資料８

今後の要望募集の取り扱い（案）について

１．現状の整理

①　第Ⅰ回及び第Ⅱ回要望品の進捗状況（表参照）

○ 第Ⅰ回と第Ⅱ回を比較した際、要望に占める適応外薬の割合が増加している。

○ 第Ⅰ回の医療上の必要性の評価は終了している。

➢未承認薬：３３品目は治験を実施中

➢適応外薬：４８品目は治験を実施中。

○ 第Ⅱ回の医療上の必要性の評価については２４件残っているところ。

すでに必要性の評価が済んだ品目についても、第Ⅰ回に比べ治験の実施が必要な品目の割合が多い。

表　第Ⅰ回及び第Ⅱ回要望品目の進捗状況

第Ⅰ回	要望を受けた品目数	医療上の必要性が高いとして開発を要請した品目		承認したもの		治験中のもの※
		治験が必要な品目※	公知申請をしたもの	治験	公知申請	
未承認薬	86	57		24		33
適応外薬	288	69	59	22	58	48
合計	374	126	59	46	58	81

第Ⅱ回	要望を受けた品目数	医療上の必要性が高いとして開発を要請した品目		承認したもの		治験中のもの※
		治験が必要な品目※	公知申請をしたもの	治験	公知申請	
未承認薬	50	25		1		24
適応外薬	240	53	20	1	11	61
合計	290	78	20	2	11	85

※実施が必要な試験や公知申請の妥当性について検討中のものも含む　　平成25年3月末現在

②　未承認薬リストについて

○ FDA（2009 年 4 月～2013 年 3 月）及び EMA（2009 年 4 月～2013 年 3 月）で承認されており、日本での未承認の医薬品は別添のとおり

２．今後の要望の取り扱い（案）

【基本的な方針】

○ 引き続き医療上必要性の高い医薬品のラグ解消に係る要望があることを踏まえつつ、第Ⅰ回及び第Ⅱ回の開発に相当のリソースが割かれている状況を考慮し、特に医療上の必要性が高いと考えられる以下のものを優先的に取り扱うこととする。

○ 患者団体、個人が要望する場合は第Ⅱ回と同様関連する学会を指定していただくこととする。

○ 要望は継続的に受け付けることとするが、まずは 12 月末までで締め切り、医療上の必要性等の評価に着手することとする。

【優先的に取り扱う対象】

➢ 未承認薬： 今回は 2009 年 4 月以降に、FDA 及び EMA で承認された医薬品のうち、国内で承認のない品目から選択することとし、医療上の必要性のあるものについては開発要請を追加する。

➢ 適応外薬：速やかに医師主導治験や先進医療 B（ただし、ICH-GCP を準拠できたものに限る。）等が実施された医薬品のうち、医療上の必要性のあるものについては優先的に取り扱う。

✯ 先進医療 B や医師主導治験が終了し、エビデンスが示された場合に要望を可能とする。（治験以外の臨床試験についても、必要に応じて GCP 調査を実施することができる）

✯ 適応外薬の要望を行う場合は「適応外使用に係る医療用医薬品の取扱いについて」（平成 11 年 2 月 1 日付け研第 4 号・医薬審第 104 号）の記２（１）～（３）のいずれかに基づくこと。

（参考１）「適応外使用に係る医療用医薬品の取扱いについて」（平成 11 年 2 月 1 日付け研第 4 号・医薬審第 104 号）抜粋

（１） 外国（本邦と同等の水準にあると認められる承認の制度又はこれに相当する制度を有している国（例えば、米国）をいう。以下同じ。）において、既に当該効能又は効果等により承認され、医療における相当の使用実績があり、その審査当局に対する承認申請に添付されている資料が入手できる場合

（２） 外国において、既に当該効能又は効果等により承認され、医療における相当の使用実績があり、国際的に信頼できる学術雑誌に掲載された科学的根拠となり得る論文又は国際機関で評価された総説等がある場合

（３） 公的な研究事業の委託研究等により実施されるなどその実施に係る倫理性、科学性及び信頼性が確認し得る臨床試験の試験成績がある場合

（参考２）要望の範囲について：

①未承認薬：欧米等 6 ヶ国（米、英、独、仏、加、豪）での承認を要件とする。
EU で中央承認されているものは、英、独、仏における承認があるものと見なす。

②適応外薬：欧米等 6 か国（米、英、独、仏、加、豪）のいずれかの国で承認された適応（欧米等 6 か国のいずれかの国で、一定のエビデンスに基づき特定の用法・用量で広く使用されていることが確認できる場合を含む）

３．今後のスケジュール

- 6 月 19 日　医療上の必要性の高い未承認薬･適応外薬検討会議（当該資料を HP 掲載）
- 8 月 1 日　 正式募集開始
- 12 月 27 日　とりまとめのための締め切り（募集に関しては継続する）

