jun-01	1877	631		Clinical	96,000	30	No	No	No	No
miglitol	A10B5	Diabetes mellitus	L	Germany	No	18-Dec-96	15-Aug-97	11-Oct-05	3219	679		NA	269,000	162	No	No	No	No
rabeprazole	A2B2	Ulcerative gastroesophageal reflux disease	L	Japan	No	19-Aug-99	15-May-98	14-Oct-97	0			Registered			No	No	No	No
pantoprazole	A2B2	Gastroesophageal reflux disease	L	Germany	No	2-Feb-00	15-Sep-94				Clinical pII	Clinical phase II			No	No	No	No
insulin glargine	A10C	Diabetes mellitus	L	Germany	Yes	20-Apr-00	9-Jun-00	16-Oct-03	1274	542		Clinical phase III	445,000	200	No	No	No	No
insulin aspart	A10C	Diabetes mellitus	L	Denmark	Yes	7-Jun-00	7-Sep-99	2-Oct-01	756	475		Clinical phase III	173,000	80	No	No	No	No
balsalazide	A7E	Ulcerative colitis	L	UK	No	18-Jul-00	15-Jul-97				NA	NA			No	No	No	No
nateglinide	A10B9	Diabetes mellitus	L	Japan	No	22-Dec-00	3-Apr-01	16-Jun-99	0			Registered			No	No	No	No
rosiglitazone, metformin	A10B8	Diabetes mellitus	L	UK	No	10-Oct-02	20-Oct-03				NA	NA			No	No	No	No
palonosetron	A4A	Prevention of nausea	L	USA	No	25-Jul-03	22-Mar-05				Clinical pIII	NA			No	No	No	No
insulin glulisine	A10C	Diabetes mellitus	L	France	Yes	16-Apr-04	27-Sep-04				Pre-registration	Clinical			No	No	No	No
rifaximin	A7A	Traveler's diarrhea	L	Italy	No	25-May-04					NA	NA			No	No	No	No
pramlintide	A10X	Diabetes mellitus	L	USA	No	16-Mar-05					NA	NA			No	No	No	No
exenatide	A10X	Diabetes mellitus	L	USA	No	28-Apr-05	20-Nov-06				Clinical pII	Unknown			No	No	No	No
insulin detemir	A10C	Diabetes mellitus	L	Denmark	Yes	16-Jun-05	1-Jun-04	19-Oct-07	1235	693		Clinical phase III	558,000	158	No	No	No	No
lubiprostone	A6A6	Constipation	L	USA	No	31-Jan-06					Clinical pI	NA			No	No	No	No
sitagliptin	A10B9	Diabetes mellitus	L	USA	No	16-Oct-06	21-Mar-07				Pre-registration	Clinical phase III			No	No	No	No
carglumic acid	A16A	Hyperammonaemia	L	France	No		24-Jan-03				NA	NA			No	No	No	No
rimonabant	A8A	Obesity	L	France	No		19-Jun-06				Clinical pIII	Clinical phase II			No	No	No	No
vildagliptin	A10B6	Diabetes mellitus	L	Switzerland	No		26-Sep-07				Clinical pIII	Clinical			No	No	No	No
mitiglinide	A10B9	Diabetes mellitus	L	Japan	No			29-Jan-04	0	401		Registered	421,000	266	No	No	No	No
lafutidine	A2B1	Ulcer	L	Japan	No			18-Jan-00	0			Registered			No	No	No	No
egualen	A2B9	Ulcer	L	Japan	No			12-Mar-99	0			Registered			No	No	No	No
polycarbophil	A3G	Irritable bowel syndrome	L	Japan	No			3-Jul-00	0	1061		Registered			No	No	No	No
indisetron	A4A	Nausea	L	Japan	No			29-Jan-04	0	706		Registered			No	No	No	No
human albumin	A5B	Hypoalbuminemia	L	Japan	Yes			19-Oct-07	0	3642		Registered	70,000	54	No	No	No	No

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血液系

一般名 (INN)	ATC	適応症 [薬物特性・作用機序]	臨床的 重要度	オリジネーター 国籍	バイオ 医薬品	米国 承認年月日	EU 承認年月日	日本 承認年月日	日本承認 ラグ(日)	日本審査 期間(日)	現在の 日本の開発状況	世界初承認時の 日本の開発状況	日本の予測 患者数(人)	日本の予測 市場(億円)	米国 Priority	米国 FastTrack	日本 優先審査	日本 開発促進
clopidogrel	B1C	Thrombosis [platelet antiaggregant]	H	France	No	17-Nov-97	15-Jul-98	23-Jan-06	2989	699		Clinical	671,000	534	Yes	No	No	No
eptifibatide	B1C	Thrombosis [rDNA glycoprotein IIb/IIIa antagonist]	H	USA	No	18-May-98	1-Jul-99			NA		NA			Yes	No	No	No
sodium ferric gluconate complex	B3C	Anemia	H		No	18-Feb-99				NA		NA			Yes	No	No	No
eptacog alfa (activated)	B2D	Hemophilia [rDNA coagulation factor VIIa]	H	USA	Yes	25-Mar-99	23-Feb-96	10-Mar-00	1477	294		Clinical			Yes	No	Yes	No
fondaparinux	B1X	Prevention of thromboemisis [inhibitor of factor Xa]	H	France	No	7-Dec-01	21-Mar-02	18-Apr-07	1958	512		Clinical	193,000	51	Yes	No	No	No
ovine hyaluronidase	B6B	Increase the absorption and dispersion of other injected drugs	H	USA	No	5-May-04				NA		NA			Yes	No	No	No
human hyaluronidase	B6B	Increase the absorption and dispersion of other injected drugs	H	USA	Yes	2-Dec-05				NA		NA			Yes	No	No	No
eculizumab	B6C	Paroxysmal nocturnal emoglobinuria (PNH) [mAb to complement C5]	H	USA	Yes	16-Mar-07	20-Jun-07			NA		NA			Yes	No	No	Yes
methoxy PEG epoetin beta	B3X	Anemia [rDNA erythropoietin]	H	Switzerland	Yes	14-Nov-07	20-Jul-07				Clinical pII	Clinical phase II			Yes	No	No	No
human protein C	B1C	Thrombosis	H	Japan	No		16-Jul-01	22-Sep-00	0	861		Registered			No	No	Yes	No
danaparoid	B1C	Thrombosis	L	Netherlands	No	24-Dec-96	15-Jul-96	3-Jul-00	1449	1840		Pre-registration			No	No	No	No
anagrelide	B1C	Thrombosis	L	USA	No	14-Mar-97	16-Nov-04				Clinical pI	NA			No	No	No	No
cilostazol	B1C	Thrombosis	L	Japan	No	15-Jan-99	25-Apr-00	20-Jan-98	0			Registered			No	No	No	No
moroctocog alfa	B2D	Hemophilia	L	USA	Yes	6-Mar-00	13-Apr-99			NA		NA			No	No	No	No
tenecteplase	B1D	Suspected myocardial infarction	L	USA	Yes	2-Jun-00	23-Feb-01			NA		NA			No	No	No	No
argatroban	B1C	Thrombosis	L	Japan	No	30-Jun-00	6-Jun-05	23-Jan-90	0			Registered			No	No	No	No
tinzaparin	B1B2	Thrombosis	L	Denmark	No	14-Jul-00	15-Dec-92				Discontinued	Unknown			No	No	No	No
bivalirudin	B1E	Thrombosis	L	USA	No	15-Dec-00	20-Sep-04			NA		NA			No	No	No	No
darbepoetin alfa	B3C	Anemia	L	USA	Yes	17-Sep-01	8-Jun-01	18-Apr-07	2140	709		Clinical phase I	153,000	549	No	No	No	No
reviparin	B1B2	Thrombosis	L	Switzerland	No		30-Jun-93	22-Sep-99	2275			Clinical			No	No	No	No
epoetin delta	B3C	Anemia	L	USA	Yes		18-Mar-02			NA		NA			No	No	No	No

