Brand Name Annual Review

YEAR 2022

A review of brand names from a name safety perspective focusing on brand (invented) names approved by the **European Medicines Agency** (EMA) for new products including new molecular entities and biologics.

European Medicines Agency (EMA)

Welcome to Brand Name Annual Review of 2022!

Brand (invented) names are reviewed and approved by the Name Review Group (NRG) of the European Medicine's Agency throughout the year. Per revision 7 of the EMA Guidance[1], "The checking of the (invented) name is part of the EMA's role in evaluating the safety of medicinal products within the authorisation procedure, as the proposed (invented) name(s) could create a public health concern or potential safety risk. Such an evaluation should be performed based on best available evidence and research." Since 2017, SafeMark Regulatory Consulting ("SafeMark") conducts this type of research referred to as "name safety testing" on proposed brand (invented) names being considered for submission to the NRG for review.

SafeMark Regulatory Consulting ("SafeMark") merged with Brandsymbol to become Brandsymbol Regulatory Division and provides services to branding agencies and healthcare industry for the evaluation of proprietary (brand) and nonproprietary (active ingredient) names that are being considered for regulatory submission. Our services apply to drugs for human use, combination products, biologics including biosimilars and vaccines, and animal health products.

This publication is prepared to increase awareness of new brand names approved for medicinal products approved under the Centralized Procedure by the EMA and ultimately help prevent medication errors in healthcare practice.

Our review does not include every brand name reviewed by the Name Review Group (NRG) and/or adopted at a CHMP Meeting in the year 2022. For this edition, we focused on **40 approved brand (invented) names** by the NRG.

In this review, we incorporate our **SafeMark Name Safety Tools** such as the FDA Phonetic and Orthographic Computer Analysis (POCA) System and our proprietary Word Construction Analysis (WCA) used to identify sound-alike and look-alike existing product names. A name pair is defined as a new brand name compared to an existing product name. The tools use a numeric system and as a rule, *the higher the value*, *the more similar a name pair*.

For each brand name selected for this review, we provide comments on naming strategies we find are relevant based on the limited profile information.

Guideline on the Acceptability of Names for Human Medicinal Products Processed through the Centralised Procedure (EMA/CHMP/287710/2014)
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-acceptability-names-human-medicinal-products-processed-through-centralised-procedure_en.pdf.

We prepared a **Name Safety Tools Chart** on each name that answers the following question: "When conducting the initial brand name review, were there any cited names identified by the FDA POCA System or SafeMark's Word Construction Analysis formula that showed high similarity?" See Example chart below.

Name Safety Tools Chart Example

Names with a Combined POCA Score 70% -100%	Names with similarity when written or an orthographic score of 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis Point Range 6-10
None or Cited Name(s)	None or Cited Name(s)	None or Cited Name(s)	None or Cited Name(s)

See Appendix I and II for details on information found in the Name Safety Tools Chart.

For this review, out of 40 brand names selected, **4 brand names or 10% showed no results or "none" for each column in the name safety results chart indicating "no cited names" were identified using the POCA system or the WCA results that were "highly similar."** This data set supports the use of the POCA system and SafeMark's WCA tool in an initial brand name review of a proposed proprietary name. However, the remaining 36 names or 90% showed highly similar names identified and therefore further evaluation (e.g., prescription simulation study, Name Pair Analysis (NPA), Failure Modes & Effects Analysis or Patient Harm Analysis, etc.) would be needed to determine whether these names would be appropriate for consideration to a regulatory agency.

In addition, as shown in the chart below, **there were only 19 out of 40 selected brand names approved in 2022 that have *at least one cited name* with a Combined POCA score of 70% or above.** This data point supports the initiative for sponsors to avoid proposed brand name candidates that have "highly similar" cited names based on a Combined POCA score of 70% or above. In addition, there were only 14 out of 40 selected brand names approved in 2022 that have at least one cited name with a WCA score of 6-10 which supports our WCA "going beyond POCA" to help prioritize names in the safety review.

Products (Names) Cited	Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
Number of Brand names	**19**	**25**	**17**	**14**

Thank you. We hope you enjoy this review!

Disclaimer

In the review of each brand, we include summary of product information from the Summary of Product Characteristics (SmPC) and/or the European Public Assessment Repot (EPAR) that appears on the EMA website (www.ema.europa.eu). For each brand selected for this edition, we use our Name Safety Tools to identify any sound-alike and/or look-alike cited names. The information presented on a Name Safety Tools Chart is prepared for informational purposes only.

The information provided in this review is based on publicly available information and the experience of Dyan Rowe Davis, President of Brandsymbol Regulatory Division (formerly SafeMark), on using name safety testing tools to evaluate a proprietary name being considered for regulatory review.

A brand name selected for this review does not imply that Brandsymbol, SafeMark or any of its employees, affiliates or partners evaluated the name prior to EMA approval. Any brand names cited in the commentary are for informational purposes only.

To learn more about Brandsymbol, please visit www.brandsymbol.com

Table of Contents

PAXLOVID (nirmatrelvir and ritonavir)	
EMA Approval Date	**27 January 2022**
Agency Product Number	EMEA/H/C/005973
Company	Pfizer Europe MA EEIG
Therapeutic Class	Antiviral
Pharmacological Class	COVID 3CL protease inhibitor and pharmacokinetic booster
Indication	Treatment of COVID-19 in adults who do not require supplemental oxygen and who are at increased risk of the disease becoming severe
Dosage Strength(s)	150 mg nirmatrelvir and 100 mg ritonavir
Dosage Form	Tablet
Route	Oral
Product Use Comments	• The recommended dose is two tablets, each containing 150 mg nirmatrelvir, plus one tablet containing 100 mg ritonavir, to be taken together by mouth twice a day for 5 days. • Paxlovid should be given as soon as possible after a diagnosis of COVID-19 has been made and within 5 days of the start of symptoms.
Active Ingredient Comments	• "Nirmatrelvir" was published on Recommended INN List 88 in October 2022. • The "trelvir" stem was first published by USAN in December 2021 for an "inhibitor of COVID 3CL protease"
Brand Name Comments	• The suffix connotes the COVID-19 indication • Percent Derivation (PD) results identified the following international nonproprietary names (INNs) that have a 50% or higher percent derivation score when compared to the brand name: "loviride" (50%) and "povidone" (50%)

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
None	Palixid; Axalid; Valoid; Aloxidil	None	None