米国承認済み(2009.4－2013.3)で日本で未承認の医薬品

別添

No.	国名	有効成分名	企業名	承認日	効能・効果	調査日
1	アメリカ	ARTEMETHER/ LUMEFANTRINE	NOVARTIS	2009/4/7	・Coartem (artemether and lumefantrine) Tablets are indicated for treatment of acute, uncomplicated malaria infections duc to Plasmodium falciparum in patients of 5 kg bodyweight and above (1) ・ Coartem Tablets have been shown to be effective in geographical regions where resistance to chloroquine has becn reported (I) . ・Coartem Tablets should not be used to treat severe malaria or to prevent malaria (1)	2013/4/3
2	アメリカ	BENZYL ALCOHOL	SHIONOGI INC	2009/4/9	TRADENAME*Ⅰ) Lotion is a pediculocide indicated for the topical treatment of head lice infestation in patients 6 months of age and older. (1.1) TRADENAME Lotion does not have ovocidal activity. (1.2)	2013/4/3
3	アメリカ	abobotulinumtoxinA*Ⅱ)	IPSEN BIOPHARM LTD	2009/4/29	DYSPORT™ is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for: · the treatment of adults with cervical dystonia to reduce the severity of abnonnal head position and neck pain in both toxin-naïve and previously treated patients (1.1) · the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adult patients < 65 years of age (1.2)	2013/4/3
4	アメリカ	ILOPERIDONE	NOVARTIS	2009/5/6	FANAPT is an atypical antipsychotic agent indicated for the acute treatment of schizophrenia in adults (1). In choosing among treatments, prescribers should consider the ability of FANAPT to prolong the QT interval and the use of other drugs first. Prescribers should also consider the need to titrate FANAPT slowly to avoid orthostatic hypotension, which may lead to delayed effectiveness compared to some other drugs that do not require similar titration.	2013/4/3
5	アメリカ	BESIFLOXACIN HYDROCHLORIDE	BAUSCH AND LOMB	2009/5/28	Besivancee™(besifloxacin ophthalmic suspension) 0.6%, is a quinolone antimicrobial indicated for the treatment of bacterial conjunctivitis caused by susceptible isolates of the following bacteria: CDC coryneform group G, Corynebacterium pseudodiphtheriticum*, Corynebacterium striatum*, Haemophilus influenzae, Moraxella lacunata*, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus hominis*, Staphylococcus lugdunensis*, Streptococcus mitis group, Streptococcus oralis, Streptococcus pneumoniae, Streptococcus salivarius* *Efficacy for this organism was studied in fewer than 10 infections. (1)	2013/4/3
6	アメリカ	DRONEDARONE HYDROCHLORIDE	SANOFI AVENTIS US	2009/7/1	MULTAQ is an antiarrhythmic drug indicated to reduce the risk of cardiovascular hospitalization in patients with paroxysmal or persistent atrial fibrillation (AF) or atrial flutter (AFL), with a recent episode of AF/AFL and associated cardiovascular risk factors (i.e., age >70, hypertension, diabetes, prior cerebrovascular accident, left atrial diameter ≥50 mm or left ventricular ejection fraction [LVEF] <40%), who are in sinus rhythm or who will be cardioverted (1, 14).	2013/4/3
7	アメリカ	PRASUGREL HYDROCHLORIDE	ELI LILLY AND CO	2009/7/10	Effient is a $P2Y_{12}$ platelet inhibitor indicated for the reduction of thrombotic cardiovascular events (including stent thrombosis) in patients with acute coronary syndrome who are to be managed with PCI as follows: ·Patients with unstable angina or, non-ST-elevation myocardial infarction (NSTEMI) (1.1) ·Patients with ST-elevation myocardial infarction (STEMI) when managed with either primary or delayed PCI (1.1).	2013/4/3
8	アメリカ	ASENAPINE MALEATE	ORGANON SUB MERCK	2009/8/13	SAPHRIS is an atypical antipsychotic indicated for: ·Acute treatment of schizophrenia in adults (1.1) ·Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults (1.2)	2013/4/3
9	アメリカ	VIGABATRIN	LUNDBECK LLC	2009/8/21	SABRIL is an antiepileptic drug (AED) indicated for: · Refractory Complex Partial Seizures in Adults (1.1). It should be used as adjunctive therapy in patients who have responded inadequately to several alternative treatments.	2013/4/3
10	アメリカ	VIGABATRIN*Ⅲ)	LUNDBECK LLC	2009/8/21	SABRIL is an antiepileptic drug (AED) indicated for: ・ Infantile Spasms (IS) – 1 Month to 2 Years of Age (1.1)	2013/4/3
11	アメリカ	TELAVANCIN HYDROCHLORIDE	THERAVANCE INC	2009/9/11	VIBATIV is a lipoglycopeptide antibacterial indicated for the treatment of adult patients with complicated skin and skin structure infections (cSSSI) caused by susceptible Gram-positive bacteria. (1.1)	2013/4/3
12	アメリカ	PRALATREXATE	ALLOS	2009/9/24	FOLOTYN is a folate analogue metabolic inhibitor indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL). This indication is based on overall response rate. Clinical benefit such as improvement in progression free survival or overall survival has not been demonstrated. (1)	2013/4/3
13	アメリカ	ROMIDEPSIN	CELGENE	2009/11/5	ISTODAX is a histone deacetylase (HDAC) inhibitor indicated for: · Treatment of cutaneous T-cell lymphoma (CTCL) in patients who have received at least one prior systemic therapy (1).	2013/4/3
14	アメリカ	ECALLANTIDE	DYAX CORP.	2009/11/27	KALBITOR is a plasma kallikrein inhibitor indicated for treatment of acute attacks of hereditary angioedema (HAE) in patients 16 years of age and older. (1)	2013/4/3
15	アメリカ	DALFAMPRIDINE	ACORDA	2010/1/22	AMPYRA™ (dalfampridine) is a potassium channel blocker indicated to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed (1, 14).	2013/4/3
16	アメリカ	COLLAGENASE CLOSTRIDIUM HISTOLYTICUM	AUXILIUM PHARMS	2010/2/2	XIAFLEX is indicated for the treatment of adult patients with Dupuytren's contracture with a palpable cord. (1)	2013/4/3
17	アメリカ	VELAGLUCERASE ALFA	SHIRE HUMAN GENETIC	2010/2/26	VPRIV (velaglucerase alfa for injection) is a hydrolytic lysosomal glucocerebroside-specific enzyme indicated for long-term enzyme replacement therapy (ERT) for pediatric and adult patients with type 1 Gaucher disease (1).	2013/4/3
18	アメリカ	CARGLUMIC ACID	ORPHAN EUROPE	2010/3/18	Carbaglu (carglumic acid) is a Carbamoyl Phosphate Synthetase 1 (CPS 1) activator indicated as: ·Adjunctive therapy for the treatment of acute hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS). (1.1) ·Maintenance therapy for the treatment of chronic hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS). (1.2)	2013/4/3
19	アメリカ	DIENOGEST/ ESTRADIOL VALERATE	BAYER HLTHCARE	2010/5/6	·Natazia is an estrogen/progestin COC indicated for use by women to prevent pregnancy. (1) ·The efficacy of Natazia in women with a body mass index (BMI) of >30 kg/m^2 has not been evaluated. (1, 8.8)	2013/4/3
20	アメリカ	CABAZITAXEL	SANOFI AVENTIS US	2010/6/17	JEVTANA is a microtubule inhibitor indicated in combination with prednisone for treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen. (1)	2013/4/3

米国承認済み(2009.4－2013.3)で日本で未承認の医薬品

No.	国名	有効成分名	企業名	承認日	効能・効果	調査日
21	アメリカ	ALCAFTADINE	ALLERGAN	2010/7/28	LASTACAFT™ is a H_1 histamine receptor antagonist indicated for the prevention of itching associated with allergic conjunctivitis (1)	2013/4/3
22	アメリカ	incobotulinumtoxinA(*Ⅱ)	MERZ PHARMS	2010/7/30	XEOMIN is an acetylcholine release inhibitor and neuromuscular blocking agent indicated for the treatment of: ·Adults with cervical dystonia, to decrease the severity of abnormal head position and neck pain in both botulinum toxin-naïve and previously treated patients (1.1). ·Blepharospasm in adults previously treated with onabotulinumtoxinA (Botox®) (1.2).	2013/4/3
23	アメリカ	ULIPRISTAL ACETATE	LAB HRA PHARMA	2010/8/13	ella is a progesterone agonist/antagonist emergency contraceptive indicated for prevention of pregnancy following unprotected intercourse or a known or suspected contraceptive failure. ella is not intended for routine use as a contraceptive. (1)	2013/4/3
24	アメリカ	PEGLOTICASE	SAVIENT PHARMS	2010/9/14	KRYSTEXXA™ (pegloticase) is a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. (1) Important Limitations of Use: KRYSTEXX is not recommended for the treatment of asymptomatic hyperuricemia. (1)	2013/4/3
25	アメリカ	LURASIDONE HYDROCHLORIDE	SUNOVION PHARMS INC	2010/10/28	LATUDA is an atypical antipsychotic agent indicated for the treatment of patients with schizophrenia (1). Efficacy was established in four 6-week controlled studies of adult patients with schizophrenia (14.1).	2013/4/3
26	アメリカ	CEFTAROLINE FOSAMIL	CEREXA	2010/10/29	Teflaro™ is a cephalosporin antibacterial indicated for the treatment of the following infections caused by designated susceptible bacteria: ·Acute bacterial skin and skin structure infections (ABSSSI) (1.1) ·Community-acquired bacterial pneumonia (CABP) (1.2)	2013/4/3
27	アメリカ	TESAMORELIN ACETATE	EMD SERONO	2010/11/10	EGRIFTA™ is a growth hormone releasing factor (GRF) analog indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. (1) Limitations of use (1): ·Long-term cardiovascular benefit and safety of EGRIFTA™ have not been studied. ·Not indicated for weight loss management (weight neutral effect). ·There are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking EGRIFTA™.	2013/4/3
28	アメリカ	IOFLUPANE I-123	GE HLTHCARE INC	2011/1/14	DaTscan (Ioflupane I 123 Injection) is a radiopharmaceutical indicated for striatal dopamine transporter visualization using single photon emission computed tomography (SPECT) brain imaging to assist in the evaluation of adult patients with suspected Parkinsonian syndromes (PS). In these patients, DaTscan may be used to help differentiate essential tremor from tremor due to PS (idiopathic Parkinson's disease, multiple system atrophy and progressive supranuclear palsy). DaTscan is an adjunct to other diagnostic evaluations. (1)	2013/4/3
29	アメリカ	SPINOSAD	PARAPRO LLC	2011/1/18	NATROBA Topical Suspension is a pediculicide indicated for the topical treatment of head lice infestations in patients four (4) years of age and older.(1)	2013/4/3
30	アメリカ	VILAZODONE HYDROCHLORIDE	FOREST LABS INC	2011/1/21	VIIBRYD is indicated for the treatment of major depressive disorder (MDD). The efficacy of VIIBRYD was established in two 8-week, placebo-controlled trials in adult patients with MDD (1, 14).	2013/4/3
31	アメリカ	AZILSARTAN KAMEDOXOMIL(*Ⅱ)	TAKEDA PHARMS USA	2011/2/25	Edarbi is an angiotensin II receptor blocker indicated for the treatment of hypertension, either alone or in combination with other antihypertensive agents. (1)	2013/4/3
32	アメリカ	ROFLUMILAST	FOREST RES INST INC	2011/2/28	DALIRESP is indicated as a treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations. (1, 14) Limitations of Use: DALIRESP is not a bronchodilator and is not indicated for the relief of acute bronchospasm. (1, 14)	2013/4/3
33	アメリカ	BELIMUMAB	HUMAN GENOME SCIENCES INC.	2011/3/9	BENLYSTA is a B-lymphocyte stimulator (BLyS)-specific inhibitor indicated for the treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy. (1, 14) Limitations of Use: The efficacy of BENLYSTA has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus (1). BENLYSTA has not been studied in combination with other biologics or intravenous cyclophosphamide (1). Use of BENLYSTA is not recommended in these situations.	2013/4/3
34	アメリカ	GADOBUTROL	BAYER HLTHCARE	2011/3/14	Gadavist is a gadolinium-based contrast agent indicated for intravenous use in diagnostic MRI in adults and children (2 years of age and older) to detect and visualize areas with disrupted blood brain barrier (BBB) and/or abnormal vascularity of the central nervous system. (1)	2013/4/3
35	アメリカ	IPILIMUMAB	BRISTOL MYERS SQUIBB	2011/3/25	YERVOY is a human cytotoxic T-lymphocyte antigen 4 (CTLA-4)-blocking antibody indicated for the treatment of unresectable or metastatic melanoma.(1)	2013/4/3
36	アメリカ	VANDETANIB	IPR PHARMS INC	2011/4/6	Vandetanib is a kinase inhibitor indicated for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease. Use of vandetanib in patients with indolent, asymptomatic or slowly progressing disease should be carefully considered because of the treatment related risks of vandetanib.	2013/4/3
37	アメリカ	ABIRATERONE ACETATE	JANSSEN BIOTECH	2011/4/28	ZYTIGA is a CYP17 inhibitor indicated for use in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer who have received prior chemotherapy containing docetaxel.(1)	2013/4/3
38	アメリカ	BOCEPREVIR	MERCK SHARP DOHME	2011/5/13	VICTRELIS is a hepatitis C virus (HCV) NS3/4A protease inhibitor indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients (≥18 years of age) with compensated liver disease, including cirrhosis, who are previously untreated or who have failed previous interferon and ribavirin therapy. (1) VICTRELIS must not be used as a monotherapy. (1)	2013/4/3
39	アメリカ	FIDAXOMICIN	OPTIMER PHARMS	2011/5/27	DIFICID is a macrolide antibacterial drug indicated in adults (≥18 years of age) for treatment of Clostridium difficile-associated diarrhea (1.1).	2013/4/3
40	アメリカ	EZOGABINE	GLAXOSMITHKLINE	2011/6/10	POTIGA is a potassium channel opener indicated as adjunctive treatment of partial-onset seizures in patients aged 18 years and older. (1)	2013/4/3