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心血管系

一般名 (INN)	ATC	適応症 [薬物特性・作用機序]	臨床的 重要度	オリジネーター 国籍	バイオ 医薬品	米国 承認年月日	EU 承認年月日	日本 承認年月日	日本承認 ラグ(日)	日本審査 期間(日)	現在の 日本の開発状況	世界初承認時の 日本の開発状況	日本の予測 患者数(人)	日本の予測 市場(億円)	米国 Priority	米国 FastTrack	日本 優先審査	日本 開発促進
epoprostenol	C2A	Pulmonary hypertention [prostagrandin I2]	H	UK	No	20-Sep-95		25-Jan-99				Clinical			No	No	Yes	No
bosentan	C2A	Pulmonary arterial hypertension [endothelin antagonist]	H	Switzerland	No	20-Nov-01	15-May-02	11-Apr-05	1238			Clinical	700	39	No	No	Yes	No
treprostinil	C2A	Pulmonary arterial hypertension [prostacyclin mimetic]	H	USA	No	21-May-02	15-Mar-05			NA	NA				Yes	No	No	No
iloprost	C2A	Pulmonary arterial hypertension [prostagrandin derivative]	H	Germany	No	29-Dec-04	16-Sep-03				Pre-registration	Pre-registration			Yes	No	No	No
conivaptan	C3A	Hyponatremia [vasopressin receptor antagonist]	H	Japan	No	29-Dec-05				NA	Discontinued				No	No	No	Yes
ambrisentan	C1X	Pulmonary arterial hypertension [endothelin antagonist]	H	Germany	No	15-Jun-07				NA	NA				Yes	No	No	No
mozavaptan	C3A	Hyponatremia in SIADH patients [vasopressin receptor antagonist]	H	Japan	No			26-Jul-06	0	516		Registered	400	0	No	No	Yes	No
esmolol	C7A	Arhythmia	L	USA	No	29-Dec-86	23-Mar-88	8-Oct-02	5762	686		NA	12,000	1	No	No	No	No
torasemide	C3A	Edema	L	Belgium	No	23-Aug-93	15-Feb-92	12-Mar-99	2582			NA			No	No	No	No
fenofibrate	C10A9	Hyperglycemia	L	Belgium	No	31-Dec-93	30-Jun-75	12-Mar-99	8656			NA			No	No	No	No
atorvastatin	C10A9	Hypercholesterolemia	L	USA	No	17-Dec-96	15-Nov-96	10-Mar-00	1211	564		Clinical phase II			No	No	No	No
valsartan	C9C	Hypertention	L	Switzerland	No	23-Dec-96	15-May-96	22-Sep-00	1591	429		Clinical			No	No	No	No
candesartan cilexetil	C9C	Hypertention	L	Japan	No	4-Jun-98	15-Oct-97	12-Mar-99	513			Pre-registration			No	No	No	No
telmisartan	C9C	Hypertention	L	Germany	No	10-Nov-98	16-Dec-98	8-Oct-02	1428	629		Clinical phase III	1,070,000	420	No	No	No	No
colesevelam	C10A9	Hypercholesterolemia	L	USA	No	26-May-00	10-Mar-04			NA	NA				No	No	No	No
nesiritide	C1D	Congestive heart failure	L	USA	Yes	10-Aug-01					Clinical pII	Unknown			No	No	No	No
olmesartan medoxomil	C9C	Hypertention	L	Japan	No	25-Apr-02	15-Aug-02	29-Jan-04	644	608		Clinical phase III	820,000	480	No	No	No	No
eplerenone	C2A	Hypertention	L	Switzerland	No	27-Sep-02	15-Aug-04	31-Jul-07	1768	1909		Pre-registration	450,000	186	No	No	No	No
ezetimibe	C10A9	Hypercholesterolemia	L	USA	No	25-Oct-02	17-Oct-02	18-Apr-07	1644	1265		Clinical phase III	306,000	243	No	No	No	No
rosuvastatin	C10A9	Hypercholesterolemia	L	Japan	No	12-Aug-03	15-Mar-03	19-Jan-05	676	1002		Pre-registration	938,000	477	No	No	No	No
omega-3-acid ethyl esters	C10A9	Hyperlipidemia	L	Norway	No	10-Nov-04	15-Aug-02				Clinical pI	NA			No	No	No	No
ranolazine	C1D	Chronic angina	L	USA	No	27-Jan-06					Clinical pI	Clinical phase I			No	No	No	No
aliskiren	C9X	Hypertension	L	Switzerland	No	5-Mar-07	22-Aug-07				Clinical pIII	Clinical phase III			No	No	No	No
ivabradine	C1D	Chronic angina	L	France	No		25-Oct-05				NA	NA			No	No	No	No
sitaxentan	C2A	Pulmonary arterial hypertention	L	USA	No		10-Aug-06				NA	NA			No	No	No	No
colestimide	C10A9	Hypercholesterolemia	L	Japan	No			12-Mar-99	0			Registered			No	No	No	No
pitavastatin	C10A9	Hypercholesterolemia	L	Japan	No			17-Jul-03	0	1331		Registered	850,000	540	No	No	No	No
nifekalant	C1B	Arhythmia	L	Japan	No			16-Jun-99	0			Registered			No	No	No	No
landiolol	C7A	Arhythmia	L	Japan	No			5-Jul-02	0	1789		Registered	15,400	1	No	No	No	No
azelnidipine	C8A	Hypertention	L	Japan	No			31-Jan-03	0	2011		Registered	450,000	150	No	No	No	No

Appendix 分析対象新医薬品一覧

皮膚系

一般名 (INN)	ATC	適応症 [薬物特性・作用機序]	臨床的 重要度	オリジネーター 国籍	バイオ 医薬品	米国 承認年月日	EU 承認年月日	日本 承認年月日	日本承認 ラグ(日)	日本審査 期間(日)	現在の 日本の開発状況	世界初承認時の 日本の開発状況	日本の予測 患者数(人)	日本の予測 市場(億円)	米国 Priority	米国 FastTrack	日本 優先審査	日本 開発促進
palifermin	D3A	Mucositis [rDNA keratinocyte growth factor]	H	USA	Yes	15-Dec-04	25-Oct-05				Clinical pII	NA			Yes	Yes	No	No
calcipotriol	D5A	Psoriasis	L	Denmark	No	29-Dec-93	15-Jan-91	18-Jan-00	3290			Unknown	5,600	15	No	No	No	No
imiquimod	D6D	Viral infection (topical)	L	USA	No	27-Feb-97	18-Sep-98	31-Jul-07	3806	426		Clinical	32,000	11	No	No	No	No
becaplermin	D3A	Diabetic ulcers	L	USA	Yes	16-Dec-97	29-Mar-99				NA	NA			No	No	No	No
finasteride	D11A	Alopecia	L	USA	No	19-Dec-97	15-Dec-98	11-Oct-05	2853	953		Clinical			No	No	No	No
aminolevulinic acid	D11A	Actinic keratosis	L	Canada	No	3-Dec-99					NA	NA			No	No	No	No
mequinol, Tretinoin	D11A	Solar lentigines	L	France	No	10-Dec-99					NA	NA			No	No	No	No
eflornithine	D11A	Facial hirsutism	L	France	No	27-Jul-00	20-Mar-01				NA	NA			No	No	No	No
pimecrolimus	D5X	Atopic dermatitis	L	Switzerland	No	13-Dec-01	15-Aug-02				Clinical pIII	Unknown			No	No	No	No
alefacept	D5B	Psoriasis	L	USA	Yes	30-Jan-03					NA	NA			No	No	No	No
efalizumab	D5B	Psoriasis	L	USA	Yes	27-Oct-03	20-Sep-04				NA	NA			No	No	No	No
tinidazole	G1A	Trichomoniasis	L	USA	No	17-May-04	15-Apr-82	15-Jun-92	3714			NA			No	No	No	No
kunecatechins	D6D	Genital wart	L	Germany	No	31-Oct-06					NA	NA			No	No	No	No
retapamulin	D6A	Impetigo	L	UK	No	12-Apr-07	24-May-07				NA	NA			No	No	No	No
trafermin	D3A	Cutaneous ulcer	L	USA	Yes			4-Apr-01	0	1741		Registered	100,000	52	No	No	No	No

Appendix 分析対象新医薬品一覧

泌尿器・生殖器官系

一般名 (INN)	ATC	適応症 [薬物特性・作用機序]	臨床的 重要度	オリジネーター 国籍	バイオ 医薬品	米国 承認年月日	EU 承認年月日	日本 承認年月日	日本承認 ラグ(日)	日本審査 期間(日)	現在の 日本の開発状況	世界初承認時の 日本の開発状況	日本の予測 患者数(人)	日本の予測 市場(億円)	米国 Priority	米国 FastTrack	日本 優先審査	日本 開発促進
raloxifene	G3J	Postmenopausal osteoporosis [estrogen receptor modulator]	H	USA	No	9-Dec-97	5-Aug-98	29-Jan-04	2242	602		Clinical	620,000	204	Yes	No	No	No
mifepristone	G2X9	Abortion [blocker of progesteron receptor]	H	France	No	28-Sep-00	15-Oct-88				Clinical	NA			Yes	No	No	No
desogestrel, ethinylestradiol	G3A	Contraception	L	Netherlands	No	10-Dec-92		16-Jun-99				Unknown			No	No	No	No
bicalutamide	G4C	Prostate cancer	L	UK	No	4-Oct-95	15-Mar-95	12-Mar-99	1458			Unknown			No	No	No	No
folitropin alfa	G3G	Ovulation stimulation	L	Switzerland	Yes	29-Sep-97	20-Oct-95	23-Jan-06	3748	724		Unknown	1,195	20	No	No	No	No
folitropin beta	G3G	Ovulation stimulation	L	Netherlands	Yes	29-Sep-97	3-May-96	11-Apr-05	3265	1092		Clinical			No	No	No	No
tolterodine	G4B4	Overactive bladder	L	Sweden	No	25-Mar-98	17-Sep-97	20-Apr-06	3137	1512		Clinical	443,000	174	No	No	No	No
sildenafil	G4B3	Erectile dysfunction	L	USA	No	27-Mar-98	15-Sep-98	25-Jan-99	304	194		Pre-registration			No	No	No	No
choriogonadotropin alfa	G3G	Induction of follicular maturation	L	Switzerland	Yes	20-Sep-00	2-Feb-01				NA	NA			No	No	No	No
drospirenone, ethinylestradiol	G3A	Contraception	L	Germany	No	11-May-01	24-Aug-00				Clinical pIII	Unknown			No	No	No	No
dutasteride	G4C	Benign prostatic hyperplasia	L	UK	No	20-Nov-01	9-Dec-00				Clinical pIII	Unknown			No	No	No	No
norelgestromin, ethinylestradiol	G3A	Contraception	L	USA	No	20-Nov-01	22-Aug-02				NA	NA			No	No	No	No
alfuzosin	G4C	Benign prostatic hyperplasia	L	France	No	12-Jun-03	30-Jun-88				Clinical pIII	NA			No	No	No	No
vardefafil	G4B3	Erectile dysfunction	L	Germany	No	19-Aug-03	6-Mar-03	23-Apr-04	414	872		Pre-registration			No	No	No	No
tadalafil	G4B3	Erectile dysfunction	L	USA	No	21-Nov-03	12-Nov-02	31-Jul-07	1722			Clinical			No	No	No	No
lutropin alfa	G3G	Stimulation of follicular development	L	Switzerland	Yes	8-Oct-04	29-Nov-00				Clinical pI	Clinical phase I			No	No	No	No
solifenacin	G4B4	Overactive bladder	L	Japan	No	19-Nov-04	15-Jul-04	20-Apr-06	644	602		Clinical phase III	657,000	213	No	No	No	No
darifenacin	G4B4	Overactive bladder	L	USA	No	22-Dec-04	22-Oct-04				NA	NA			No	No	No	No
atosiban	G2E	Imminent pre-term birth	L	Switzerland	No		20-Jan-00				NA	NA			No	No	No	No
fesoterodine	G4D	Overactive bladder	L	Germany	No		20-Apr-07				NA	NA			No	No	No	No
dienogest	G2X9	Endometriosis	L	Germany	No			19-Oct-07	0	539		Registered	6,500	22	No	No	No	No
ethinylestradiol, levonorgestrel	G3A	Contraception	L	Germany	No			16-Jun-99				NA			No	No	No	No
silodosin	G4C	Benign prostate hypertrophy	L	Japan	No			23-Jan-06	0	574		Registered	561,000	379	No	No	No	No
imidafenacin	G4D	Overactive bladder	L	Japan	No			18-Apr-07	0	908		Registered	448,000	140	No	No	No	No