BREYANZI (lisocabtagene maraleucel)	
EMA Approval Date	**27 January 2022**
Agency Product Number	EMEA/H/C/004731
Company	Bristol-Myers Squibb Pharma EEIG
Therapeutic Class	Anti-Neoplastic
Pharmacological Class	Genetically modified cell therapy (autologous CAR+ T cells)
Indication	Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), primary mediastinal large B-cell lymphoma (PMBCL) and follicular lymphoma grade 3B (FL3B), after two or more lines of systemic therapy
Dosage Strength(s)	1.1-70 × 10^6 cells/mL (CD4+ cells) / 1.1-70 × 10^6 cells/mL (CD8+ cells) dispersion for infusion.
Dosage Form	Dispersion for infusion
Route	Intravenous infusion
Product Use Comments	• Must be administered in a qualified treatment center
Active Ingredient Comments	• The second word uses a fantasy prefix “mara” although the product utilizes autologous cells. Lisocabtagene maraleucel was first published in July 2018 (pINN 119) prior to the adoption of the prefix “auto” for autologous cell-based gene therapies (67th INN Consultation, October 2018).
Brand Name Comments	• None

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
Brentan	Bezanin; Dibenzyran; Dibenzyran 10	None	None

KIMMTRAK (tebentafusp)	
EMA Approval Date	**25 February 2022**
Agency Product Number	EMEA/H/C/004929
Company	Immunocore Ireland Limited
Therapeutic Class	Anti-Neoplastic
Pharmacological Class	Bispecific fusion protein (gp100 peptide-HLA-directed CD3 T cell engager)
Indication	Treatment of human leukocyte antigen (HLA)-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma
Dosage Strength(s)	100 mcg/0.5 mL
Dosage Form	Injectable
Route	Intravenous infusion
Product Use Comments	• First three doses should be administered in a hospital setting with overnight monitoring for signs and symptoms of cytokine release syndrome for at least 16 hours
Active Ingredient Comments	• The stem, "fusp", indicates the product is a "fusion protein" that contains more than one pharmacologically active component. The infix letter "t" connotes a "T-cell receptor" and the "a" connotes "antibody" (-tafusp). • Second fusion protein approved after tagraxofusp (Elzonris®, 2021)
Brand Name Comments	• The brand name includes the letters "**i-m-m**" which is also noted in the name of the sponsor, **I-m-m**-u-n-o-c-o-r-e. A sponsor or manufacturer name is an attribute that may change over the life cycle of a product and should be avoided in the brand name to avoid confusion. The use of double letters is an option to use letters from the sponsor's name that may create a brand-link to the sponsor, but not a sufficient amount of the entire name to be an obvious association or reference an attribute that may change over the life cycle of the product.

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
None	Kimura; Klimakt; Arkvimma	Cometriq; Centrac	None

KAPRUVIA (difelikefalin)	
EMA Approval Date	**25 February 2022**
Agency Product Number	EMEA/H/C/005612
Company	Vifor Fresenius Medical Care Renal Pharma France
Therapeutic Class	Anti-Pruritic Agent
Pharmacological Class	Kappa opioid receptor (KOR) agonist
Indication	Treatment of moderate-to-severe pruritus associated with chronic kidney disease
Dosage Strength(s)	50 mcg/mL
Dosage Form	Injection solution
Route	Intravenous bolus
Product Use Comments	• Kapruvia should be restricted for in-center hemodialysis (HD) use only • Administered 3 times per week by intravenous bolus injection into the venous line of the dialysis circuit at the end of the hemodialysis treatment during rinse-back or after rinse-back (maximum 4 doses/week even if more than 4 HD sessions/week are performed).
Active Ingredient Comments	• The USAN/INN stem for difelikefalin is the infix -kef- for "enkephalin/enkefalin agonists". In August/September 2021, INN published a 2018 Stem Book addendum that changed the -kef- stem definition from "enkephalin agonists" to "enkephalin, endorphin and dynorphin opioid δ, μ and κ receptor agonists".
Brand Name Comments	• The invented name appears to connote the "kappa" receptor and "pruritus" • Approved in the US under the brand name Korsuva® in 2021.

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
Suprovia	None	Suprovia	None

ORGOVYX (relugolix)	
EMA Approval Date	**25 February 2022**
Agency Product Number	EMEA/H/C/005353
Company	Myovant Sciences Ireland Limited
Therapeutic Class	Anti-Neoplastic
Pharmacological Class	Gonadotropin releasing hormone (GnRH) antagonists
Indication	Treatment of adult patients with advanced hormone-sensitive prostate cancer
Dosage Strength(s)	120 mg
Dosage Form	Tablet
Route	Oral
Product Use Comments	• Therapy is initiated with a 3 tablet (360 mg) loading dose on Day 1 followed by one tablet (120 mg) once daily at approximately the same time each day
Active Ingredient Comments	• Relugolix was first approved in the European Union in 2021 in combination with norethisterone acetate and estradiol hemihydrate for the treatment of moderate to severe symptoms of uterine fibroids (Ryeqo®)
Brand Name Comments	• Both invented names for relugolix also contain the letter string “go”: Ryego and Orgovyx • Percent Derivation (PD) results identified the following international nonproprietary names (INNs) that have a 50% or higher percent derivation score when compared to the brand name: “orgotein” (50%)

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
None	None	None	None

QUVIVIQ (daridorexant)	
EMA Approval Date	**25 February 2022**
Agency Product Number	EMEA/H/C/005634
Company	Idorsia Pharmaceuticals Deutschland GmbH
Therapeutic Class	Sleep Aid
Pharmacological Class	Orexin receptor antagonist
Indication	Treatment of adult patients with insomnia characterized by symptoms present for at least 3 months and considerable impact on daytime functioning
Dosage Strength(s)	25 mg, 50 mg
Dosage Form	Tablet
Route	Oral
Product Use Comments	• The recommended dose 25 mg when used with moderate CYP3A4 inhibitors • Time to sleep onset may be delayed if taken soon after a large meal
Active Ingredient Comments	• Compound is an orexin receptor antagonist (-orexant stem) • First "orexant" medication approved in the European Union
Brand Name Comments	• Intended pronunciation is "cue-VIH-viq" • The letter string "viv" connotes "life, alive, lively" • The use of the letter "Q" as a starting letter and ending letter is unique in both sound (prefix, "qu" vs. "vic") and appearance (i.e., Mistral font and Brittany Signature handwriting examples: Quiviq and Quiviq. • Starting letter "Q" with second letter "u" helps with pronunciation • Ending letter "q" may look like a "g" when combined with the letter "-i-".