米国承認済み(2009.4－2013.3)で日本で未承認の医薬品

No.	国名	有効成分名	企業名	承認日	効能・効果	調査日
41	アメリカ	BELATACEPT	BRISTOL MYERS SQUIBB	2011/6/15	·NULOJIX is a selective T-cell costimulation blocker indicated for prophylaxis of organ rejection in adult patients receiving a kidney transplant. (1.1) ·Use in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids. (I. I) Limitations of Use: ·Use only in patients who are EBV seropositive. (1.2,4,5. i) ·Use has not been established for the prophylaxis of organ rejection in transplanted organs other than the kidney. (1.2, 5,6)	2013/4/3
42	アメリカ	TICAGRELOR	ASTRAZENECA LP	2011/7/20	BRILINTA is a $P2Y_{12}$ platelet inhibitor indicated to reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndrome (ACS) (unstable angina, non-ST elevation myocardial infarction, or ST elevation myocardial infarction). BRILINTA has been shown to reduce the rate of a combined endpoint of cardiovascular death, myocardial infarction, or stroke compared to clopidogrel. The difference between treatments was driven by CV death and MI with no difference in stroke. In patients treated with PCI, it also reduces the rate of stent thrombosis. (1) BRILINTA has been studied in ACS in combination with aspirin. Maintenance doses of aspirin above 100 mg decreased the effectiveness of BRILINTA. Avoid maintenance doses of aspirin above 100 mg daily. (1, 5.2, 14).	2013/4/3
43	アメリカ	VEMURAFENIB	HOFFMANN LA ROCHE	2011/8/17	ZELBORAF™ is a kinase inhibitor indicated for the treatment of patients with unresectable or metastatic melanoma with $BRAF^{V600E}$ mutation as detected by an FDA-approved test. (1, 5.10) Limitation of Use: ZELBORAF is not recommended for use in patients with wild-type BRAF melanoma. (5.10, 14)	2013/4/3
44	アメリカ	BRENTUXIMAB VEDOTIN	SEATTLE GENETICS	2011/8/19	ADCETRIS is a CD30-directed antibody-drug conjugate indicated for: ·The treatment of patients with Hodgkin lymphoma after failure of autologous stem cell transplant (ASCT) or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates (1.1). ·The treatment of patients with systemic anaplastic large cell lymphoma after failure of at least one prior multi-agent chemotherapy regimen (1.2). These indications are based on response rate. There are no data available demonstrating improvement in patient reported outcomes or survival with ADCETRIS.	2013/4/3
45	アメリカ	ICATIBANT ACETATE	SHIRE ORPHAN THERAP	2011/8/25	FIRAZYR is a bradykinin B2 receptor antagonist indicated for treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older. (1)	2013/4/3
46	アメリカ	DEFERIPRONE	APOPHARMA INC	2011/10/14	FERRIPROX® (deferiprone) is an iron chelator indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate. (1) Approval is based on a reduction in serum ferritin levels. There are no controlled trials demonstrating a direct treatment benefit, such as improvement in disease-related symptoms, functioning, or increased survival.(1) Limitation of Use ·Safety and effectiveness have not been established for the treatment of transfusional iron overload in patients with other chronic anemias. (1)	2013/4/3
47	アメリカ	RUXOLITINIB PHOSPHATE	INCYTE CORP	2011/11/16	Jakafi is a kinase inhibitor indicated for treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis. (1)	2013/4/3
48	アメリカ	asparaginase Erwinia chrysanthemi	EUSA PHARMA USA	2011/11/18	ERWINAZE (asparaginase Erwinia chrysanthemi) is an asparagine specific enzyme indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia (ALL) who have developed hypersensitivity to E. coli-derived asparaginase. (1)	2013/4/3
49	アメリカ	GLUCARPIDASE	BTG INTERNATIONAL INC	2012/1/17	·VORAXAZE® (glucarpidase) is a carboxypeptidase enzyme indicated for the treatment of toxic plasma methotrexate concentrations (>1 micromole per liter) in patients with delayed methotrexate clearance due to impaired renal function. (1.1) ·Limitation of use: VORAXAZE is not indicated for use in patients who exhibit the expected clearance of methotrexate (plasma methotrexate concentrations within 2 standard deviations of the mean methotrexate excretion curve specific for the dose of methotrexate administered) or those with normal or mildly impaired renal function because of the potential risk of subtherapeutic exposure to methotrexate. (1.2)	2013/4/3
50	アメリカ	INGENOL MEBUTATE	LEO PHARMA AS	2012/1/23	Picato® gel is an inducer of cell death indicated for the topical treatment of actinic keratosis.(1)	2013/4/3
51	アメリカ	VISMODEGIB	GENENTECH	2012/1/30	ERIVEDGE™ (vismodegib) capsule is a hedgehog pathway inhibitor indicated for the treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation.(1)	2013/4/3
52	アメリカ	IVACAFTOR	VERTEX PHARMS	2012/1/31	KALYDECO is classified as a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator. KALYDECO is indicated for the treatment of cystic fibrosis (CF) in patients age 6 years and older who have a G551D mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the G551D mutation. Limitations of Use: · Not effective in patients with CF who are homozygous for the F508del mutation in the CFTR gene. (1, 14) · KALYDECO has not been studied in other populations of patients withCF. (1, 14)	2013/4/3
53	アメリカ	LUCINACTANT	DISCOVERY LABS	2012/3/6	SURFAXIN is indicated for the prevention of respiratory distress syndrome (RDS) in premature infants at high risk for RDS. (1)	2013/4/3
54	アメリカ	PEGINESATIDE ACETATE*v)	AFFYMAX	2012/3/27	OMONTYS is an erythropoiesis-stimulating agent (ESA) indicated for the treatment of anemia due to chronic kidney disease (CKD) in adult patients on dialysis (1.1). Limitations of Use OMONTYS is not indicated and is not recommended for use: · In patients with CKD not on dialysis (1.2). · In patients receiving treatment for cancer and whose anemia is not due to CKD (1.2). · As a substitute for RBC transfusions in patients who require immediate correction of anemia (1.2). · OMONTYS has not been shown to improve symptoms,physical functioning or health-related quality of life (1.2).	2013/4/3