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内分泌系

一般名 (INN)	ATC	適応症 [薬物特性・作用機序]	臨床的 重要度	オリジネーター 国籍	バイオ 医薬品	米国 承認年月日	EU 承認年月日	日本 承認年月日	日本承認 ラグ(日)	日本審査 期間(日)	現在の 日本の開発状況	世界初承認時の 日本の開発状況	日本の予測 患者数(人)	日本の予測 市場(億円)	米国 Priority	米国 FastTrack	日本 優先審査	日本 開発促進
ganirelix	H1C	Infertility [GnRH antagonist]	H	USA	No	29-Jul-99	17-May-00				Pre-registration	NA			Yes	No	No	No
pegvisomant	H4C	Acromegaly [rDNA GH receptor antagonist]	H	USA	Yes	25-Mar-03	13-Nov-02	26-Jan-07	1535	1494		Clinical	110	5	Yes	Yes	Yes	No
cinacalcet	H3B	Secondary hyperparathyroidism [calcimimetic]	H	USA	No	8-Mar-04	22-Oct-04	19-Oct-07	1320			Clinical	24,900	87	Yes	No	No	No
mecasermin	H4V	Growth failure in children [rDNA insulin-like growth factor1]	H	USA	Yes	30-Aug-05	3-Aug-07				NA	NA			Yes	No	No	No
mecasermin rinfabate	H4V	Growth failure in children [rDNA insulin-like growth factor1]	H	USA	Yes	12-Dec-05					NA	NA			Yes	No	No	No
cetorelix	H1C	Prevention of premature LH surges	L	Germany	No	11-Aug-00	13-Apr-99	20-Apr-06	2564	1940		Clinical phase III			No	No	No	No
lanreotide	H4V	Acromegaly	L	USA	No	30-Aug-07	5-Jun-94				Clinical pII	NA			No	No	No	No
falcalcitriol	H4V	Secondary hyperparathyroidism	L	USA	No			4-Apr-01	0	1496		Registered	15,000	32	No	No	No	No
maxacalcitol	H4V	Secondary hyperparathyroidism	L	Japan	No			3-Jul-00	0	875		Registered	15,000	32	No	No	No	No

Appendix 分析対象新医薬品一覧

HIV以外の感染症

一般名 (INN)	ATC	適応症 [薬物特性・作用機序]	臨床的 重要度	オリジネーター 国籍	バイオ 医薬品	米国 承認年月日	EU 承認年月日	日本 承認年月日	日本 承認 ラグ(日)	日本 審査 期間(日)	現在の 日本の開発状況	世界初承認時の 日本の開発状況	日本の予測 患者数(人)	日本の予測 市場(億円)	米国 Priority	米国 FastTrack	日本 優先審査	日本 開発促進
palivizumab	J5B	Prevention of RSV infections [mAb to RSV]	H	USA	Yes	19-Jun-98	13-Aug-99	17-Jan-02	1308	387		Clinical	12,500	84	No	No	Yes	No
zanamivir	J5B	Influenza [neuraminidase inhibitor]	H	Australia	No	26-Jul-99	15-Jun-99	27-Dec-99	195	147		Pre-registration	1,846,000	71	Yes	No	No	No
quinupristin, dalbopristin	J1X	VRE Infections [macrolids]	H	France	No	21-Sep-99	5-Jan-00	17-Jan-02	849	504		Clinical	16	0	Yes	No	Yes	No
oseltamivir	J5B	Influenza [neuraminidase inhibitor]	H	USA	No	27-Oct-99	20-Jun-02	12-Dec-00	412	140		Clinical phase III	2,093,000	83	Yes	No	No	No
linezolid	J1X	VRE Infections [oxazolidinone]	H	USA	No	18-Apr-00	15-Jan-01	4-Apr-01	351	264		Clinical	65	0	Yes	No	Yes	No
caspofungin	J2A	Fungal infections [neurocandin]	H	USA	No	26-Jan-01	24-Oct-01			NA		NA			Yes	Yes	No	No
valganciclovir	J5B	CMV retinitis [prodrug of ganciclovir]	H	Switzerland	No	29-Mar-01	15-Mar-02	5-Nov-04	1317	65		NA	140	3	Yes	No	Yes	No
adefovir	J5B	Chronic hepatitis B [reverse transcriptase inhibitor]	H	USA	No	20-Sep-02	6-Mar-03	22-Oct-04	763	241		Clinical	6,100	30	Yes	No	No	No
daptomycin	J1X	Infections	H	USA	No	12-Sep-03	19-Jan-06			NA		NA			Yes	No	No	No
miconazole	J2A	Fungal infections [ethinocandin-like lipopeptide]	H	Japan	No	16-Mar-05	17-Feb-03	8-Oct-02	0	470		Registered	80,000	116	Yes	No	No	No
entecavir	J5B	Chronic hepatitis B [inhibitor of HBV DNA polymerase]	H	USA	No	29-Mar-05	26-Jun-06	26-Jul-06	484	329		Clinical	16,509	65	Yes	No	Yes	No
tigecycline	J1A	Infections [glycocycline]	H	USA	No	15-Jun-05	24-Apr-06				Pre-registration	Clinical			Yes	No	No	No
posaconazole	J2A	Fungal infections [triazole]	H	USA	No	15-Sep-06	25-Oct-05				Clinical	NA			Yes	No	No	Yes
telbivudine	J5B	Chronic hepatitis B [nucleoside]	H	USA	No	25-Oct-06	24-Apr-07			NA		NA			No	No	No	Yes
azithromycin	J1F	Infections	L	Croatia	No	1-Nov-91	15-Apr-91	10-Mar-00	3252	805		NA			No	No	No	No
tazobactam, piperacilline	J1X	Infections	L	Japan	No	22-Oct-93	15-Oct-92	4-Apr-01	3093	2296		Clinical phase II	340,000	34	No	No	No	No
valaciclovir	J5B	Herpes zoster	L	UK	No	15-Jun-95	15-Jan-95	3-Jul-00	1996	586		Clinical			No	No	No	No
ribavirin	J5B	Chronic hepatitis C	L	USA	No	3-Jun-98	7-May-99	21-Nov-01	1267	208		Clinical	24,000	144	No	No	No	No
moxifloxacin	J1G	Infections	L	Germany	No	10-Dec-99	21-Jun-99	11-Oct-05	2304	1107		Clinical	2,512,000	56	No	No	No	No
docosanol	J5B	Infections	L	USA	No	25-Jul-00				NA		NA			No	No	No	No
cefditoren	J1D	Infections	L	Japan	No	29-Aug-01		15-Mar-94	0			Registered			No	No	No	No
ertapenem	J1P	Infections	L	UK	No	21-Nov-01	18-Apr-02			NA		NA			No	No	No	No
voriconazole	J2A	Fungal infections	L	USA	No	24-May-02	19-Mar-02	11-Apr-05	1119	655		Clinical phase III	38,200	153	No	No	No	No
gemifloxacin	J1G	Infections	L	South Korea	No	4-Apr-03					Clinical pI	Clinical			No	No	No	No
sertaconazole	J2A	Fungal infections	L	Spain	No	10-Dec-03	25-Oct-95				NA	NA			No	No	No	No
telithromycin	J1F	Infections	L	Germany	No	1-Apr-04	9-Jul-01	16-Oct-03	829	624		Clinical phase III	7,380,000	184	No	No	No	No
anidulafungin	J2A	Fungal infections	L	USA	No	17-Feb-06	20-Sep-07				NA	NA			No	No	No	No

Appendix 分析対象新医薬品一覧

HIV以外の感染症(つづき)

一般名 (INN)	ATC	適応症 [薬物特性・作用機序]	臨床的 重要度	オリジネーター 国籍	バイオ 医薬品	米国 承認年月日	EU 承認年月日	日本 承認年月日	日本承認 ラグ(日)	日本審査 期間(日)	現在の 日本の開発状況	世界初承認時の 日本の開発状況	日本の予測 患者数(人)	日本の予測 市場(億円)	米国 Priority	米国 FastTrack	日本 優先審査	日本 開発促進
doripenem	J1P	Infections	L	Japan	No	12-Oct-07		25-Jul-05	0	664	Registered	Registered	262,000	97	No	No	No	No
garenoxacin	J1G	Infections	L	Japan	No			31-Jul-07	0	427	Registered	Registered	4,300,000	161	No	No	No	No
pazufloxacin	J1G	Infections	L	Japan	No			11-Apr-02	0	745	Registered	Registered	214,000	44	No	No	No	No
prulifoxacin	J1G	Infections	L	Japan	No			8-Oct-02	0	2030	Registered	Registered	2,650,000	100	No	No	No	No
biapenem	J1P	Infections	L	Japan	No			2-Oct-01	0	789	Registered	Registered	216,000	60	No	No	No	No
liranaftate	J2A	Fungal infections	L	Japan	No			18-Jan-00	0		Registered	Registered			No	No	No	No
luliconazole	J2A	Fungal infections	L	Japan	No			11-Apr-05	0	692	Registered	Registered	850,000	20	No	No	No	No
fosfluconazole	J2A	Fungal infections	L	USA	No			16-Oct-03	0	483	Registered	Registered	28,100	46	No	No	No	No