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
None	None	Kabivit	None

VYDURA (rimegepant)	
EMA Approval Date	**25 February 2022**
Agency Product Number	EMEA/H/C/005725
Company	Biohaven Pharmaceutical Ireland DAC
Therapeutic Class	Anti-Migraine
Pharmacological Class	Calcitonin gene-related peptide (CGRP) antagonist
Indication	Acute treatment of migraine with or without aura in adults; preventive treatment of episodic migraine in adults who have at least 4 migraine attacks per month
Dosage Strength(s)	75 mg
Dosage Form	Oral lyophilisate
Route	Oral/Oromucosal Use
Product Use Comments	• The recommended dose for migraine prophylaxis is one tablet every other day • Another dose should be avoided within 48 hours when it is concomitantly administered with moderate inhibitors of CYP3A4
Active Ingredient Comments	• The intended sound of the "g" in "gepant" is soft (ri-me'-je-pant) • First CGRP antagonist (-gepant) agent approved in the European Union
Brand Name Comments	• Approved in the US under the name Nurtec® ODT (2020)

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
None	None	Feburo; Febira; Sinora; Cetura; Midora; Vetira; Siduro; Figura 1; Figura 2	None

CARVYKTI (ciltacabtagene autoleucel)	
EMA Approval Date	**25 March 2022**
Agency Product Number	EU/1/22/1648/001
Company	Janssen-Cilag International NV
Therapeutic Class	Anti-Neoplastic
Pharmacological Class	Genetically modified cell therapy (autologous CAR+ T cells)
Indication	Treatment of adult patients with relapsed and refractory multiple myeloma who have received at least three prior therapies and whose cancer has worsened since they received their last treatment
Dosage Strength(s)	$3.2 \times 10^6 – 1.0 \times 10^8$ cells dispersion for infusion
Dosage Form	Dispersion for infusion
Route	Intravenous infusion
Product Use Comments	• Must be administered in a qualified treatment center
Active Ingredient Comments	• “Autoleucel” as the second word indicates that the product is “autologous” and utilizes “lymphocytes/monocytes/APC (white cells)”
Brand Name Comments	• Name evokes “CAR” or “chimeric antigen receptor” • Conveys the English word “victory”, and “T-cells”

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
Paravict	Ardey-Aktiv; Cartia;	Torfacta; Carzap Hct; Carsaxa; Carbex; Paravict	Carvedi; Carve Tad; Carnivit; Carsaxa

CAMCEVI (leuprorelin mesilate)	
EMA Approval Date	**25 March 2022**
Agency Product Number	EMEA/H/C/005034
Company	Accord Healthcare S.L.U.
Therapeutic Class	Anti-Neoplastic
Pharmacological Class	Gonadotropin-releasing hormone receptor analogue
Indication	Treatment of hormone dependent advanced prostate cancer and for the treatment of high-risk localized and locally advanced hormone dependent prostate cancer in combination with radiotherapy
Dosage Strength(s)	42 mg
Dosage Form	Prolonged-release suspension for injection
Route	Subcutaneous injection
Product Use Comments	• Product is “ready to use” so it does not require mixing prior to injection
Active Ingredient Comments	• Considered a “hybrid medicine” of the previously approved Eligard® (leuprorelin acetate, EU 2003) due to differences in pharmaceutical form and because it contains the mesylate salt form instead of acetate
Brand Name Comments	• Intended pronunciation is “kam-SHE-vee”

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
Cablivi	None	Cablivi; Tamsuda; Sensiva	None

ZOLSKETIL PEGYLATED LIPOSOMAL (doxorubicin)

EMA Approval Date	**25 March 2022**
Agency Product Number	EMEA/H/C/005320
Company	Accord Healthcare S.L.U.
Therapeutic Class	Anti-Neoplastic
Pharmacological Class	Anthracycline, pegylated liposomal
Indication	Monotherapy for patients with metastatic breast cancer, where there is an increased cardiac risk; treatment of advanced ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen; treatment in combination with bortezomib of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplant; treatment of AIDS-related Kaposi's sarcoma (KS) in patients with low CD4 counts (< 200 CD4 lymphocytes/mm3) and extensive mucocutaneous or visceral disease
Dosage Strength(s)	2 mg/mL
Dosage Form	Concentrate for solution for infusion
Route	Intravenous infusion
Product Use Comments	• Considered a “hybrid medicine” of Adriamycin® (doxorubicin, EU 1979) because it contains the same active substance as Adriamycin, but in a pegylated liposomal formulation
Active Ingredient Comments	• None
Brand Name Comments	• Percent Derivation (PD) results identified the following international nonproprietary names (INNs) that have a 50% or higher percent derivation score when compared to the brand name: “axetil” (67%), “edetic” (50%), “lisetil” (57%), “mofetil” (57%), “octil” (60%), “proxetil” (50%) and “pactil” (50%)

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
Caelyx Pegylated Liposomal; Onivyde Pegylated Liposomal	Caelyx Pegylated Liposomal; Onivyde Pegylated Liposomal	None	None

FILSUVEZ (birch bark extract)	
EMA Approval Date	**22 April 2022**
Agency Product Number	EMEA/H/C/005035
Company	Amryt Pharmaceuticals DAC
Therapeutic Class	Inflammation Modulator; Keratinocyte Stimulant
Pharmacological Class	Phytomedicinal
Indication	Treatment of partial thickness wounds associated with dystrophic and junctional epidermolysis bullosa (EB) in patients 6 months and older
Dosage Strength(s)	n/a
Dosage Form	Topical gel
Route	Cutaneous
Product Use Comments	• Gel should not be applied sparingly and should not be rubbed into the wounds • Area should be covered with a sterile, non-adhesive dressing after treatment or the gel should be applied to the dressing
Active Ingredient Comments	• Dry extract, refined, of *Betula pendula* Roth and *Betula pubescens* Ehrh (equivalent to 0.5-1 gram birch bark) standardized to contain 84-95 mg triterpenes (sum of betulin, betulinic acid, erythrodiol, lupeol, and oleanolic acid) • Second *Betula*-derived topical product approved in the EU for wound healing after Episalvan® (betulae cortex (birch bark) extract, 2016)
Brand Name Comments	• None