米国承認済み(2009.4－2013.3)で日本で未承認の医薬品

No.	国名	有効成分名	企業名	承認日	効能・効果	調査日
55	アメリカ	FLORBETAPIR F-18	AVID RADIOPHARMS INC	2012/4/6	Amyvid is a radioactive diagnostic agent for Positron Emission Tomography (PET) imaging of the brain to estimate β-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's Disease (AD) and other causes of cognitive decline. A negative Amyvid scan indicates sparse to no neuritic plaques, and is inconsistent with a neuropathological diagnosis of AD at the time of image acquisition; a negative scan result reduces the likelihood that a patient's cognitive impairment is due to AD. A positive Amyvid scan indicates moderate to frequent amyloid neuritic plaques; neuropathological examination has shown this amount of amyloid neuritic plaque is present in patients with AD, but may also be present in patients with other types of neurologic conditions as well as older people with normal cognition. Amyvid is an adjunct to other diagnostic evaluations (1). Limitations of Use ·A positive Amyvid scan does not establish a diagnosis of AD or other cognitive disorder (1). ·Safety and effectiveness of Amyvid have not been established for: ·Predicting development of dementia or other neurologic condition; ·Monitoring responses to therapies (1).	2013/4/3
56	アメリカ	AVANAFIL	VIVUS	2012/4/27	STENDRA is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction (1)	2013/4/3
57	アメリカ	TALIGLUCERASE ALFA	PFIZER	2012/5/1	ELELYSO™ (taliglucerase alfa) for injection is a hydrolytic lysosomal glucocerebroside-specific enzyme indicated for long-term enzyme replacement therapy (ERT) for adults with a confirmed diagnosis of Type 1 Gaucher disease. (1)	2013/4/3
58	アメリカ	PERTUZUMAB	GENENTECH	2012/6/8	PERJETA is a HER2/neu receptor antagonist indicated in combination with trastuzumab and docetaxel for the treatment of patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease. (1)	2013/4/3
59	アメリカ	LORCASERIN HYDROCHLORIDE	EISAI INC	2012/6/27	BELVIQ is a serotonin 2C receptor agonist indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: ·30 kg/m^2 or greater (obese) (1) or ·27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition, (e.g., hypertension, dyslipidemia, type 2 diabetes) (1) Limitations of Use: ·The safety and efficacy of coadministration with other products for weight loss have not been established (1) ·The effect of BELVIQ on cardiovascular morbidity and mortality has not been established (1)	2013/4/3
60	アメリカ	CITRIC ACID/ MAGNESIUM OXIDE/ SODIUM PICOSULFATE	FERRING PHARMS AS	2012/7/16	PREPOPIK is a combination of sodium picosulfate, a stimulant laxative, and magnesium oxide and anhydrous citric acid which form magnesium citrate, an osmotic laxative, indicated for cleansing of the colon as a preparation for colonoscopy in adults (1)	2013/4/3
61	アメリカ	CARFILZOMIB	ONYX PHARMS	2012/7/20	KYPROLIS is a proteasome inhibitor indicated for the treatment of patients with multiple myeloma who have received at least two prior therapies including bortezomib and an immunomodulatory agent and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified. (1, 14)	2013/4/3
62	アメリカ	ACLIDINIUM BROMIDE	FOREST LABS INC	2012/7/23	TUDORZA PRESSAIR is an anticholinergic indicated for the long-term maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema(1)	2013/4/3
63	アメリカ	ZIV-AFLIBERCEPT*Ⅱ)	SANOFI AVENTIS US	2012/8/3	ZALTRAP, in combination with 5-fluorouracil, leucovorin, irinotecan-(FOLFIRI), is indicated for patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen. (1)	2013/4/3
64	アメリカ	TBO-FILGRASTIM*Ⅱ)	SICOR BIOTECH	2012/8/29	Tbo-filgrastim is a leukocyte growth factor indicated for the reduction in the duration of severe neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. (1)	2013/4/3
65	アメリカ	LINACLOTIDE	FOREST LABS INC	2012/8/30	LINZESS is a guanylate cyclase-C agonist indicated in adults for treatment of: ·Irritable bowel syndrome with constipation (IBS-C) (1.1) ·Chronic idiopathic constipation (CIC) (1.2)	2013/4/3
66	アメリカ	ENZALUTAMIDE	ASTELLAS	2012/8/31	XTANDI is an androgen receptor inhibitor indicated for the treatment of patients with metastatic castration-resistant prostate cancer who have previously received docetaxel. (1)	2013/4/3
67	アメリカ	BOSUTINIB MONOHYDRATE	WYETH PHARMS INC	2012/9/4	· BOSULIF is a kinase inhibitor indicated for the treatment of adult patients with chronic, accelerated, or blast phase Ph+ chronic myelogenous leukemia (CML) with resistance or intolerance to prior therapy. (1)	2013/4/3
68	アメリカ	CHOLINE C 11	MCPRF	2012/9/12	Choline C 11 Injection is a radioactive diagnostic agent for positron emission tomography (PET) imaging of patients with suspected prostate cancer recurrence and non-informative bone scintigraphy, computerized tomography (CT) or magnetic resonance imaging. In these patients, ^{11}C-choline PET imaging may help identify potential sites of prostate cancer recurrence for subsequent histologic confirmation. Suspected prostate recurrence is based upon elevated blood prostate specific antigen (PSA) levels following initial therapy. In clinical studies, images were produced with PET/CT coregistration. Limitation of Use: ^{11}C-choline PET imaging is not a replacement for histologic verification of recurrent prostate cancer (1).	2013/4/3
69	アメリカ	TERIFLUNOMIDE	SANOFI AVENTIS US	2012/9/12	AUBAGIO is a pyrimidine synthesis inhibitor indicated for the treatment of patients with relapsing forms of multiple sclerosis (1)	2013/4/3
70	アメリカ	OCRIPLASMIN	THROMBOGENICS, INC	2012/10/17	JETREA is a proteolytic enzyme indicated for the treatment of symptomatic vitreomacular adhesion. (1)	2013/4/3
71	アメリカ	PERAMPANEL	EISAI INC	2012/10/22	FYCOMPA, a non-competitive AMPA glutamate receptor antagonist, is indicated as adjunctive therapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy aged 12 years and older (1)	2013/4/3
72	アメリカ	OMACETAXINE MEPESUCCINATE	IVAX INTL	2012/10/26	SYNRIBO for Injection is indicated for the treatment of adult patients with chronic or accelerated phase chronic myeloid leukemia (CML) with resistance and/or intolerance to two or more tyrosine kinase inhibitors (TKI). This indication is based upon response rate. There are no trials verifying an improvement in disease-related symptoms or increased survival with SYNRIBO. (1)	2013/4/3
73	アメリカ	CABOZANTINIB S-MALATE	EXELIXIS	2012/11/29	COMETRIQ is a kinase inhibitor indicated for the treatment of patients with progressive, metastatic medullary thyroid cancer(MTC). (1)	2013/4/3