Appendix 分析対象新医薬品一覧

HIV感染症

一般名 (INN)	ATC	適応症 [薬物特性・作用機序]	臨床的 重要度	オリジネーター 国籍	バイオ 医薬品	米国 承認年月日	EU 承認年月日	日本 承認年月日	日本 承認 ラグ(日)	日本 審査 期間(日)	現在の 日本の開発状況	世界初承認時の 日本の開発状況	日本の予測 患者数(人)	日本の予測 市場(億円)	米国 Priority	米国 FastTrack	日本 優先審査	日本 開発促進
delavirdine	J5C1	HIV/AIDS [reverse transcriptase inhibitor]	H	USA	No	4-Apr-97	1-Apr-98	25-Feb-00	1057	70		Pre-registration			Yes	No	Yes	No
efavirenz	J5C1	HIV/AIDS [reverse transcriptase inhibitor]	H	USA	No	17-Sep-98	28-May-99	10-Sep-99	358			Pre-registration			Yes	Yes	Yes	No
abacavir	J5C1	HIV/AIDS [reverse transcriptase inhibitor]	H	UK	No	17-Dec-98	8-Jul-99	10-Sep-99	267	71		NA			Yes	Yes	Yes	No
amprenavir	J5C1	HIV/AIDS [proteinase inhibitor]	H	USA	No	15-Apr-99	20-Oct-00	10-Sep-99	148			Pre-registration			Yes	Yes	Yes	No
lopinavir, ritonavir	J5C1	HIV/AIDS [proteinase inhibitor]	H	USA	No	15-Sep-00	20-Mar-01	12-Dec-00	88	81		Pre-registration			Yes	Yes	Yes	No
tenofovir	J5C1	HIV/AIDS [reverse transcriptase inhibitor]	H	USA	No	26-Oct-01	5-Feb-02	25-Mar-04	881	66		NA	1,510	12	Yes	Yes	Yes	No
enfuvirtide	J5C1	HIV/AIDS [fusion inhibitor]	H	USA	No	13-Mar-03	27-May-03			NA		NA			Yes	Yes	No	No
atazanavir	J5C1	HIV/AIDS [proteinase inhibitor]	H	Switzerland	No	20-Jun-03	2-Mar-04	18-Dec-03	181	52		Pre-registration	2,300	12	Yes	No	Yes	No
emtricitabine	J5C1	HIV/AIDS [reverse transcriptase inhibitor]	H	USA	No	2-Jul-03	24-Oct-03	22-Mar-05	629	56		NA	1,530	20	No	Yes	Yes	No
fosamprenavir	J5C1	HIV/AIDS [prodrug of anprenavir]	H	UK	No	20-Oct-03	12-Jul-04	24-Dec-04	431	70		Pre-registration	1,600	11	No	Yes	Yes	No
tipranavir	J5C2	HIV/AIDS [proteinase inhibitor]	H	USA	No	22-Jun-05	25-Oct-05			NA		NA			Yes	No	No	No
darunavir	J5C2	HIV/AIDS [proteinase inhibitor]	H	Belgium	No	23-Jun-06	12-Feb-07	22-Nov-07	517			NA	1,520	10	Yes	Yes	Yes	No
maraviroc	J5C9	HIV/AIDS [CCR5 chemokine receptor antagonist]	H	USA	No	6-Aug-07	8-Sep-07			NA		NA			Yes	No	No	No
raltegravir	J5C9	HIV/AIDS [HIV-1 integrase inhibitor]	H	USA	No	12-Oct-07	20-Dec-07			NA		NA	3,600	40	Yes	No	No	No

Appendix 分析対象新医薬品一覧

一般名 (INN)	ATC	適応症 [薬物特性・作用機序]	臨床的 重要度	オリジネーター 国籍	バイオ 医薬品	米国 承認年月日	EU 承認年月日	日本 承認年月日	日本 承認 ラグ(日)	日本 審査 期間(日)	現在の 日本の開発状況	世界初承認時の 日本の開発状況	日本の予測 患者数(人)	日本の予測 市場(億円)	米国 Priority	米国 FastTrack	日本 優先審査	日本 開発促進
mitotane	L2B9	Endocrine cancer [cytostatic hormone antagonist]	H	USA	No	8-Jul-70	28-Apr-04	15-Dec-84	5274			NA			Yes	No	No	No
fludarabine	L1B	B-cell chronic lymphocytic leukemia (CLL) [nucleoside analogue]	H	USA	No	18-Apr-91	30-Oct-94	22-Sep-99	3079	357		NA			No	No	Yes	No
cladribine	L1X9	Hairy cell leukemia [purine nucleoside analogue]	H	USA	No	26-Feb-93	14-Apr-04	17-Jan-02	3247	513		NA	10	0	No	No	Yes	No
interferon beta-1b	L3B	Multiple sclerosis [rDNA interferon]	H	USA	Yes	23-Jul-93	30-Nov-95	22-Sep-00	2618	378		NA			No	No	Yes	No
mofetil	L4A	Prophylaxis of acute organ rejection [immunosuppressant]	H	USA	No	3-May-95	14-Feb-96	22-Sep-99	1603			Clinical			No	No	Yes	No
interferon beta-1a	L3B	Multiple sclerosis [rDNA interferon]	H	USA	Yes	17-May-96	13-Mar-97	26-Jul-06	3722	404		NA	2,150	45	No	No	Yes	No
rituximab	L1X3	Follicular lymphoma [mAb to CD20]	H	USA	Yes	26-Nov-97	2-Jun-98	20-Jun-01	1302	642		Clinical	4,275	55	No	No	Yes	No
capecitabine	L1B	Cancer [prodrug of fluorouracil]	H	Switzerland	No	30-Apr-98	2-Feb-01	16-Apr-03	1812	820		Clinical	7,100	48	Yes	No	No	No
basiliximab	L4A	Prophylaxis of acute organ rejection [mAb to IL2 receptor]	H	Switzerland	Yes	12-May-98	9-Oct-98	17-Jan-02	1346	349		NA	250	2	No	No	Yes	No
trastuzumab	L1X3	Breast cancer [mAb to HER2 protein]	H	USA	Yes	25-Sep-98	28-Aug-00	4-Apr-01	922	432		Clinical	4,475	77	No	Yes	Yes	No
alitretinoin	L1X9	Kaposi's sarcoma [retinoid RAR/RXR agonist]	H	USA	No	2-Feb-99	11-Oct-00				NA	NA			Yes	No	No	No
temozolomide	L1A	Malignant glioma [alkylating agent]	H	UK	No	11-Aug-99	20-Jan-99	26-Jul-06	2744	334		NA	1,046	16	Yes	No	Yes	Yes
epirubicin	L1D	Breast cancer [doxorubicin derivative]	H	Italy	No	15-Sep-99	15-Mar-85	15-Jun-89	1553			Clinical			Yes	No	No	No
sirolimus	L4A	Prophylaxis of acute organ rejection [macrolide immunosuppressant]	H	USA	No	15-Sep-99	13-Mar-01				NA	NA			Yes	No	No	No
bexarotene	L1X9	T-cell lymphoma [retinoid RXR agonist]	H	USA	No	29-Dec-99	29-Mar-01				NA	NA			Yes	No	No	No
gemtuzumab	L1X3	Acute myeloid leukemia (AML) [mAb to CD33]	H	USA	Yes	17-May-00		25-Jul-05	1895	765		Clinical phase I	742	11	Yes	No	Yes	No
arsenic trioxide	L1X9	Acute promyelocytic leukemia (APL)	H	USA	No	25-Sep-00	5-Mar-02	22-Oct-04	1488	498		NA	200	5	Yes	Yes	No	No

Appendix 分析対象新医薬品一覧

抗癌剤・免疫調整剤(つづき)