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
None	None	Calcivid	Filasel

LUNSUMIO (mosunetuzumab)	
EMA Approval Date	**22 April 2022**
Agency Product Number	EMEA/H/C/005680
Company	Roche Registration GmbH
Therapeutic Class	Anti-Neoplastic
Pharmacological Class	Bispecific monoclonal antibody (anti-CD20/CD3)
Indication	Treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least two prior systemic therapies
Dosage Strength(s)	1 mg, 30 mg
Dosage Form	Concentrate for solution for infusion
Route	Intravenous infusion
Product Use Comments	• Must be administered in a setting with appropriate medical support to manage severe reactions such as cytokine release syndrome (CRS)
Active Ingredient Comments	• According to the Summary of Product Characteristics, it is a conditional agonist: targeted B-cell killing is observed only upon simultaneous binding to CD20 on B-cells and CD3 on T-cells
Brand Name Comments	• None

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
None	Losnesium; Suomicon; Unisol	None	None

TABRECTA (capmatinib)	
EMA Approval Date	**22 April 2022**
Agency Product Number	EMEA/H/C/004845
Company	Novartis Europharm Limited
Therapeutic Class	Anti-Neoplastic
Pharmacological Class	Tyrosine Kinase inhibitor (MET inhibitor)
Indication	Treatment of adult patients with advanced non-small cell lung cancer (NSCLC) harboring alterations leading to mesenchymal epithelial transition factor gene exon 14 (METex14) skipping, who require systemic therapy following prior treatment with immunotherapy and/or platinum-based chemotherapy
Dosage Strength(s)	150 mg, 200 mg
Dosage Form	Tablet
Route	Oral
Product Use Comments	• Patients have to be selected for treatment based on the presence of genetic alterations leading to a METex14 skipping mutation in tumor tissue or plasma specimens using a validated test
Active Ingredient Comments	• The stem "metkib" for "MET (mesenchymal epithelial transition factor) kinases inhibitors" was published as an INN Prestem Suffix in September 2019 with capmatinib identified as an "INN which belong to the same group of pharmaceutical substances but in which the preferred stem has not been used" in March 2020
Brand Name Comments	• Despite several names evaluated in the Name Safety Tools Chart, this proposed invented name was ***not found unacceptable*** by the NRG due to similarity of the cited names when written or spoken.

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
Febrectal; Tobrex La; Tobrexan; Trevicta; Antabrest; Pantecta; Talrektan; Titretta; Tobrabact; Tobrex	Febrectal; Trevicta; Antabrest; Paraceta; Bravecto; Tetrac; Calbeta; Tecta; Tybeta; Ambrobeta; Tabinera; Areta; Carba Retard; Tarceva; Trarett; Abrea; Target; Batrevac Tetra; Hct Beta; Beacita; Abelcet; Betacream; Betac; Acatar Care; Beta 21; Betabere; Acetar	Zyprexa; Tadarix; Tobrex; Tobrexan; Tobrex La; Febrectal	Tabinera

CEVENFACTA (eptacog beta (activated))	
EMA Approval Date	**20 May 2022**
Agency Product Number	EMEA/H/C/005655
Company	Laboratoire Francais du Fractionnement et des Biotechnologies
Therapeutic Class	Antihemophilic Agent
Pharmacological Class	Blood coagulation factor
Indication	Treatment of bleeding episodes and for the prevention of bleeding in those undergoing surgery or invasive procedures in patients with congenital hemophilia with high-responding inhibitors to coagulation factors VIII or IX (i.e. ≥5 Bethesda Units (BU)) and patients with congenital hemophilia with low titer inhibitors (BU <5), but expected to have a high anamnestic response to factor VIII or factor IX administration or expected to be refractory to increased dosing of FVIII or FIX
Dosage Strength(s)	1 mg (45 KIU), 2 mg (90 KIU), 5 mg (225 KIU)
Dosage Form	Solution for injection
Route	Intravenous bolus
Product Use Comments	• None
Active Ingredient Comments	• Eptacog is also the INN stem (-eptacog) for blood coagulation factor VII compounds (“epta” for factor VII and “cog” for recombinant blood coagulation factors). A prefix is used to indicated that it does not match the naturally occurring material • The Greek letter suffix indicates a unique glycoprotein or glycosylation pattern
Brand Name Comments	• The invented name connotes the active ingredient, factor VII • Approved in the US as Sevenfact® (coagulation factor VIIa (recombinant)-jncw) in 2020 • Percent Derivation (PD) results identified the following international nonproprietary names (INNs) that have a 50% or higher percent derivation score when compared to the brand name: “actarit” (57%), “revenast” (57%) and “pactil” (50%)

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
None	Entact; Aceclofenac Teva; Venlafaxin Ct; Cenat; Factane	None	None

UPSTAZA (eladocagene exuparvovec)	
EMA Approval Date	**20 May 2022**
Agency Product Number	EMEA/H/C/005352
Company	PTC Therapeutics International Limited
Therapeutic Class	Amino Acid Metabolism, Inborn Errors
Pharmacological Class	Gene therapy
Indication	Treatment of aromatic L-amino acid decarboxylase (AADC) deficiency
Dosage Strength(s)	2.8 x 10^{11} vector genomes/0.5 mL
Dosage Form	Solution for infusion
Route	Intraputaminal infusion (Intracranial Use)
Product Use Comments	• The product is administered as a bilateral, intraputaminal infusion at two sites per putamen (anterior and posterior) in one surgical session using an intracranial cannula • The recommended total dose is 1.8 × 10^{11} vg delivered as four 0.08 mL (0.45 × 10^{11} vg) infusions (two per putamen)
Active Ingredient Comments	• The "doc(a)" infix refers to the gene component or mechanism of action, a human dopa decarboxylase (DOC or DDC) variant, which encodes human called aromatic-L-amino-acid decarboxylase (AACD) isoform 1 • The second word, "parvovec", indicates that the vector component is a non-replicating (-vec) adeno-associated virus (-parvo-)
Brand Name Comments	• Percent Derivation (PD) results identified the following international nonproprietary names (INNs) that have a 50% or higher percent derivation score when compared to the brand name: "azabon" (50%) and "tazide" (50%)