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No.	国名	有効成分名	企業名	承認日	効能・効果	調査日
74	アメリカ	RAXIBACUMAB	HUMAN GENOME SCIENCES INC.	2012/12/14	Raxibacumab is indicated for the treatment of adult and pediatric patients with inhalational anthrax due to Bacillus anthracis in combination with appropriate antibacterial drugs, and for prophylaxis of inhalational anthrax when alternative therapies are not available or are not appropriate. (1) Limitations of Use: ・The effectiveness of raxibacumab is based solely on efficacy studies in animal models of inhalational anthrax. (1.2, 14.1) ・There have been no studies of raxibacumab in the pediatric population. Dosing in pediatric patients was derived using a population PK approach. (1.2, 8.4) ・Raxibacumab does not cross the blood-brain barrier and does not prevent or treat meningitis. Raxibacumab should be used in combination with appropriate antibacterial drugs. (1.2)	2013/4/3
75	アメリカ	PASIREOTIDE DIASPARTATE	NOVARTIS	2012/12/14	SIGNIFOR is a somatostatin analog indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative (1)	2013/4/3
76	アメリカ	PONATINIB HYDROCHLORIDE	ARIAD	2012/12/14	Iclusig is a kinase inhibitor indicated for the treatment of adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) that is resistant or intolerant to prior tyrosine kinase inhibitor therapy or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL) that is resistant or intolerant to prior tyrosine kinase inhibitor therapy (1). This indication is based upon response rate. There are no trials verifying an improvement in disease-related symptoms or increased survival with Iclusig.	2013/4/3
77	アメリカ	LOMITAPIDE MESYLATE	AEGERION	2012/12/21	JUXTAPID is a microsomal triglyceride transfer protein inhibitor indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-highdensity lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH) (1). Limitations of Use ·The safety and effectiveness of JUXTAPID have not been established in patients with hypercholesterolemia who do not have HoFH (1). ·The effect of JUXTAPID on cardiovascular morbidity and mortality has not been determined (1).	2013/4/3
78	アメリカ	TEDUGLUTIDE RECOMBINANT	NPS PHARMS INC	2012/12/21	GATTEX® (teduglutide [rDNA origin]) for injection is a glucagon-like peptide-2 (GLP-2) analog indicated for the treatment of adult patients with Short Bowel Syndrome (SBS) who are dependent on parenteral support. (1).	2013/4/3
79	アメリカ	BEDAQUILINE FUMARATE	JANSSEN THERAP	2012/12/28	SIRTURO is a diarylquinoline antimycobacterial drug indicated as part of combination therapy in adults (≥ 18 years) with pulmonary multi-drug resistant tuberculosis (MDR-TB). Reserve SIRTURO for use when an effective treatment regimen cannot otherwise be provided. SIRTURO is not indicated for the treatment of latent, extra-pulmonary or drug-sensitive tuberculosis. (1)	2013/4/3
80	アメリカ	CROFELEMER	SALIX PHARMS	2012/12/31	FULYZAQ is an anti-diarrheal indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy (1)	2013/4/3
81	アメリカ	ALOGLIPTIN BENZOATE/ METFORMIN HYDROCHLORIDE	TAKEDA PHARMS USA	2013/1/25	KAZANO is a dipeptidyl-peptidase-4 (DPP-4) inhibitor and a biguanide combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. (1.1) Important Limitation of Use: Not for treatment of type 1 diabetes or diabetic ketoacidosis. (1.2)	2013/4/3
82	アメリカ	MIPOMERSEN SODIUM	GENZYME CORP	2013/1/29	KYNAMRO™ is an oligonucleotide inhibitor of apolipoprotein B-100 synthesis indicated as an adjunct to lipid-lowering medications and diet to reduce low density lipoprotein-choleste rol (LDL-C), apolipoprotein B (apoB), total cholesterol (TC), and non-high density lipoprotein-cholesterol (nonHDL-C) in patients with homozygous familial hypercholesterolemia (HoFH)(1). Limitations of Use: ・The safety and effectiveness of KYNAMRO have not been established in patients with hypercholesterolemia who do not have HoFH. ・The effect of KYNAMRO on cardiova scular morbidity and mortality has not been determined. ・The use of KYNAMRO as an adjunct to LDL apheresis is not recommended.	2013/4/3
83	アメリカ	POMALIDOMIDE	CELGENE	2013/2/8	POMALYST is a thalidomide analogue indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms,has not been verified.	2013/4/3
84	アメリカ	ADO-TRASTUZUMAB EMTANSINE	GENENTECH	2013/2/22	KADCYLA is a HER2-targeted antibody and microtubule inhibitor conjugate indicated, as a single agent, for the treatment of patients with HER2-positive,metastatic breast cancer who previously received trastuzumab and a taxane,separately or in combination. Patients should have either: ・Received prior therapy for metastatic disease, or ・Developed disease recurrence during or within six months of completing adjuvant therapy. (1)	2013/4/3
85	アメリカ	OSPEMIFENE	SHIONOGI INC	2013/2/26	OSPHENA is an estrogen agonist/antagonist indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy,due to menopause (1)	2013/4/3
86	アメリカ	TECHNETIUM TC 99M TILMANOCEPT	NAVIDEA BIOPHARMACEUTICALS INC	2013/3/13	Lymphoseek (technetium Tc 99m tilmanocept) Injection is a radioactive diagnostic agent indicated for lymphatic mapping with a hand-held gammacounter to assist in the localization of lymph nodes draining a primary tumor site in patients with breast cancer or melanoma. (1)	2013/4/3
87	アメリカ	DIMETHYL FUMARATE	BIOGEN IDEC INC	2013/3/27	TECFIDERA is indicated for the treatment of patients with relapsing forms of multiple sclerosis (1)	2013/4/3
88	アメリカ	CANAGLIFLOZIN	JANSSEN RES AND DEV	2013/3/29	INVOKANA is a sodium-glucose co-transporter 2 (SGLT2) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (1) Limitation of Use: ・Not for treatment of type 1 diabetes mellitus or diabetic ketoacidosis (1)	2013/4/3

FDA__HPにあるSearch Drug Approvals by Month Using Drugs@FDAよりNDA Chemical Typesが1(New molecular entity (NME))およびBLAとして承認されたもののうち、日本で2013年5月31日時点で未承認のものを掲載した。(引き続き調査中)