一般名 (INN)	ATC	適応症 [薬物特性・作用機序]	臨床的 重要度	オリジネーター 国籍	バイオ 医薬品	米国 承認年月日	EU 承認年月日	日本 承認年月日	日本承認 ラグ(日)	日本審査 期間(日)	現在の 日本の開発状況	世界初承認時の 日本の開発状況	日本の予測 患者数(人)	日本の予測 市場(億円)	米国 Priority	米国 FastTrack	日本 優先審査	日本 開発促進
alemtuzumab	L1X3	Chronic lymphocytic leukemia (CLL) [mAb to CD52]	H	UK	Yes	7-May-01	6-Jul-01				NA	NA			No	Yes	No	Yes
imatinib	L1X9	Chronic myeloid leukemia (CML) [tyrosine kinase inhibitor]	H	Switzerland	No	10-May-01	7-Nov-01	21-Nov-01	195	208		Pre-registration	3,400	165	Yes	Yes	Yes	No
ibrutinib	L1X3	Non-Hodgkin's lymphoma [mAb to CD20 conjugated to yttrium90]	H	USA	Yes	19-Feb-02	16-Jan-04				Pre-registration	NA	273	7	No	Yes	No	Yes
oxaliplatin	L1X2	Colorectal cancer [platinum complex]	H	Japan	No	9-Aug-02	15-Apr-96	18-Mar-05	3259	387		NA	3,200	24	Yes	Yes	No	Yes
gefitinib	L1X9	Non-small cell lung cancer [tyrosine kinase inhibitor]	H	UK	No	5-May-03		5-Jul-02	0	161		Registered	19,800	172	Yes	Yes	Yes	No
bortezomib	L1X9	Multiple myeloma [proteasome inhibitor]	H	USA	No	13-May-03	26-Apr-04	20-Oct-06	1256	373		NA	1,700	57	Yes	Yes	Yes	Yes
tositumomab	L1X3	Non-Hodgkin's lymphoma [mAb to CD20 linked to I131]	H	USA	Yes	27-Jun-03					NA	NA			Yes	Yes	No	No
pemetrexed	L1B	Malignant pleural mesothelioma [thymidylate synthase inhibitor]	H	USA	No	4-Feb-04	20-Sep-04	26-Jan-07	1087	214		Clinical	1,240	16	Yes	Yes	Yes	Yes
cetuximab	L1X3	Colorectal cancer [mAb to EGFR]	H	France	Yes	12-Feb-04	29-Jun-04				Pre-registration	NA			Yes	Yes	No	Yes
bevacizumab	L1X3	Colorectal cancer [mAb to VEGF]	H	USA	Yes	26-Feb-04	12-Jan-05	18-Apr-07	1147	362		NA	18,400	301	Yes	Yes	Yes	Yes
azacitidine	L1B	Myelodysplastic syndrome [pyrimidine nucleoside analogue]	H	USA	No	19-May-04					Clinical pI	NA			Yes	Yes	No	No
erlotinib	L1X9	Non-small cell lung cancer [EGFR kinase inhibitor]	H	USA	No	18-Nov-04	19-Sep-05	19-Oct-07	1065	553		Clinical	11,000	156	Yes	Yes	Yes	Yes
clofarabine	L1X9	Acute lymphoblastic leukemia (ALL) [purine nucleoside analogue]	H	USA	No	28-Dec-04	29-May-06				NA	NA			Yes	Yes	No	Yes
nelarabine	L1X9	T-cell lymphoblastic lymphoma [prodrug of arabinosylguanine]	H	UK	No	28-Oct-05	22-Aug-07	19-Oct-07	721	490		NA	139	3	Yes	Yes	Yes	Yes
sorafenib	L1X9	Advanced renal cell carcinoma [tyrosine kinase inhibitor]	H	Germany	No	20-Dec-05	19-Jul-06				Pre-registration	Clinical	1,965	51	Yes	Yes	No	Yes
lenalidomide	L1X9	Myelodysplastic syndrome / Multiple myeloma [thalidomide derivative]	H	USA	No	27-Dec-05	14-Jun-07				Clinical pII	NA			Yes	Yes	No	Yes
sunitinib	L1X9	Gastrointestinal stromal tumor (GIST), renal cell carcinoma [tyrosine kinase inhibitor]	H	USA	No	26-Jan-06	19-Jul-06				Pre-registration	Clinical	3,018	141	Yes	No	No	Yes

Appendix 分析対象新医薬品一覧

抗癌剤・免疫調整剤(つづき)

一般名 (INN)	ATC	適応症 [薬物特性・作用機序]	臨床的 重要度	オリジネーター 国籍	バイオ 医薬品	米国 承認年月日	EU 承認年月日	日本 承認年月日	日本承認 ラグ(日)	日本審査 期間(日)	現在の 日本の開発状況	世界初承認時の 日本の開発状況	日本の予測 患者数(人)	日本の予測 市場(億円)	米国 Priority	米国 FastTrack	日本 優先審査	日本 開発促進
decitabine	L1X9	Myelodysplastic syndrome [DNA methyltransferase inhibitor]	H	Slovak Repu	No	2-May-06					NA	NA			No	Yes	No	Yes
dasatinib	L1X9	Acute lymphoblastic leukemia (ALL), Chronic lymphocytic leukemia (CLL) [tyrosine kinase inhibitor]	H	USA	No	28-Jun-06	20-Nov-06				Pre-registration	Clinical			Yes	Yes	No	Yes
panitumumab	L1X3	Colorectal cancer [mAb to EGFR]	H	USA	Yes	27-Sep-06	3-Dec-07				Clinical pIII	Clinical			Yes	Yes	No	No
vorinostat	L1X9	Cutaneous T cell lymphoma (CTCL) [polar cytodifferentiation agent]	H	USA	No	6-Oct-06					NA	NA			Yes	Yes	No	Yes
lapatinib	L1X9	Breast cancer [HER2/EGFR inhibitor]	H	UK	No	13-Mar-07					Pre-registration	Clinical			Yes	Yes	No	No
temsirolimus	L1D	Renal cancer [sirolimus analogue]	H	USA	No	30-May-07	19-Nov-07				Pre-registration	Clinical			Yes	No	No	No
ixabepilone	L1X9	Breast cancer [epothilone B analogue]	H	USA	No	16-Oct-07					Pre-registration	Clinical			Yes	No	No	No
everolimus	L4A	Prophylaxis of acute organ rejection [rapamycin analogue]	H	Switzerland	No		15-Dec-03	26-Jan-07	1138	584		NA	69	1	No	No	Yes	No
tamibarotene	L1X3	Acute promyelocytic leukemia (APL) [retinoid]	H	Japan	No			11-Apr-05	0	767		Registered	110	1	No	No	Yes	No
tocilizumab	L1X3	Catsleman's Disease [mAb to IL6]	H	Japan	Yes			11-Apr-05	0	724		Registered	120	4	No	No	Yes	No
paclitaxel	L1C	Ovarian cancer	L	USA	No	29-Dec-92	19-Jul-99	2-Jul-97	1646			Clinical			No	No	No	No
vinorelbine	L1X9	Non-small cell lung cancer	L	France	No	23-Dec-94	15-Jul-89	12-Mar-99	3527			Clinical phase II			No	No	No	No
anastrozole	L2B3	Breast cancer	L	UK	No	27-Dec-95	6-Jun-95	2-Dec-00	2006	379		Clinical phase I	40,000	100	No	No	No	No
gemcitabine	L1B	Pancreatic cartinoma	L	USA	No	15-May-96	30-Jun-03	12-Mar-99	1031			Clinical phase II			No	No	No	No
topotecan	L1C	Ovarian cancer	L	UK	No	28-May-96	12-Nov-96	22-Dec-00	1669			Clinical	1,700	5	No	No	No	No
letrozole	L2B3	Breast cancer	L	Switzerland	No	25-Jul-97	15-Aug-96	23-Jan-06	3448	1292		Clinical	36,000	86	No	No	No	No
daclizumab	L4A	Prophylaxis of acute organ rejection	L	USA	Yes	10-Dec-97	26-Feb-99				NA	NA			No	No	No	No
denileukin difitox	L1X9	T-cell lymphoma	L	USA	Yes	5-Feb-99					NA	NA			No	No	No	No
exemestane	L2B3	Breast cancer	L	Italy	No	21-Oct-99	15-Sep-99	5-Jul-02	1024	561		Clinical phase II	25,000	40	No	No	No	No
triptorelin	L2A3	Advanced prostate cancer	L	USA	No	15-Jun-00	15-Jun-86				NA	NA			No	No	No	No
peginterferon alfa-2b	L3B	Chronic hepatitis C	L	USA	Yes	19-Jan-01	25-May-00	22-Oct-04	1611	238		Clinical	14,900	144	No	No	No	No
pegfilgrastim	L3A1	Neutropenia	L	USA	Yes	31-Jan-02	22-Aug-02				NA	NA			No	No	No	No
fulvestrant	L2B1	Breast cancer	L	UK	No	25-Apr-02	10-Mar-04				Clinical pII	Unknown			No	No	No	No
peginterferon alfa-2a	L3B	Chronic hepatitis C	L	Switzerland	Yes	16-Oct-02	20-Jun-02	16-Oct-03	483	332		Clinical	12,200	130	No	No	No	No
nilotinib	L1X9	Chronic Myeloid Leukemia (CML)	L	Switzerland	No	29-Oct-07	19-Nov-07				Pre-registration	Pre-registration			No	No	No	No
levofolinic acid	L1X	Gastric cancer	L	USA	No		30-Jun-88	16-Jun-99	4003			NA			No	No	No	No

Appendix 分析対象新医薬品一覧

抗癌剤・免疫調整剤(つづき)

一般名 (INN)	ATC	適応症 [薬物特性・作用機序]	臨床的 重要度	オリジネーター 国籍	バイオ 医薬品	米国 承認年月日	EU 承認年月日	日本 承認年月日	日本承認 ラグ(日)	日本審査 期間(日)	現在の 日本の開発状況	世界初承認時の 日本の開発状況	日本の予測 患者数(人)	日本の予測 市場(億円)	米国 Priority	米国 FastTrack	日本 優先審査	日本 開発促進
tasonermin	L1X9	Ajunct to surgery for subsequent removal of the tumou	L	USA	Yes		13-Apr-99				Discontinued	Clinical phase I			No	No	No	No
temoporfin	L1X9	Advanced head and neck squamous cell carcinoma	L	UK	No		24-Oct-01				NA	NA			No	No	No	No
trabectedin	L1A	Soft tissue sarcoma	L	USA	No		17-Sep-07				NA	NA			No	No	No	No
amrubicin	L1D	Small cell lung cancer	L	Japan	No			11-Apr-02	0	941		Registered	10,600	38	No	No	No	No
oteracil, gimeracil, tegafur	L1X	Gastric cancer	L	Japan	No			25-Jan-99	0			Registered			No	No	No	No
talaporfin	L1X9	Early pulmonary cancer, in combination with laser therapy	L	Japan	No			16-Oct-03	0	741		Registered	300	1	No	No	No	No