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
None	None	None	Upsa-C

XENPOZYME (olipudase alfa)	
EMA Approval Date	**20 May 2022**
Agency Product Number	EMEA/H/C/004850
Company	Genzyme Europe BV
Therapeutic Class	Enzyme Replacement Therapy
Pharmacological Class	Recombinant human acid sphingomyelinase
Indication	Treatment of non-central nervous system (CNS) manifestations of acid sphingomyelinase deficiency (ASMD) type A/B or type B
Dosage Strength(s)	20 mg
Dosage Form	Powder to be reconstituted into a concentrate for solution for infusion
Route	Intravenous infusion
Product Use Comments	• Dose is based on the actual body weight for patient with a body mass index (BMI) ≤ 30 or an optimal body weight for patient with a BMI > 30
Active Ingredient Comments	• First and only disease-specific treatment for ASMD and the only recombinant human acid sphingomyelinase INN/USAN
Brand Name Comments	• Contains the term "enzyme" and may also connote the manufacturer, Genzyme • The "NP" may refer to Niemann-Pick disease, a historical/common name for acid sphingomyelinase deficiency. • An "X" in the first position may sound like a "z" or "s" giving it a similar sounding starting sound to Sensodyne (cited below) in addition to the overall similarity of the vowels which is seen in the high phonetic similarity (zen-po-zime vs sen-so-dine) • Percent Derivation (PD) results identified the following international nonproprietary names (INNs) that have a 50% or higher percent derivation score when compared to the brand name: "xenon" (60%)

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
Sensodyne	None	Vinpoven; Sensodyne	Xenazina; Xenazine

ZOKINVY (lonafarnib)	
EMA Approval Date	**20 May 2022**
Agency Product Number	EMEA/H/C/005271
Company	EigerBio Europe Limited
Therapeutic Class	Progeria/Laminopathies
Pharmacological Class	Farnesyl transferase inhibitor
Indication	Treatment of patients 12 months of age and older with a genetically confirmed diagnosis of Hutchinson-Gilford progeria syndrome or a processing-deficient progeroid laminopathy associated with either a heterozygous LMNA mutation with progerin-like protein accumulation or a homozygous or compound heterozygous ZMPSTE24 mutation
Dosage Strength(s)	50 mg and 75 mg
Dosage Form	Capsule
Route	Oral
Product Use Comments	• Dose is based on Body Surface Area (BSA) with the Du Bois formula specifically recommended by the Summary of Product Characteristics for calculating dosing BSA.
Active Ingredient Comments	• First farnesyl transferase inhibitor (-farnib) compound approved in the EU
Brand Name Comments	• Percent Derivation (PD) results identified the following international nonproprietary names (INNs) that have a 50% or higher percent derivation score when compared to the brand name: "izokibep" (50%)

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
None	None	None	None

KINPEYGO (budesonide, micronized)	
EMA Approval Date	**20 May 2022**
Agency Product Number	EMEA/H/C/005653
Company	Calliditas Therapeutics AB
Therapeutic Class	Immunosuppressant
Pharmacological Class	Corticosteroid
Indication	Treatment of primary immunoglobulin A (IgA) nephropathy (IgAN) in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/gram.
Dosage Strength(s)	4 mg
Dosage Form	Modified-release capsule
Route	Oral
Product Use Comments	• Kinpeygo is considered a "hybrid" medicine because it contains the same active substance as its reference medicine, Entocort®, but is used for a different disease or administered in a different way
Active Ingredient Comments	• The "onide" stem is officially defined as "topical steroids (acetal derivatives)"
Brand Name Comments	• The "pey" letter string may refer to Peyer's patches: clusters of subepithelial, lymphoid follicles found in the intestine which express glucocorticoid receptors and are responsible for the production of galactose-deficient IgA1 antibodies (Gd-Ag1) causing IgA nephropathy • Approved in the US under the brand name Tarpeyo® (2021)

Name Safety Tools Chart

Highly Similar (Combined POCA 70% - 100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
None	None	None	None

PEPAXTI (melphalan flufenamide)

EMA Approval Date	**24 June 2022**
Agency Product Number	EMEA/H/C/005681
Company	Oncopeptides AB
Therapeutic Class	Anti-Neoplastic
Pharmacological Class	Alkylating agents, (b-chloroethyl)amine derivatives
Indication	Treatment of adult patients with multiple myeloma in combination with dexamethasone who have received at least three prior lines of therapies, whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one anti-CD38 monoclonal antibody, and who have demonstrated disease progression on or after the last therapy.
Dosage Strength(s)	20 mg
Dosage Form	Powder for concentrate for solution for infusion
Route	Intravenous infusion
Product Use Comments	• None
Active Ingredient Comments	• Melphalan flufenamide is an alkylating nitrogen mustard but does not contain the preferred suffix stem for the class (-mustine)
Brand Name Comments	• The “pep” may refer to melphalan flufenamide being a “peptide conjugated alkylating drug” or to the marketing authorization holder, Oncopeptides • Approved in the US under the brand name Pepaxto® (2021), but it has since been voluntarily and temporarily discontinued

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
Nepexto, Paxtin, Paxetin, Pinexet	Paxtin, Paxetin, Paxtibi, Pentaxim, Pevanti, Texpami, Peptirex	Nepexto, Pipexus	Peptirex

RAYVOW (lasmiditan)	
EMA Approval Date	**24 June 2022**
Agency Product Number	EMEA/H/C/005332
Company	Eli Lilly Nederland B.V.
Therapeutic Class	Anti-Migraine
Pharmacological Class	5-hydroxytriptamine 1F (5-HT_1F) receptor agonist
Indication	Acute treatment of the headache phase of migraine attacks, with or without aura in adults.
Dosage Strength(s)	50 mg, 100 mg, 200 mg
Dosage Form	Tablet
Route	Oral
Product Use Comments	• If a patient does not respond to the first dose, it is unlikely that a second dose will be of benefit in the same attack • Maximum dose is 200 mg in a 24-hour period
Active Ingredient Comments	• First "antimigraine, serotonin 5-HT_1 receptor agonist" compound (-ditan, USAN) approved in the EU. • The related stem "triptan" is specifically for "serotonin 5-HT_1 receptor agonists, *sumatriptan derivatives*"
Brand Name Comments	• Approved in the US under the brand name, Reyvow® (2019) • ***Sometimes a single letter is the difference between an approval and a rejection. We often consider the names identified in the Name Safety Tools Chart and the difference in a letter or letter string that is considered "sufficient."*** For this approval, there is ***sufficient difference*** in sound and/or appearance of the name pair, Rayvow vs. Ralvo in the prefix, ("Ra**y**-" vs "**Ra**l-) and suffix, ("-vo" vs. "-vo**w**").