注1)企業名は調査時、効能・効果は承認時の情報に基づき記載している。

注2)マーカーは米国および欧州の未承認薬一覧のうち、米国と欧州で有効成分名が同じ医薬品。

＊Ⅰ)販売名がULESFIAに変更されている。

＊Ⅱ)類似医薬品が日本で承認されている。

＊Ⅲ)№9と同じ成分であるが別申請として扱われている。

＊Ⅳ)現在販売されていない。

欧州承認済み(2009.4-2013.3)で日本で未承認の医薬品

No.	国名	有効成分名	企業名	承認日	効能・効果	調査日
1	EU	catumaxomab	Fresenius Biotech GmbH	2009/4/20	①Removab 10 microgram concentrate for solution for infusion Removab is indicated for the intraperitoneal treatment of malignant ascites in patients with EpCAM-positive carcinomas where standard therapy is not available or no longer feasible. ②Removab 50 microgram concentrate for solution for infusion Removab is indicated for the intraperitoneal treatment of malignant ascites in patients with EpCAM-positive carcinomas where standard therapy is not available or no longer feasible.	2012/10/5
2	EU	eslicarbazepine acetate*Ⅰ)	BIAL – Portela & Ca, S.A.	2009/4/21	①Exalief 400 mg tablets Exalief is indicated as adjunctive therapy in adults with partial-onset seizures with or without secondary generalisation. ②Exalief 600 mg tablets Exalief is indicated as adjunctive therapy in adults with partial-onset seizures with or without secondary generalisation. ③Exalief 800 mg tablets Exalief is indicated as adjunctive therapy in adults with partial-onset seizures with or without secondary generalisation.	2012/10/9
3	EU	ulipristal	Laboratoire HRA Pharma	2009/5/15	Emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure.	2012/9/11
4	EU	plerixafor	Genzyme Europe B.V.	2009/7/31	Mozobil is indicated in combination with G-CSF to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with lymphoma and multiple myeloma whose cells mobilise poorly (see section 4.2).	2012/12/25
5	EU	vinflunine	Pierre Fabre Mé dicament	2009/9/21	Javlor is indicated in monotherapy for the treatment of adult patients with advanced or metastatic transitional cell carcinoma of the urothelial tract after failure of a prior platinum-containing regimen Efficacy and safety of vinflunine have not been studied in patients with Performance Status ≥ 2.	2013/1/8
6	EU	aztreonam lysine*Ⅱ)	Gilead Sciences International Limited	2009/9/21	Cayston is indicated for the suppressive therapy of chronic pulmonary infections due to Pseudomonas aeruginosa in patients with cystic fibrosis (CF) aged 6 years and older. Consideration should be given to official guidance on the appropriate use of antibacterial agents.	2012/12/14
7	EU	characterised viable autologous cartilage cells expanded ex vivo expressing specific marker proteins	TiGenix NV	2009/10/5	Repair of single symptomatic cartilage defects of the femoral condyle of the knee (International Cartilage Repair Society [ICRS] grade III or IV) in adults. Concomitant asymptomatic cartilage lesions (ICRS grade I or II) might be present. Demonstration of efficacy is based on a randomized controlled trial evaluating the efficacy of Chondrocelect in patients with lesions between 1-5cm².	2012/10/9
8	EU	prucalopride	Movetis NV	2009/10/15	①Resolor 1 mg film-coated tablets. Resolor is indicated for symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief. ②Resolor 2 mg film-coated tablets Resolor is indicated for symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief.	2012/10/4
9	EU	rilonacept*Ⅰ)	Regeneron UK Limited	2009/10/23	Rilonacept Regeneron is indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) with severe symptoms, including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS), in adults and children aged 12 years and older.	2012/10/1
10	EU	epoetin theta	ratiopharm GmbH	2009/10/29	①Eporatio 1,000 IU/0.5 ml solution for injection in pre-filled syringe - Treatment of symptomatic anaemia associated with chronic renal failure in adult patients. - Treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy. ②Eporatio 2,000 IU/0.5 ml solution for injection in pre-filled syringe - Treatment of symptomatic anaemia associated with chronic renal failure in adult patients. - Treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy. ③Eporatio 3,000 IU/0.5 ml solution for injection in pre-filled syringe - Treatment of symptomatic anaemia associated with chronic renal failure in adult patients. - Treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy. ④Eporatio 4,000 IU/0.5 ml solution for injection in pre-filled syringe - Treatment of symptomatic anaemia associated with chronic renal failure in adult patients. - Treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy. ⑤Eporatio 5,000 IU/0.5 ml solution for injection in pre-filled syringe - Treatment of symptomatic anaemia associated with chronic renal failure in adult patients. - Treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy. ⑥Eporatio 10,000 IU/1 ml solution for injection in pre-filled syringe - Treatment of symptomatic anaemia associated with chronic renal failure in adult patients. - Treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy. ⑦Eporatio 20,000 IU/1 ml solution for injection in pre-filled syringe - Treatment of symptomatic anaemia associated with chronic renal failure in adult patients. - Treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy. ⑧Eporatio 30,000 IU/1 ml solution for injection in pre-filled syringe - Treatment of symptomatic anaemia associated with chronic renal failure in adult patients. - Treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy.	2012/9/27
11	EU	dronedarone	sanofi-aventis	2009/11/26	MULTAQ is indicated for the maintenance of sinus rhythm after successful cardioversion in adult clinically stable patients with paroxysmal or persistent atrial fibrillation (AF). Due to its safety profile (see sections 4.3 and 4.4), Multaq should only be prescribed after alternative treatment options have been considered. MULTAQ should not be given to patients with left ventricular systolic dysfunction or to patients with current or previous episodes of heart failure.	2012/9/13
12	EU	amifampridine	BioMarin Europe Ltd	2009/12/23	Symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults.	2012/12/12
13	EU	besilesomab	CIS bio international	2010/1/11	This medicinal product is for diagnostic use only. Scintigraphic imaging, in conjunction with other appropriate imaging modalities, for determining the location of inflammation/infection in peripheral bone in adults with suspected osteomyelitis. Scintimun should not be used for the diagnosis of diabetic foot infection	2012/10/12

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No.	国名	有効成分名	企業名	承認日	効能・効果	調査日
14	EU	corifollitropin alfa	N.V. Organon	2010/1/25	①Elonva 100 micrograms solution for injection. Controlled Ovarian Stimulation (COS) in combination with a GnRH antagonist for the development of multiple follicles in women participating in an Assisted Reproductive Technology (ART) program. ②Elonva 150 micrograms solution for injection. Controlled Ovarian Stimulation (COS) in combination with a GnRH antagonist for the development of multiple follicles in women participating in an Assisted Reproductive Technology (ART) program.	2012/9/28
15	EU	roflumilast	Takeda GmbH	2010/7/5	Daxas is indicated for maintenance treatment of severe chronic obstructive pulmonary disease (COPD) (FEV1 post-bronchodilator less than 50% predicted) associated with chronic bronchitis in adult patients with a history of frequent exacerbations as add on to bronchodilator treatment.	2012/9/7
16	EU	velaglucerase alfa	Shire Pharmaceuticals Ireland Ltd.	2010/8/26	①VPRIV 200 Units powder for solution for infusion VPRIV is indicated for long-term enzyme replacement therapy (ERT) in patients with type 1 Gaucher disease. ②VPRIV 400 Units powder for solution for infusion VPRIV is indicated for long-term enzyme replacement therapy (ERT) in patients with type 1 Gaucher disease.	2012/9/11
17	EU	asenapine maleate	N.V. Organon	2010/9/1	①Sycrest 5 mg sublingual tablets Sycrest is indicated for the treatment of moderate to severe manic episodes associated with bipolar I disorder in adults. ②Sycrest 10 mg sublingual tablets Sycrest is indicated for the treatment of moderate to severe manic episodes associated with bipolar I disorder in adults.	2012/9/13
18	EU	vernakalant hydrochloride	Merck Sharp & Dohme Ltd.	2010/9/1	Rapid conversion of recent onset atrial fibrillation to sinus rhythm in adults -For non-surgery patients: atrial fibrillation ≤ 7 days duration -For post-cardiac surgery patients: atrial fibrillation ≤ 3 days duration	2012/10/9
19	EU	regadenoson	Rapidscan Pharma Solutions EU Ltd.	2010/9/6	This medicinal product is for diagnostic use only. Rapiscan is a selective coronary vasodilator for use as a pharmacological stress agent for radionuclide myocardial perfusion imaging (MPI) in adult patients unable to undergo adequate exercise stress.	2012/9/26
20	EU	conestat alfa	Pharming Group N.V.	2010/10/28	Ruconest is indicated for treatment of acute angioedema attacks in adults with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency.	2012/9/25
21	EU	ticagrelor	AstraZeneca AB	2010/12/3	Brilique, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with Acute Coronary Syndromes (unstable angina, non ST elevation Myocardial Infarction [NSTEMI] or ST elevation Myocardial Infarction [STEMI]); including patients managed medically, and those who are managed with percutaneous coronary intervention (PCI) or coronary artery by-pass grafting (CABG). For further information, please refer to section 5.1.	2012/9/5
22	EU	collagenase Clostridium histolyticum	Auxilium UK Limited	2011/2/28	Xiapex is indicated for the treatment of Dupuytren's contracture in adult patients with a palpable cord.	2012/9/6
23	EU	cabazitaxel	sanofi-aventis groupe	2011/3/17	JEVTANA in combination with prednisone or prednisolone is indicated for the treatment of patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen (see section 5.1).	2012/9/11
24	EU	retigabine	Glaxo Group Ltd.	2011/3/28	①Trobalt 50 mg film-coated tablets Trobalt is indicated as adjunctive treatment of partial onset seizures with or without secondary generalisation in adults aged 18 years and above with epilepsy. ②Trobalt 100 mg film-coated tablets Trobalt is indicated as adjunctive treatment of partial onset seizures with or without secondary generalisation in adults aged 18 years and above with epilepsy. ③Trobalt 200 mg film-coated tablets Trobalt is indicated as adjunctive treatment of partial onset seizures with or without secondary generalisation in adults aged 18 years and above with epilepsy. ④Trobalt 300 mg film-coated tablets Trobalt is indicated as adjunctive treatment of partial onset seizures with or without secondary generalisation in adults aged 18 years and above with epilepsy. ⑤Trobalt 400 mg film-coated tablets Trobalt is indicated as adjunctive treatment of partial onset seizures with or without secondary generalisation in adults aged 18 years and above with epilepsy. ⑥Treatment initiation pack Trobalt 50 mg film-coated tablets Trobalt 100 mg film-coated tablets Trobalt is indicated as adjunctive treatment of partial onset seizures with or without secondary generalisation in adults aged 18 years and above with epilepsy.	2012/9/7
25	EU	belatacept	Bristol-Myers Squibb Pharma EEIG	2011/6/17	NULOJIX, in combination with corticosteroids and a mycophenolic acid (MPA), is indicated for prophylaxis of graft rejection in adults receiving a renal transplant (see section 5.1 for data on renal function). It is recommended to add an interleukin (IL)-2 receptor antagonist for induction therapy to this belatacept-based regimen.	2012/9/5
26	EU	ipilimumab	Bristol-Myers Squibb Pharma EEIG	2011/7/13	YERVOY is indicated for the treatment of advanced (unresectable or metastatic) melanoma in adults who have received prior therapy.	2012/9/5
27	EU	belimumab	Glaxo Group Ltd.	2011/7/13	①Benlysta 120 mg powder for concentrate for solution for infusion. Benlysta is indicated as add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g positive anti-dsDNA and low complement) despite standard therapy (see section 5.1). ②Benlysta 400 mg powder for concentrate for solution for infusion. Benlysta is indicated as add-on therapy in adult patients with active autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g. positive anti-dsDNA and low complement) despite standard therapy (see section 5.1).	2012/9/11
28	EU	boceprevir	Merck Sharp & Dohme Ltd.	2011/7/18	Victrelis is indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients with compensated liver disease who are previously untreated or who have failed previous therapy.See sections 4.4 and 5.1.	2012/9/7
29	EU	fampridine	Biogen Idec Ltd.	2011/7/20	Fampyra is indicated for the improvement of walking in adult patients with multiple sclerosis with walking disability (EDSS 4-7).	2012/9/5