Appendix 分析対象新医薬品一覧

筋骨格系

一般名 (INN)	ATC	適応症 [薬物特性・作用機序]	臨床的 重要度	オリジネーター 国籍	バイオ 医薬品	米国 承認年月日	EU 承認年月日	日本 承認年月日	日本承認 ラグ(日)	日本審査 期間(日)	現在の 日本の開発状況	世界初承認時の 日本の開発状況	日本の予測 患者数(人)	日本の予測 市場(億円)	米国 Priority	米国 FastTrack	日本 優先審査	日本 開発促進
etanercept	M1C	Rheumatoid arthritis [rDNA TNF receptor]	H	USA	Yes	2-Nov-98	3-Feb-00	19-Jan-05	2270	793		NA	23,000	368	No	Yes	No	No
celecoxib	M1A3	Osteoarthritis, Rheumatoid arthritis [Cox 2 inhibitor]	H	USA	No	31-Dec-98	15-May-00	26-Jan-07	2948	1501		Clinical	600,000	150	Yes	No	No	No
zoledronic acid	M5B2	Tumor-induced hypercalcemia [bisphosphonate]	H	Switzerland	No	20-Aug-01	20-Mar-01	22-Oct-04	1312	722		Clinical	14,000	7	Yes	No	No	No
abatacept	M1C	Rheumatoid arthritis [rDNA CTLA4lg]	H	USA	Yes	23-Dec-05	21-May-07				Clinical pIII	NA			Yes	Yes	No	Yes
rocuronium bromide	M3A	Muscle relaxation	L	Netherlands	No	17-Mar-94	15-May-94	31-Jul-07	4884	1037		Clinical phase III	1,448,000	25	No	No	No	No
leflunomide	M1C	Rheumatoid arthritis	L	Germany	No	10-Sep-98	2-Sep-99	16-Apr-03	1679	671		Unknown	121,000	101	No	No	No	No
doxercalciferol	M5B9	Secondary hyperparathyroidism	L	USA	No	9-Jun-99					NA	NA			No	No	No	No
meloxicam	M1A3	Osteoarthritis	L	Germany	No	13-Apr-00	8-May-95	22-Dec-00	2055	1459		Clinical phase III	340,000	124	No	No	No	No
risedronic acid	M5B9	Osteoporosis	L	USA	No	14-Apr-00	15-Feb-00	17-Jan-02	702	541		Clinical	800,000	467	No	No	No	No
botulinum toxin type b	M3A	Cervical dystonia	L	USA	No	8-Dec-00	22-Jan-01				Pre-registration	NA			No	No	No	No
eptotermin alfa	M5B9	Musculoskeletal disorder	L	USA	Yes	15-Oct-01	17-May-01				NA	NA			No	No	No	No
anakinra	M1C	Rheumatoid arthritis	L	USA	Yes	14-Nov-01	8-Mar-02				NA	NA			No	No	No	No
dibotermin alfa	M5X	Substitute for autogenous bone graft	L	USA	Yes	15-Jul-02	9-Sep-02				Clinical pIII	Clinical phase III			No	No	No	No
teriparatide	M5B9	Osteoporosis	L	USA	Yes	26-Nov-02	10-Jun-03				Clinical pIII	Unknown			No	No	No	No
adalimumab	M1C	Rheumatoid arthritis	L	Switzerland	Yes	31-Dec-02	8-Sep-03				Pre-registration	Clinical phase I	22,400	389	No	No	No	No
ibandronic acid	M5B1	Postmenopausal osteoporosis	L	Germany	No	16-May-03	23-Feb-04				Clinical pII	Clinical			No	No	No	No
lornoxicam	M1A3	Reumatioid arthritis	L	Switzerland	No		6-Jun-96	22-Dec-00	1660	1365		Clinical phase III	1,940,000	41	No	No	No	No
parecoxib	M1A3	Postoperative pain	L	USA	No		22-Mar-02				Clinical pII	Unknown			No	No	No	No
strontium ranelate	M5B9	Osteoporosis	L	France	No		21-Sep-04				Discontinued	Clinical phase II			No	No	No	No
human parathyroid hormone	M5B9	Osteoporosis	L	Canada	Yes		24-Apr-06				NA	NA			No	No	No	No

Appendix 分析対象新医薬品一覧

神経系

一般名 (INN)	ATC	適応症 [薬物特性・作用機序]	臨床的 重要度	オリジネーター 国籍	バイオ 医薬品	米国 承認年月日	EU 承認年月日	日本 承認年月日	日本 承認 ラグ(日)	日本 審査 期間(日)	現在の 日本の開発状況	世界初承認時の 日本の開発状況	日本の予測 患者数(人)	日本の予測 市場(億円)	米国 Priority	米国 FastTrack	日本 優先審査	日本 開発促進
gabapentin	N3A	Epilepsy [GABA analogue]	H	USA	No	30-Dec-93	15-May-93	26-Jul-06	4820	833		Clinical	27,000	24	Yes	No	No	No
oxcarbazepine	N3A	Epilepsy [carbamazepine derivative]	H	Switzerland	No	14-Jan-00	15-Dec-99				NA	NA			No	No	No	Yes
sodium oxybate	N7X	Cataplexy associated with narcolepsy	H	USA	No	17-Jul-02	13-Oct-05				NA	NA			Yes	No	No	No
acamprosate	N7E	Alcohol dependence [GABA agonist]	H	France	No	29-Jul-04	15-Mar-96				Clinical pII	NA			Yes	No	No	No
natalizumab	N7X	Multiple sclerosis [mAb to integrin]	H	Ireland	Yes	23-Nov-04	27-Jun-06				NA	NA			Yes	No	No	No
ziconotide	N2B	Severe chronic pain [calcium channel blocker]	H	USA	No	28-Dec-04	21-Feb-05				NA	NA			Yes	No	No	No
pregabalin	N2B	Neuropathic pain in diabetes [GABA analogue]	H	USA	No	30-Dec-04	6-Jul-04				Clinical pII	Clinical			Yes	No	No	No
varenicline	N7B	Smoking cessation [nicotinic alpha4beta2 agonist]	H	USA	No	10-May-06	26-Sep-06				Pre-registration	Clinical	309,000	68	Yes	No	No	No
piracetam	N7X	Myoclonus [GABA analogue]	H	Belgium	No		14-Dec-92	22-Sep-99				NA			No	No	Yes	No
stiripentol	N3A	Epilepsy	H	France	No		4-Jan-07				NA	NA			No	No	No	Yes
rufinamide	N3A	Epilepsy [triazole]	H	Switzerland	No		16-Jan-07				NA	NA			No	No	No	Yes
taltirelin	N7X	Neurodegeneration [TRH analogue]	H	Japan	No			3-Jul-00	0	444		Registered			No	No	Yes	No
quazepam	N5B	Insomnia	L	USA	No	27-Dec-85		16-Jun-99	4919			Clinical			No	No	No	No
sertraline	N6A4	Major depression	L	USA	No	30-Dec-91	15-Dec-90	20-Apr-06	5605	2949		NA	571,000	482	No	No	No	No
zolpidem	N5B	Insomnia	L	France	No	16-Dec-92	15-May-88	22-Sep-00	4513	2811		Clinical			No	No	No	No
sumatriptan	N2C1	Migrane	L	UK	No	28-Dec-92	15-Aug-91	18-Jan-00	3078			Clinical phase II			No	No	No	No
paroxetine	N6A5	Major depression	L	Denmark	No	29-Dec-92	11-Dec-99	22-Sep-00	2824	644		Clinical phase II			No	No	No	No
strontium-89 chloride	N2B	Pain due to bone metastasis	L	UK	No	18-Sep-93	15-Nov-89	31-Jul-07	6467	4120		Clinical phase II	1,460	5	No	No	No	No
fluvoxamine	N6A4	Obsessive compulsory disorder	L	Belgium	No	5-Dec-94	15-Mar-96	7-Apr-99	1584			Clinical phase III			No	No	No	No
remifentanyl	N1A	Pain	L	UK	No	12-Jul-96	15-May-96	20-Oct-06	3810	1400		NA	1,108,000	62	No	No	No	No
ropivacaine	N1B	Postoperative pain	L	Sweden	No	24-Sep-96	15-Apr-96	4-Apr-01	1815	677		Clinical	804,000	16	No	No	No	No
olanzapine	N5A	Schizophrenia	L	USA	No	30-Sep-96	27-Sep-96	22-Dec-00	1547	450		Clinical phase III	125,000	155	No	No	No	No
donepezil	N7D1	Alzheimer's disease	L	Japan	No	25-Nov-96	15-Feb-97	8-Oct-99	1047	434		Clinical phase II			No	No	No	No
cabergoline	N4A	Parkinson's disease	L	Italy	No	23-Dec-96	15-Dec-95	16-Jun-99	1279			Clinical phase II			No	No	No	No
topiramate	N3A	Epilepsy	L	USA	No	24-Dec-96	15-Oct-95	31-Jul-07	4307	1098		Clinical phase II	34,000	64	No	No	No	No
pramipexole	N4A	Parkinson's disease	L	Germany	No	1-Jul-97	14-Oct-97	16-Oct-03	2298	672		Clinical	19,000	91	No	No	No	No
ropinirole	N4A	Parkinson's disease	L	UK	No	17-Sep-97	15-Jul-96	20-Oct-06	3749	3766		Pre-registration	23,000	109	No	No	No	No
quetiapine	N5A	Schizophrenia	L	UK	No	26-Sep-97	15-Jul-97	12-Dec-00	1246	715		Clinical	53,000	115	No	No	No	No
zolmitriptan	N2C1	Migrane	L	UK	No	25-Nov-97	7-Mar-97	20-Jun-01	1566	464		Clinical	38,000	15	No	No	No	No
rizatriptan	N2C1	Migrane	L	USA	No	29-Jun-98	24-Jun-98	17-Jul-03	1849	594		Clinical phase II	174,000	100	No	No	No	No
modafinil	N6B	Narcolepsy	L	France	No	24-Dec-98	15-Feb-92	26-Jan-07	5459	652		NA	1,560	5	No	No	No	No
zaleplon	N5B	Insomnia	L	USA	No	13-Aug-99	12-Mar-99				Discontinued	NA			No	No	No	No
entacapone	N4A	Parkinson's disease	L	Finland	No	19-Oct-99	22-Sep-98	26-Jan-07	3048	652		Clinical	18,700	61	No	No	No	No
levetiracetam	N3A	Epilepsy	L	Belgium	No	30-Nov-99	29-Sep-00				Clinical pIII	Clinical phase I			No	No	No	No
dexmedetomidine	N1B	Sedation in ventilation	L	Finland	No	17-Dec-99		29-Jan-04	1504	783		NA	179,000	3	No	No	No	No