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
Ralvo	None	None	None

ROCTAVIAN (valoctocogene roxaparvovec)	
EMA Approval Date	**24 June 2022**
Agency Product Number	EMEA/H/C/005830
Company	BioMarin International Limited
Therapeutic Class	Antihemophilic Agent
Pharmacological Class	Gene therapy
Indication	Treatment of severe hemophilia A (congenital factor VIII deficiency) in adult patients without a history of factor VIII inhibitors and without detectable antibodies to adeno associated virus serotype 5 (AAV5).
Dosage Strength(s)	2 x 10^{13} vg/mL
Dosage Form	Solution for infusion
Route	Intravenous infusion
Product Use Comments	• Should only be administered to patients who have demonstrated absence of anti-AAV5 antibodies by a validated assay
Active Ingredient Comments	• The "octoco" infix refers to the gene component or mechanism of action, SQ variant of human blood *coagulation factor VIII* (F8, FVIII)
Brand Name Comments	• The invented name, Roctavian, appears to connote both the factor VIII gene component ("octoco") and the viral vector (roxaparvovec) • "Octavian" is the original name for Caesar Augustus, nephew and heir to Julius Caesar and the first Roman emperor. Roctavian is the first gene therapy approved for the treatment of severe hemophilia A. • Eight (8) names identified with high Combined POCA scores and 30 names identified with high orthographic similarity. • Percent Derivation (PD) results identified the following: "octanoic" (50%), "octaverine" (50%) and "octil" (60%)

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%- 100%	Word Construction Analysis (WCA) Point Range 6-10
Octiveran, Roctylan, Arctuvan, Broxivan, Proxacin, Roxitan, Ractilen, Roclarin	Octiveran, Roctylan, Arctuvan, Roclarin, Prostavasin, Oxaviatin, Octanine, Noctaval, Proactin, Roaccutan, Octocaine, Ritonavir, Trolactin, Adproctin, Promictan, Rovatina, Spiroctan, Concavit, Travilan, Aerocortin, Arteria-Vita N, Cavinton, Carbocain, Irinotecan Vitane, Tavonin, Orocal Vitamine D3, Procain Actavis, Tavanic, Cavinton-Vr, Ropivacain Altan	Broxivan, Proxacin, Roxibron, Rexazon, Luxazone	Roctylan, Roclarin

SCEMBLIX (asciminib)	
EMA Approval Date	**24 June 2022**
Agency Product Number	EMEA/H/C/005605
Company	Novartis Europharm Limited
Therapeutic Class	Anti-Neoplastic
Pharmacological Class	Kinase inhibitor
Indication	Treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP) previously treated with two or more tyrosine kinase inhibitors.
Dosage Strength(s)	20 mg, 40 mg
Dosage Form	Tablet
Route	Oral
Product Use Comments	• Avoid food for at least 2 hours before and 1 hour after administration.
Active Ingredient Comments	• Contains the USAN stem, -minib, for “kinase inhibitor, binds to myristoyl binding site”. Asciminib inhibits the ABL1 kinase activity of the BCRABL1 fusion protein, by binding to the ABL myristoyl pocket. It is the only USAN or INN with this suffix, and the current USAN/INN stem for tyrosine kinase inhibitors is -tinib.
Brand Name Comments	• The intended pronunciation is "sem-blix". The "Scem" prefix is similar to the "scim" letter string in the non-proprietary name.

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
Simplex, Asembix, Semprex, Sebolox	Asembix, Celixib	Simplex, Asembix, Semprex, Cenlax, Femaplex, Femlax, Femmlux, Synflex, Fendrix, Simdax, Tamoplex, Centrax, Pendrex	None

SUNLENCA (lenacapavir)	
EMA Approval Date	**24 June 2022**
Agency Product Number	EMEA/H/C/005638
Company	Gilead Sciences Ireland Unlimited Company
Therapeutic Class	Antiretroviral Therapy
Pharmacological Class	Viral capsid inhibitor
Indication	Injection: treatment, in combination with other antiretroviral(s), of adults with multidrug-resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen Tablet: treatment, in combination with other antiretroviral(s), of adults with multidrug-resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen, for oral loading prior to administration of long-acting lenacapavir injection
Dosage Strength(s)	300 mg tablet and a 464 mg/1.5 mL solution for injection
Dosage Form	Tablet; Solution for Injection
Route	Oral; Subcutaneous
Product Use Comments	• Treatment is initiated with 600 mg (two 300 mg tablets) orally on Days 1 and 2 then 300 mg orally on Day 8 then 927 mg subcutaneously on Day 15 (two 1.5 mL injections) • The maintenance dose is 927 mg by subcutaneous injection every 6 months (26 week +/- 2 weeks)
Active Ingredient Comments	• First "viral capsid and nucleocapsid inhibitor" compound (-capavir) approved in the EU and the first HIV medication approved that targets the viral capsid • The stem "capavir" was first published as "viral capsid inhibitor" INN Prestem in 2019 then amended to "viral capsid *and nucleocapsid* inhibitor" in 2021.
Brand Name Comments	• The suffix "**lenca**" evokes the non-proprietary name, **len**a**ca**pavir

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
Sublana	Slenma, Sasulen, Selenase, Aesculan, Lencya	None	None

VYVGART (efgartigimod alfa)	
EMA Approval Date	**24 June 2022**
Agency Product Number	EMEA/H/C/005849
Company	Argenx
Therapeutic Class	Immunomodulator
Pharmacological Class	Neonatal Fc receptor blocker
Indication	Add-on to standard therapy for the treatment of adult patients with generalized Myasthenia Gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.
Dosage Strength(s)	400 mg/20 mL vial (20 mg/mL)
Dosage Form	Concentrate for solution for infusion
Route	Intravenous infusion
Product Use Comments	• Administered in cycles of once weekly infusions for 4 weeks with subsequent treatment cycles according to clinical evaluation. The frequency of treatment cycles may vary by patient.
Active Ingredient Comments	• The non-proprietary contains both a prefix stem, “ef”, to designate a constant fragment of an immunoglobulin molecule (Fc), and a suffix stem, “imod” for “immunomodulators, both stimulant/suppressive and stimulant”. Efgartigimod alfa is a human IgG1 antibody fragment engineered for increased affinity to the neonatal Fc Receptor (FcRn). • The “ig” letter string in the fantasy infix may connote the engineered IgG fragment or the reduction in circulating IgG and IgG autoantibodies.
Brand Name Comments	• The invented name suffix connotes the non-proprietary compound, ef**gart**igimod alfa

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
None	None	Viscard	None

AMVUTTRA (vutrisiran)