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No.	国名	有効成分名	企業名	承認日	効能・効果	調査日
30	EU	telavancin	Theravance UK Limited	2011/9/2	①VIBATIV 250 mg powder for concentrate for solution for infusion VIBATIV is indicated for the treatment of adults with nosocomial pneumonia (NP) including ventilator associated pneumonia, known or suspected to be caused by methicillin-resistant Staphylococcus aureus (MRSA). VIBATIV should be used only in situations where it is known or suspected that other alternatives are not suitable (see sections 4.3, 4.4, 4.8 and 5.1). Consideration should be given to official guidance on the appropriate use of antibacterial agents. ②VIBATIV 750 mg powder for concentrate for solution for infusion VIBATIV is indicated for the treatment of adults with nosocomial pneumonia (NP) including ventilator associated pneumonia, known or suspected to be caused by methicillin-resistant Staphylococcus aureus (MRSA). VIBATIV should be used only in situations where it is known or suspected that other alternatives are not suitable (see sections 4.3, 4.4, 4.8 and 5.1). Consideration should be given to official guidance on the appropriate use of antibacterial agents.	2012/9/6
31	EU	abiraterone acetate	Janssen-Cilag International N.V.	2011/9/5	ZYTIGA is indicated with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.	2012/8/31
32	EU	piperaquine tetraphosphate / dihydroartemisinin	Sigma-Tau Industrie Farmaceutiche Riunite S.p.A	2011/10/27	①Eurartesim 160 mg/20 mg film-coated tablets Eurartesim is indicated for the treatment of uncomplicated Plasmodium falciparum malaria in adults,children and infants 6 months and over and weighing 5 kg or more. Consideration should be given to official guidance on the appropriate use of antimalarial agents. ②Eurartesim 320 mg/40 mg film-coated tablets Eurartesim is indicated for the treatment of uncomplicated Plasmodium falciparum malaria in adults,children and infants 6 months and over and weighing 5 kg or more. Consideration should be given to official guidance on the appropriate use of antimalarial agents.	2012/9/24
33	EU	tafamidis	Pfizer Specialty UK Ltd.	2011/11/16	Vyndaqel is indicated for the treatment of transthyretin amyloidosis in adult patients with stage 1symptomatic polyneuropathy to delay peripheral neurologic impairment.	2012/9/24
34	EU	emtricitabine / rilpivirine hydrochloride /tenofovir disoproxil fumarate	Gilead Sciences International Ltd.	2011/11/28	Eviplera is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve adult patients with a viral load ≤ 100,000 HIV-1 RNA copies/ml. The demonstration of the benefit of the combination emtricitabine, rilpivirine hydrochloride and tenofovir disoproxil fumarate in antiretroviral therapy is based on week 48 safety and efficacy analyses from two randomised, double-blind, controlled Phase III studies in treatment-naïve patients (see section 5.1). As with other antiretroviral medicinal products, genotypic resistance testing should guide the use of Eviplera (see sections 4.4 and 5.1).	2012/8/31
35	EU	fidaxomicin	Astellas Pharma Europe BV	2011/12/5	DIFICLIR is indicated in adults for the treatment of Clostridium difficile infections (CDI) also known as C. difficile-associated diarrhoea (CDAD) (see section 5.1). Consideration should be given to official guidelines on the appropriate use of antibacterial agents.	2012/9/3
36	EU	azilsartan medoxomil*Ⅱ)	Takeda Global Research and Development Centre (Europe) Ltd.	2011/12/7	①Edarbi 20 mg tablets Edarbi is indicated for the treatment of essential hypertension in adults. ②Edarbi 40 mg tablets Edarbi is indicated for the treatment of essential hypertension in adults. ③Edarbi 80 mg tablets Edarbi is indicated for the treatment of essential hypertension in adults.	2012/9/3
37	EU	vandetanib	AstraZeneca AB	2012/2/17	①Caprelsa 100 mg film-coated tablets. Caprelsa is indicated for the treatment of aggressive and symptomatic medullary thyroid cancer (MTC) in patients with unresectable locally advanced or metastatic disease. For patients in whom Rearranged during Transfection (RET) mutation is not known or is negative, a possible lower benefit should be taken into account before individual treatment decision (see important information in sections 4.4 and 5.1). ②Caprelsa 300 mg film-coated tablets. Caprelsa is indicated for the treatment of aggressive and symptomatic medullary thyroid cancer(MTC) in patients with unresectable locally advanced or metastatic disease. For patients in whom Rearranged during Transfection (RET) mutation is not known or is negative, a possible lower benefit should be taken into account before individual treatment decision (see important information in sections 4.4 and 5.1).	2012/8/30
38	EU	vemurafenib	Roche Registration Ltd.	2012/2/17	Vemurafenib is indicated in monotherapy for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma (see section 5.1).	2012/8/30
39	EU	pasireotide diaspartate	Novartis Europharm Ltd.	2012/4/24	①Signifor 0.3 mg solution for injection Signifor is indicated for the treatment of adult patients with Cushing's disease for whom surgery is not an option or for whom surgery has failed. ②Signifor 0.6 mg solution for injection Signifor is indicated for the treatment of adult patients with Cushing's disease for whom surgery is not an option or for whom surgery has failed. ③Signifor 0.9 mg solution for injection Signifor is indicated for the treatment of adult patients with Cushing's disease for whom surgery is not an option or for whom surgery has failed.	2012/11/5
40	EU	pixantrone dimaleate	CTI Life Sciences Ltd.	2012/5/10	Pixuvri is indicated as monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive Non-Hodgkin B-cell Lymphomas (NHL). The benefit of pixantrone treatment has not been established in patients when used as fifth line or greater chemotherapy in patients who are refractory to last therapy.	2012/11/5
41	EU	ferumoxytol	Takeda Global Research and Development Centre (Europe) Ltd.	2012/6/15	Rienso is indicated for the intravenous treatment of iron deficiency anaemia in adult patients with chronic kidney disease (CKD). The diagnosis of iron deficiency must be based on appropriate laboratory tests (see section 4.2).	2012/11/5
42	EU	aclidinium bromide, micronised	Almirall, S.A.	2012/7/20	Eklira Genuair is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).	2013/2/7
43	EU	ivacaftor	Vertex Pharmaceuticals (U.K.) Ltd.	2012/7/23	Kalydeco is indicated for the treatment of cystic fibrosis (CF) in patients age 6 years and older who have a G551D mutation in the CFTR gene (see sections 4.4 and 5.1).	2012/11/5