Appendix 分析対象新医薬品一覧

神経系

一般名 (INN)	ATC	適応症 [薬物特性・作用機序]	臨床的 重要度	オリジネーター 国籍	バイオ 医薬品	米国 承認年月日	EU 承認年月日	日本 承認年月日	日本 承認 ラグ(日)	日本 審査 期間(日)	現在の 日本の開発状況	世界初承認時の 日本の開発状況	日本の予測 患者数(人)	日本の予測 市場(億円)	米国 Priority	米国 FastTrack	日本 優先審査	日本 開発促進
zonisamide	N3A	Epilepsy	L	Japan	No	27-Mar-00	10-Mar-05	15-Jun-89	0			Registered			No	No	No	No
rivastigmine	N7D1	Alzheimer's disease	L	Switzerland	No	21-Apr-00	12-May-98				Clinical pII	Clinical			No	No	No	No
ziprasidone	N5A	Schizophrenia	L	USA	No	5-Feb-01	15-Mar-02				Clinical pII	Clinical			No	No	No	No
galantamine	N7D1	Alzheimer's disease	L	UK	No	28-Feb-01	12-Jul-00				Clinical pIII	Clinical			No	No	No	No
almotriptan	N2C1	Migrane	L	Spain	No	7-May-01	26-Jul-00				NA	NA			No	No	No	No
frovatriptan	N2C1	Migrane	L	UK	No	8-Nov-01	21-Jul-00				NA	NA			No	No	No	No
aripiprazole	N5A	Schizophrenia	L	Japan	No	15-Nov-02	4-Jun-04	23-Jan-06	1165	1034		Clinical phase III	145,000	121	No	No	No	No
atomoxetine	N7X	ADHD	L	USA	No	26-Nov-02	15-May-04				Pre-registration	Clinical phase I			No	No	No	No
eletriptan	N2C1	Migrane	L	USA	No	26-Dec-02	16-Jun-01	11-Apr-02	299	650		Pre-registration	586,000	182	No	No	No	No
levodopa, carbidopa, entacapone	N4A	Parkinson's disease	L	Finland	No	11-Jun-03	17-Oct-03				NA	NA			No	No	No	No
memantine	N7D9	Alzheimer's disease	L	Germany	No	16-Oct-03	17-May-02				Clinical pIII	Unknown			No	No	No	No
duloxetine	N6A5	Major depression	L	USA	No	3-Aug-04	17-Dec-04				Clinical pIII	Pre-registration			No	No	No	No
eszopiclone	N5B	Insomnia	L	USA	No	15-Dec-04					NA	NA			No	No	No	No
ramelteon	N5B	Insomnia	L	Japan	No	22-Jul-05					Clinical pIII	Clinical phase III			No	No	No	No
rasagiline	N4A	Parkinson's disease	L	Israel	No	16-May-06	21-Feb-05				NA	NA			No	No	No	No
paliperidone	N5A	Schizophrenia	L	Belgium	No	19-Dec-06	25-Jun-07				Clinical pIII	Clinical			No	No	No	No
lisdexamfetamine	N6B	ADHD	L	USA	No	23-Feb-07					NA	NA			No	No	No	No
rotigotine	N4X	Parkinson's disease	L	USA	No	9-May-07	15-Feb-06				Clinical pII	Clinical phase II			No	No	No	No
clobazam	N3A	Epilepsy	L	Germany	No		15-Feb-79	10-Mar-00	7694	1088		NA			No	No	No	No
milnacipran	N6A5	Major depression	L	France	No		15-Jun-96	22-Sep-99	1194			Clinical phase III			No	No	No	No
lomerizine	N2C1	Migrane	L	Japan	No			12-Mar-99	0			Registered			No	No	No	No
perospirone	N5A	Schizophrenia	L	Japan	No			22-Dec-00	0	1365		Registered	81,000	90	No	No	No	No
edaravone	N7X	Brain ischemia	L	Japan	No			4-Apr-01	0	1100		Registered	75,000	208	No	No	No	No

Appendix 分析対象新医薬品一覧

寄生虫

一般名 (INN)	ATC	適応症 [薬物特性・作用機序]	臨床的 重要度	オリジネーター 国籍	バイオ 医薬品	米国 承認年月日	EU 承認年月日	日本 承認年月日	日本承認 ラグ(日)	日本審査 期間(日)	現在の 日本の開発状況	世界初承認時の 日本の開発状況	日本の予測 患者数(人)	日本の予測 市場(億円)	米国 Priority	米国 FastTrack	日本 優先審査	日本 開発促進
mefloquine	P1D	Malaria [quinoline methanol derivative]	H	USA	No	2-May-89		4-Apr-01		463		NA	100	0	No	No	Yes	No
ivermectin	P1G	Strongyloidiasis [avermectin derivative]	H		No	22-Nov-96	15-Mar-93	9-Oct-02	3495	496		NA	850	0	No	No	Yes	No
nitazoxanide	P1G	Parasitic infection [nitrothiazole]	H	USA	No	22-Nov-02					NA	NA			Yes	No	No	No

Appendix 分析対象新医薬品一覧

呼吸器系

一般名 (INN)	ATC	適応症 [薬物特性・作用機序]	臨床的 重要度	オリジネーター 国籍	バイオ 医薬品	米国 承認年月日	EU 承認年月日	日本 承認年月日	日本 承認 ラグ(日)	日本 審査 期間(日)	現在の 日本の開発状況	世界初承認時の 日本の開発状況	日本の予測 患者数(人)	日本の予測 市場(億円)	米国 Priority	米国 FastTrack	日本 優先審査	日本 開発促進
nitric oxide	R7X	Hypoxic respiratory failure	H	USA	No	23-Dec-99	1-Aug-01				Clinical	Clinical			Yes	No	No	No
loratadine	R6A	Allergic rhinitis	L	USA	No	12-Apr-93	15-Mar-88	5-Jul-02	5225	323		Clinical phase II	2,890,000	198	No	No	No	No
levocabastine	R6A	Allergic rhinitis	L	Belgium	No	10-Nov-93	30-Jun-93	16-Jun-99	2177			Clinical			No	No	No	No
salmeterol	R3A	Asthma	L	UK	No	4-Feb-94	25-Oct-90	11-Apr-02	4186	3093		Clinical phase II	270,000	130	No	No	No	No
fexofenadine	R6A	Allergic rhinitis	L	Germany	No	15-Jul-96	11-Mar-96	22-Sep-00	1656	421		Clinical			No	No	No	No
zafirlukast	R3J	Asthma	L	UK	No	26-Sep-96	18-Jun-98	22-Dec-00	1548	731		Clinical phase II	80,000	99	No	No	No	No
montelukast	R3J	Asthma	L	USA	No	20-Feb-98	15-Jan-98	20-Jun-01	1252	506		Clinical	768,000	926	No	No	No	No
poractant alfa	R7C	Respiratory Distress Syndrome	L	Italy	No	18-Nov-99	30-Jun-93				NA	NA			No	No	No	No
desloratadine	R6A	Allergic rhinitis	L	USA	No	21-Dec-01	15-Jan-01				NA	NA			No	No	No	No
omalizumab	R3X	Asthma	L	USA	Yes	20-Jun-03	25-Oct-05				Pre-registration	Clinical phase III			No	No	No	No
human alpha-1 proteinase inhibitor	R7X	Alfa1 antitripsin deficiency with emphysema	L	USA	No	8-Jul-03					NA	NA			No	No	No	No
tiotropium bromide	R3G	Bronchospasm associated with COPD	L	Germany	No	30-Jan-04	15-Apr-02	22-Oct-04	921	847		Clinical phase III	358,000	178	No	No	No	No
ciclesonide	R3D	Asthma	L	Spain	No	20-Oct-06	1-Apr-04	18-Apr-07	1112	1178		Pre-registration	300,000	86	No	No	No	No
ramatroban	R3C	Asthma	L	Germany	No			10-Mar-00	0	1227		Registered			No	No	No	No
fudosteine	R5C	Expectorant	L	Japan	No			2-Oct-01	0	707		Registered	350,000	46	No	No	No	No
siverestat	R7X	Systemic inflammatory response syndrome	L	Japan	No			11-Apr-02	0	1625		Registered	8,000	15	No	No	No	No

Appendix 分析対象新医薬品一覧

感覚器系

一般名 (INN)	ATC	適応症 [薬物特性・作用機序]	臨床的 重要度	オリジネーター 国籍	バイオ 医薬品	米国 承認年月日	EU 承認年月日	日本 承認年月日	日本承認 ラグ(日)	日本審査 期間(日)	現在の 日本の開発状況	世界初承認時の 日本の開発状況	日本の予測 患者数(人)	日本の予測 市場(億円)	米国 Priority	米国 FastTrack	日本 優先審査	日本 開発促進
verteporfin	S1P	Age-related macular degeneration (AMD) [benzoporphyrin derivative]	H	Canada	No	12-Apr-00	27-Jul-00	16-Oct-03	1282	541		Clinical	15,450	53	Yes	No	Yes	No
unoprostone	S1E	Glaucoma [prostaglandin metabolite-related agent]	H	Japan	No	3-Aug-00		1-Jul-94	0			Registered			Yes	No	No	No
travoprost	S1E	Glaucoma [prostaglandin FP receptor agonist]	H	USA	No	16-Mar-01	27-Nov-01	31-Jul-07	2328	1035		Clinical	168,000	100	Yes	No	No	No
bimatoprost	S1E	Glaucoma [prostaglandin derivative]	H	USA	No	16-Mar-01	8-Mar-02				Pre-registration	NA			Yes	No	No	No
pegaptanib	S1P	Age-related macular degeneration (AMD) [aptamer, inhibitor of VEGF]	H	USA	No	17-Dec-04	31-Jan-06				Pre-registration	Clinical			Yes	Yes	No	No
nepafenac	S1X	Pain and inflammation associated with cataract surgery [anfenac analogue]	H	USA	No	19-Aug-05	11-Dec-07				Clinical	Clinical			Yes	No	No	No
ranibizumab	S1P	Age-related macular degeneration (AMD) [mAb to VEGF-A]	H	USA	Yes	30-Jun-06	22-Jan-07				Clinical pII	Clinical			Yes	No	No	No
levobunolol	S1E	Glaucoma	L	USA	No	19-Dec-85	2-Jan-85	3-Jul-00	5661	1222		NA			No	No	No	No
dorzolamide	S1E	Glaucoma	L	USA	No	9-Dec-94	15-Feb-95	12-Mar-99	1554			Clinical phase III			No	No	No	No
latanoprost	S1E	Glaucoma	L	Sweden	No	5-Jun-96	15-Dec-96	12-Mar-99	1010			Clinical phase III			No	No	No	No
brinzolamide	S1E	Glaucoma	L	USA	No	1-Apr-98	9-Mar-00	8-Oct-02	1651	466		Unknown	70,000	36	No	No	No	No
cevimeline	S1X	Mucositis in Sjogren's syndrome	L	Israel	No	11-Jan-00		20-Jun-01	526	616		Pre-registration	13,000	22	No	No	No	No
acitazanolast	S1G	Allergic conjunctivitis	L	Japan	No			22-Sep-00	0	2061		Registered			No	No	No	No