EMA Approval Date	**21 July 2022**
Agency Product Number	EMEA/H/C/005852
Company	Alnylam Netherlands B.V.
Therapeutic Class	Amyloid Neuropathies, Familial
Pharmacological Class	Double-stranded small interfering ribonucleic acid (siRNA)
Indication	Treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adult patients with stage 1 or stage 2 polyneuropathy.
Dosage Strength(s)	25 mg
Dosage Form	Solution for injection
Route	Subcutaneous use
Product Use Comments	• Administered once every three months
Active Ingredient Comments	• Vutrisiran is the fifth "siran" compound approved in the EU
Brand Name Comments	• The "am" prefix may connote "**am**yloidosis" while the "vuttr" connotes both the non-proprietary name, **vutr**isiran, and the therapeutic targets, variant and wild-type transthyretin (**TTR**) mRNA

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
None	None	None	None

LUPKYNIS (voclosporin)	
EMA Approval Date	**21 July 2022**
Agency Product Number	EMEA/H/C/005256
Company	Otsuka Pharmaceutical Netherlands B.V.
Therapeutic Class	Immunosuppressant
Pharmacological Class	Calcineurin-inhibitor immunosuppressant
Indication	Treatment of adult patients with active class III, IV or V (including mixed class III/V and IV/V) lupus nephritis (LN) in combination with mycophenolate mofetil.
Dosage Strength(s)	7.9 mg
Dosage Form	Capsule
Route	Oral
Product Use Comments	• Three tablets (23.7 mg) twice daily starting dose. Administer on an empty stomach as close to a 12-hour schedule as possible (minimum 8 hours). • Patients should be counseled to avoid eating grapefruit or drinking grapefruit juice. • Monitor blood pressure every 2 weeks for the first month of therapy. • Should be used in combination with mycophenolate mofetil
Active Ingredient Comments	• Voclosporin is a cyclosporine A analog. • Considered “first-in-class” for treatment of adults with active lupus nephritis
Brand Name Comments	• "Lup" letter string evokes the indication - lupus nephritis.

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
None	Lunis	None	None

MOUNJARO (tirzepatide)	
EMA Approval Date	**21 July 2022**
Agency Product Number	EMEA/H/C/005620
Company	Eli Lilly Nederland B.V.
Therapeutic Class	Anti-diabetic Agent
Pharmacological Class	Dual glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide 1 (GLP-1) receptor agonist
Indication	Treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise as monotherapy when metformin is considered inappropriate due to intolerance or contraindications in addition to other medicinal products for the treatment of diabetes.
Dosage Strength(s)	2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg per 0.5 mL in single-dose pens
Dosage Form	Solution for injection in a pre-filled pen
Route	Subcutaneous
Product Use Comments	• Once weekly administration
Active Ingredient Comments	• According to the INN Biologics Review 2022, tirzepatide (rINN List 81, 2019) would now be classified under the “dutide” stem, published in 2021 for “oxyntomodulin analogs and other dual agonists of glucagon-like peptide 1 receptor (GLP-1R) and glucagon receptor (GCGR)” (Prestem Suffixes, Aug. 2021)
Brand Name Comments	• The intended pronunciation is “mown-JAHR-oh”

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
None	None	None	None

NULIBRY (fosdenopterin)	
EMA Approval Date	**21 July 2022**
Agency Product Number	EMEA/H/C/005378
Company	Comharsa Life Sciences Ltd
Therapeutic Class	Substrate Replacement (Inborn Error of Metabolism)
Pharmacological Class	Cyclic pyranopterin monophosphate (cPMP)
Indication	Treatment of patients with molybdenum cofactor deficiency (MoCD) Type A.
Dosage Strength(s)	9.5 mg
Dosage Form	Powder for solution for injection
Route	Intravenous infusion
Product Use Comments	• Improved the 3-year survival rate from 55% to 84% in clinical trials. • Administered as a daily IV infusion.
Active Ingredient Comments	• The first and only therapy approved for the treatment of MoCD. It was given orphan designation during its development
Brand Name Comments	• Percent Derivation (PD) results identified the following international nonproprietary names (INNs) that have a 50% or higher percent derivation score when compared to the brand name: "fibrin" (50%) and "tibric" (50%)

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
Kolibri	Yulir	Kolibri, Zilibra	None

OPDUALAG (nivolumab/relatlimab)	
EMA Approval Date	**21 July 2022**
Agency Product Number	EMEA/H/C/005481
Company	Bristol-Myers Squibb Pharma EEIG
Therapeutic Class	Anti-Neoplastic
Pharmacological Class	Monoclonal Antibodies (combination)
Indication	First line treatment of advanced (unresectable or metastatic) melanoma in adults and adolescents 12 years of age and older with tumor cell PD-L1 expression < 1%.
Dosage Strength(s)	240 mg/80 mg
Dosage Form	Concentrate for solution for infusion
Route	Intravenous infusion
Product Use Comments	• Patients treated with Opdualag must be given the patient card and be informed about the risks of therapy
Active Ingredient Comments	• Combination of nivolumab, a programmed death receptor-1 (PD-1) blocking antibody, and relatlimab, a lymphocyte activation gene-3 (LAG-3) blocking antibody (anti-LAG-3) • Nivolumab, an anti- PD-1/PDL-1 (Programmed cell death protein 1/ death ligand 1), was first authorized in the European Union in 2015 under the brand name Opdivo®
Brand Name Comments	• The invented name connotes the nivolumab brand, Opdivo, the dual monoclonal antibody therapy, and the LAG-3 inhibition by relatlimab

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
Optallerg	None	Optallerg	None

TECVAYLI (teclistamab)	
EMA Approval Date	**21 July 2022**
Agency Product Number	EMEA/H/C/005865
Company	Janssen-Cilag International N.V.
Therapeutic Class	Anti-Neoplastic
Pharmacological Class	Bispecific monoclonal antibody (anti-CD3 and BCMA)
Indication	Monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.
Dosage Strength(s)	10 mg/mL, 90 mg/mL
Dosage Form	Solution for injection
Route	Subcutaneous
Product Use Comments	• Once weekly maintenance injections • Due to the risk of cytokine release syndrome, patients should be instructed to remain within proximity of a healthcare facility, and monitored for signs and symptoms daily for 48 hours after administration of all doses within the step-up dosing schedule
Active Ingredient Comments	• None
Brand Name Comments	• Both the brand and non-proprietary names have the prefix “tec” and the letter string “li”