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No.	国名	有効成分名	企業名	承認日	効能・効果	調査日
44	EU	perampanel	Eisai Europe Ltd.	2012/7/23	① Fycompa 2 mg film-coated tablets Fycompa is indicated for the adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older. ②Fycompa 4 mg film-coated tablets Fycompa is indicated for the adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older. ③Fycompa 6 mg film-coated tablets Fycompa is indicated for the adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older. ④Fycompa 8 mg film-coated tablets Fycompa is indicated for the adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older. ⑤Fycompa 10 mg film-coated tablets Fycompa is indicated for the adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older. ⑥Fycompa 12 mg film-coated tablets Fycompa is indicated for the adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older.	2012/11/5
45	EU	copper (64Cu) chloride	Sparkle S.r.l	2012/8/23	Cuprymina is a radiopharmaceutical precursor. It is not intended for direct use in patients. This medicinal product must be used only for the radiolabelling of carrier molecules, which have been specifically developed and authorised for radiolabelling with this radionuclide.	2012/11/5
46	EU	ceftaroline fosamil	AstraZeneca AB	2012/8/23	Zinforo is indicated in adults for the treatment of the following infections (see sections 4.4 and 5.1): · Complicated skin and soft tissue infections (cSSTI) · Community-acquired pneumonia (CAP) Consideration should be given to official guidance on the appropriate use of antibacterial agents.	2012/11/5
47	EU	ruxolitinib (as phosphate)	Novartis Europharm Ltd.	2012/8/23	① Jakavi 5 mg tablets Jakavi is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis. ②Jakavi 15 mg tablets Jakavi is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis. ③Jakavi 20 mg tablets Jakavi is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.	2012/11/5
48	EU	teduglutide	Nycomed Danmark ApS	2012/8/30	Revestive is indicated for the treatment of adult patients with Short Bowel Syndrome. Patients should be stable following a period of intestinal adaptation after surgery.	2012/11/5
49	EU	catridecacog	Novo Nordisk A/S	2012/9/3	Long term prophylactic treatment of bleeding in patients 6 years and above with congenital factor XIII A-subunit deficiency.	2012/11/5
50	EU	decitabine	Janssen-Cilag International N V	2012/9/20	Dacogen is indicated for the treatment of adult patients aged 65 years and above with newly diagnosed de novo or secondary acute myeloid leukaemia (AML), according to the World Health Organisation (WHO) classification, who are not candidates for standard induction chemotherapy.	2012/11/5
51	EU	brentuximab vedotin	Takeda Global Research and Development Centre (Europe) Ltd.	2012/10/25	ADCETRIS is indicated for the treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (HL): 1. following autologous stem cell transplant (ASCT) or 2. following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option. ADCETRIS is indicated for the treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL).	2013/2/7
52	EU	dapagliflozin propanediol monohydrate	Bristol-Myers Squibb / AstraZeneca EEIG	2012/11/12	①Forxiga 5 mg film-coated tablets Forxiga is indicated in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as: Monotherapy When diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance. Add-on combination therapy In combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control (see sections 4.4, 4.5 and 5.1 for available data on different combinations). ②Forxiga 10 mg film-coated tablets Forxiga is indicated in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as: Monotherapy When diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance. Add-on combination therapy In combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control (see sections 4.4, 4.5 and 5.1 for available data on different combinations).	2013/2/7
53	EU	ingenol mebutate	LEO Pharma A/S	2012/11/15	①Picato 150 micrograms/gram gel Picato is indicated for the cutaneous treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis in adults. ②Picato 500 micrograms/gram gel Picato is indicated for the cutaneous treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis in adults.	2013/2/7
54	EU	linaclotide	Almirall, S.A.	2012/11/26	Constella is indicated for the symptomatic treatment of moderate to severe irritable bowel syndrome with constipation (IBS-C) in adults.	2013/2/7
55	EU	pegloticase	Savient Pharma Ireland Ltd.	2013/1/8	KRYSTEXXA is indicated for the treatment of severe debilitating chronic tophaceous gout in adul tpatients who may also have erosive joint involvement and who have failed to ormalize serum uric acid with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these medicines are contraindicated (see section 4.4). The decision to treat with KRYSTEXXA should be based on an on-going assessment of the benefits and risks for the individual patient (see section 4.4).	2013/5/13

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No.	国名	有効成分名	企業名	承認日	効能・効果	調査日
56	EU	florbetapir (18F)	Eli Lilly Nederland B.V.	2013/1/14	①Amyvid 800 MBq/mL solution for injection This medicinal product is for diagnostic use only. Amyvid is a radiopharmaceutical indicated for Positron Emission Tomography (PET) imaging of β-amyloid neuritic plaque density in the brains of adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD) and other causes of cognitive impairment. Amyvid should be used in conjunction with a clinical evaluation. A negative scan indicates sparse or no plaques, which is not consistent with a diagnosis of AD. For the limitations in the interpretation of a positive scan, see sections 4.4 and 5.1. ②Amyvid 1900 MBq/mL solution for injection This medicinal product is for diagnostic use only. Amyvid is a radiopharmaceutical indicated for Positron Emission Tomography (PET) imaging of β-amyloid neuritic plaque density in the brains of adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD) and other causes of cognitive impairment. Amyvid should be used in conjunction with a clinical evaluation. A negative scan indicates sparse or no plaques, which is not consistent with a diagnosis of AD. For the limitations in the interpretation of a positive scan, see sections 4.4 and 5.1.	2013/5/13
57	EU	lixisenatide	Sanofi-Aventis	2013/2/1	① Lyxumia 10 micrograms solution for injection Lyxumia is indicated for the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control (see sections 4.4 and 5.1 for available data on the different combinations) ② Lyxumia 20 micrograms solution for injection Lyxumia is indicated for the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose-lowering medicinal products and /or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control (see sections 4.4 and 5.1 for available data on the different combinations). ③ Treatment initiation pack Lyxumia 10 micrograms solution for injection Lyxumia 20 micrograms solution for injection Lyxumia is indicated for the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control (see sections 4.4 and 5.1 for available data on the different combinations).	2013/5/14
58	EU	nalmefene hydrochloride dihydrate	H. Lundbeck A/S	2013/2/25	Selincro is indicated for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (DRL) [see section 5.1], without physical withdrawal symptoms and who do not require immediate detoxification. Selincro should only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption. Selincro should be initiated only in patients who continue to have a high DRL two weeks after initial assessment.	2013/5/15
59	EU	pertuzumab	Roche Registration Limited	2013/3/4	Perjeta is indicated for use in combination with trastuzumab and docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.	2013/5/16
60	EU	ocriplasmin	ThromboGenics NV	2013/3/13	JETREA is indicated in adults for the treatment of vitreomacular traction (VMT), including when associated with macular hole of diameter less than or equal to 400 microns (see section 5.1).	2013/5/16
61	EU	bosutinib (as monohydrate)	Pfizer Ltd	2013/3/27	①Bosulif 100 mg film-coated tablets Bosulif is indicated for the treatment of adult patients with chronic phase (CP), accelerated phase(AP), and blast phase (BP) Philadelphia chromosome positive chronic myelogenous leukaemia (Ph+CML) previously treated with one or more tyrosine kinase inhibitor(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options. ②Bosulif 500 mg film-coated tablets Bosulif is indicated for the treatment of adult patients with chronic phase (CP), accelerated phase(AP), and blast phase (BP) Philadelphia chromosome positive chronic myelogenous leukaemia (Ph+ CML) previously treated with one or more tyrosine kinase inhibitor(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options.	2013/5/16

EMA__HPにあるEuropean public assessment reports等よりNew Active Substance (NAS)として承認されたもの(ワクチンを除く)のうち、日本で2013年5月31日時点で未承認のものを掲載した。(引き続き調査中)

注1)データは調査時の情報に基づき記載している。

注2)マーカーは米国および欧州の未承認薬一覧のうち、米国と欧州で有効成分名が同じ医薬品。

＊Ⅰ)現在販売されていない。

＊Ⅱ)類似医薬品が日本で承認されている。