Appendix 分析対象新医薬品一覧

診断薬

一般名 (INN)	ATC	適応症 [薬物特性・作用機序]	臨床的 重要度	オリジネーター 国籍	バイオ 医薬品	米国 承認年月日	EU 承認年月日	日本 承認年月日	日本承認 ラグ(日)	日本審査 期間(日)	現在の 日本の開発状況	世界初承認時の 日本の開発状況	日本の予測 患者数(人)	日本の予測 市場(億円)	米国 Priority	米国 FastTrack	日本 優先審査	日本 開発促進
thyrotropin alfa	T1X	Adjunct to thyroglobulin testing [rDNA TSH]	H	USA	Yes	30-Nov-98	9-Mar-00				Pre-registration	NA			Yes	No	No	No
adenosine	T2B	Diagnosis of ischemic heart diseases	L	USA	No	18-May-95	15-Jun-95	11-Apr-05	3616	2016		NA	36,000	5	No	No	No	No
iodixanol	T1G	Diagnosis of heart disease	L	Denmark	No	15-Mar-96	15-Mar-93	3-Jul-00	2667			Clinical phase III			No	No	No	No
13C-urea	T2X	Diagnosis of Helicobacter pylori infection	L		No	17-Sep-96	7-May-98	16-Jun-99	1002			Clinical			No	No	No	No
gadoversetamide	T1E	Diagnosis of abnormal vascularity in brain	L	USA	No	8-Dec-99	23-Jul-07				Clinical pI	Clinical phase I			No	No	No	No
perflutren	T1F	Echo contrast diagnosis	L	USA	No	31-Jul-01	20-Sep-06				Pre-registration	Pre-registration			No	No	No	No
perflexane	T1F	Echo contrast diagnosis	L	USA	No	31-May-02					NA	NA			No	No	No	No
gadobenic acid	T1E	Diagnosis of abnormal vascularity in brain	L	Italy	No	23-Nov-04	15-Apr-99				Discontinued	Clinical phase III			No	No	No	No
ammonia	T2	Diagnosis of coronary artery diseases (PET)	L		No	23-Aug-07					NA	NA			No	No	No	No
gadoteric acid	T1E	Diagnosis	L	France	No		30-Jun-89	22-Sep-00	4102	1484		Clinical	80,000	9	No	No	No	No
galactose, palminic acid	T1E	Diagnosis of cardiac disease	L	Germany	No		15-Dec-95	16-Jun-99	1279			Unknown			No	No	No	No
ioflupane	T1G	Diagnosis of loss of functional dopaminergic neuron terminals	L	Denmark	No			27-Jul-00			NA	NA			No	No	No	No
sulphur hexafluoride	T1F	Enhancement of echogenicity in ultrasound imaging	L	Italy	No		26-Mar-01				Discontinued	Clinical phase I			No	No	No	No
ferucarbotran	T1E	Diagnosis of liver cartinoma	L	Germany	No		15-Aug-01	8-Oct-02	419	1489		Pre-registration	170,000	33	No	No	No	No
gadoxetic acid	T1E	Diagnosis	L	Germany	No		15-Sep-04	19-Oct-07	1129			Pre-registration	282,000	54	No	No	No	No
gadofosveset	T1E	Diagnosis of vascular diseases	L	USA	No		3-Oct-05				NA	NA			No	No	No	No
perflubutane	T1F	Echo contrast diagnosis	L	USA	No			20-Oct-06	0	872		Registered	35,000	26	No	No	No	No
pralmorelin	T1X	Diagnosis of GH deficiency	L	USA	No			22-Oct-04	0	885		Registered	8,000	1	No	No	No	No
iomazenil (123I)	T2B	Diagnosis of epilepsy	L		No			23-Apr-04	0	3102		Registered	3,100	2	No	No	No	No

Appendix 分析対象新医薬品一覧

先天性代謝異常症

一般名 (INN)	ATC	適応症 [薬物特性・作用機序]	臨床的 重要度	オリシネーター 国籍	バイオ 医薬品	米国 承認年月日	EU 承認年月日	日本 承認年月日	日本承認 ラグ(日)	日本審査 期間(日)	現在の 日本の開発状況	世界初承認時の 日本の開発状況	日本の予測 患者数(人)	日本の予測 市場(億円)	米国 Priority	米国 FastTrack	日本 優先審査	日本 開発促進
sodium phenylbutyrate	V3X	Urea cycle disorders	H	USA	No	13-May-96	8-Dec-99				NA	NA			No	No	Yes	Yes
betaine	V3X	Homocystinuria	H		No	25-Oct-96	15-Feb-07				NA	NA			Yes	No	Yes	Yes
nitisinone	V3X	Tyrosinemia type 1 [inhibitor of 4- hydroxyphenylpyruvate dioxygenase]	H	UK	No	18-Jan-02	21-Feb-05				NA	NA			Yes	Yes	Yes	Yes
agalsidase beta	V3X	Fabry disease [rDNA alpha-galactosidase A]	H	USA	Yes	24-Apr-03	3-Aug-01	29-Jan-04	909	545		Clinical	100	23	No	Yes	Yes	No
laronidase	V3X	MPS I [rDNA alpha-L-iduronidase]	H	USA	Yes	30-Apr-03	10-Jun-03	20-Oct-06	1269	445		NA	65	22	No	Yes	Yes	Yes
miglustat	V3X	Gaucher disease [glucosyl transferase inhibitor]	H	Japan	No	31-Jul-03	20-Nov-02				NA	NA			No	Yes	No	No
galsulfase	V3X	MPS VI [rDNA arylsulfatase B]	H	USA	Yes	31-May-05	24-Jan-06				Pre-registration	NA	5	2	Yes	Yes	Yes	Yes
alglucosidase alfa	V3H	Pompe disease [rDNA alpha glucosidase]	H	USA	Yes	28-Apr-06	29-Mar-06	18-Apr-07	385	292		NA	135	33	Yes	Yes	Yes	Yes
idursulfase	V3X	MPS II [rDNA idursulfase]	H	USA	Yes	24-Jul-06	8-Jan-07	4-Oct-07	437	246		NA	150	65	Yes	Yes	Yes	Yes
agalsidase alfa	V3X	Fabry disease [rDNA alpha-galactosidase A]	H	USA	Yes		3-Aug-01	20-Oct-06	1904	1439		Clinical	81	20	No	No	Yes	No
zinc acetate dihydrate	V3X	Wilson's disease	L	Israel	No	28-Jan-97	13-Oct-04				Pre-registration	NA	1,000	3	No	No	No	No

Appendix 分析対象新医薬品一覧

その他

一般名 (INN)	ATC	適応症 [薬物特性・作用機序]	臨床的 重要度	オリジネーター 国籍	バイオ 医薬品	米国 承認年月日	EU 承認年月日	日本 承認年月日	日本承認 ラグ(日)	日本審査 期間(日)	現在の 日本の開発状況	世界初承認時の 日本の開発状況	日本の予測 患者数(人)	日本の予測 市場(億円)	米国 Priority	米国 FastTrack	日本 優先審査	日本 開発促進
dexrazoxane	V3D	Cytoprotect to antineoplastic treatment [catalytic inhibitor of topoisomerase II]	H	UK	No	26-May-95	28-Jul-06				NA	NA			Yes	No	No	No
pentetate calcium trisodium	V3X	Internal contamination with plutonium, americium or curium	H		No	11-Aug-04					NA	NA			Yes	No	No	No
pentetate zinc trisodium	V3X	Internal contamination with plutonium, americium or curium	H		No	11-Aug-04					NA	NA			Yes	No	No	No
deferasirox	V3F	Iron overload [iron chelator]	H	Switzerland	No	2-Nov-05	28-Aug-06				Pre-registration	NA	3,940	113	Yes	Yes	Yes	Yes
sevelamer	V3G	Hyperphosphatemia	L	USA	No	30-Oct-98	28-Jan-00	31-Jan-03	1554	406		Clinical phase II	66,000	126	No	No	No	No
drotrecogin alfa (activated)	V3X	Severe sepsis	L	USA	Yes	21-Nov-01	22-Aug-02				NA	NA			No	No	No	No
rasburicase	V3D	Prophylaxis of acute hyperuricaemia	L	France	Yes	12-Jul-02	23-Feb-01				Clinical pII	NA			No	No	No	No
icodextrin	V3X	Peritoneal dialysis	L	UK	No	10-Dec-02	15-Mar-93	16-Apr-03	3684	656		NA	6,900	60	No	No	No	No
lanthanum	V3G	Hyperphosphatemia	L	UK	No	26-Oct-04	15-Mar-05				Pre-registration	Clinical			No	No	No	No
deferiprone	V3F	Iron overload	L	UK	No		25-Aug-99				NA	NA			No	No	No	No