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
None	Exacyl I.V.	None	None

TEZSPIRE (tezepelumab)	
EMA Approval Date	**21 July 2022**
Agency Product Number	EMEA/H/C/005588
Company	AstraZeneca AB
Therapeutic Class	Asthma
Pharmacological Class	Monoclonal antibody (IgG2 lambda)
Indication	Add-on maintenance treatment in adults and adolescents 12 years and older with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids plus another medicinal product for maintenance treatment.
Dosage Strength(s)	210 mg
Dosage Form	Solution for injection
Route	Subcutaneous
Product Use Comments	• Administer every 4 weeks
Active Ingredient Comments	• None
Brand Name Comments	• Invented name suffix evokes non-proprietary prefix, “tez”, and the English word “respire”

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
None	Telzir, Respir, Espiro, Theospirex, Eteplirsen, Spiretic	None	None

See Appendix II for Abbreviation Meanings

VABYSMO (faricimab)	
EMA Approval Date	**21 July 2022**
Agency Product Number	EMEA/H/C/005642
Company	Roche Registration GmbH
Therapeutic Class	Ophthalmic disorders
Pharmacological Class	Bispecific monoclonal antibody (anti-vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2))
Indication	Treatment of adult patients with neovascular (wet) age-related macular degeneration (nAMD) and visual impairment due to diabetic macular oedema (DME).
Dosage Strength(s)	120 mg/mL
Dosage Form	Solution for injection
Route	Intravitreal
Product Use Comments	• None
Active Ingredient Comments	• Although approved for ophthalmological indications, the "ci" infix connotes a "cardiovascular" target under both the previous and current monoclonal antibodies naming schemes

Brand Name Comments	• The letters that are used in the brand name may be forcefully associated (versus obviously associated) with the pharmacological class:
	  • V-A (anti-**va**scular endothelial growth factor)
	  • B-Y-S-M-O (**Bis**pecific **mo**noclonal antibody)

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
None	Vablys	None	Vablys

See Appendix II for Abbreviation Meanings

ENJAYMO (sutimlimab)	
EMA Approval Date	**16 September 2022**
Agency Product Number	EMEA/H/C/005776
Company	Genzyme Europe BV
Therapeutic Class	Anemia, Hemolytic, Autoimmune
Pharmacological Class	Monoclonal antibody (classical complement inhibitor)
Indication	Treatment of hemolytic anemia in adult patients with cold agglutinin disease (CAD).
Dosage Strength(s)	50 mg/mL
Dosage Form	Solution for Infusion
Route	Intravenous infusion
Product Use Comments	• The recommended dose is based on body weight range
Active Ingredient Comments	• Considered a "first in class" therapy • First and only treatment approved for people with CAD that decreases the need for transfusion
Brand Name Comments	• None

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
None	Fenamon	None	None

LIVTENCITY (maribavir)	
EMA Approval Date	**16 September 2022**
Agency Product Number	EMEA/H/C/005787
Company	Takeda Pharmaceuticals International AG Ireland Branch
Therapeutic Class	Cytomegalovirus Infections
Pharmacological Class	Antiviral
Indication	Treatment of cytomegalovirus (CMV) infection and/or disease that are refractory (with or without resistance) to one or more prior therapies, including ganciclovir, valganciclovir, cidofovir or foscarnet in adult patients who have undergone a hematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT).
Dosage Strength(s)	200 mg
Dosage Form	Tablet
Route	Oral
Product Use Comments	• The usual dose is two tablets (400 mg) twice daily. • May increase the drug concentrations of immunosuppressants that are substrates of CYP3A4 and/or P-gp including tacrolimus, sirolimus, everolimus, and cyclosporine.
Active Ingredient Comments	• First agent to target CMV pUL97 kinase instead of CMV DNA polymerase such as ganciclovir or foscarnet.
Brand Name Comments	• The prefix connotes the English word “live” while the rest of the invented name seems to connote “intensity”

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
None	Liten Hct, Evenity, Clivoten	None	None

MYCAPSSA (octreotide)	
EMA Approval Date	**16 September 2022**
Agency Product Number	EMEA/H/C/005826
Company	Amryt Pharmaceuticals DAC
Therapeutic Class	Acromegaly
Pharmacological Class	Somatostatin analogue
Indication	Maintenance treatment in adult patients with acromegaly who have responded to and tolerated treatment with somatostatin analogues.
Dosage Strength(s)	20 mg
Dosage Form	Gastro-resistant capsule
Route	Oral
Product Use Comments	• The only oral formulation of octreotide currently available in the EU • Considered a "hybrid" medicine of Sandostatin IR® (1995) since it has the same active substance, but a different dosage form and route of administration
Active Ingredient Comments	• None
Brand Name Comments	• Invented name connotes both the **cap**sule dosage form ("cap") and the pharmacological category, somatostatin analog ("SSA")

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
Mycota	Mycota, Capsicam	None	None

PYRUKYND (mitapivat)	
EMA Approval Date	**16 September 2022**
Agency Product Number	EMEA/H/C/005540
Company	Agios Netherlands B.V.
Therapeutic Class	Inborn Genetic Diseases
Pharmacological Class	Pyruvate kinase activator
Indication	Treatment of pyruvate kinase deficiency (PK deficiency) in adult patients
Dosage Strength(s)	5 mg, 20 mg, 50 mg
Dosage Form	Tablet
Route	Oral
Product Use Comments	• Avoid abrupt interruption or discontinuation to reduce the risk of acute hemolysis. Dosage should be gradually tapered if therapy is discontinued.
Active Ingredient Comments	• The USAN/INN stem for "pyruvate kinase activators" is "pivat". • First "pivat" compound approved in the EU
Brand Name Comments	• Invented name connotes "pyruvate kinase"

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
Pyroscint	None	Pyroscint, Tirosint	Pyroscint

ELADYNOS (abaloparatide)	
EMA Approval Date	**14 October 2022**
Agency Product Number	EMEA/H/C/005928
Company	Radius Health Ireland Ltd
Therapeutic Class	Osteoporosis
Pharmacological Class	Parathyroid hormone related peptide
Indication	Treatment of osteoporosis in postmenopausal women at increased risk of fracture.
Dosage Strength(s)	80 mcg/dose
Dosage Form	Solution for subcutaneous injection
Route	Subcutaneous injection
Product Use Comments	• The maximum total duration of treatment should be 18 months
Active Ingredient Comments	• None
Brand Name Comments	• Abaloparatide is approved in the US under the brand name, Tymlos® (April 2017) • Dyno – short name for Dynamometer – a device for measuring force, torque, or power. Invented name also contains the English word “lady” when the product is approved for postmenopausal women. • Percent Derivation (PD) results identified the following international nonproprietary names (INNs) that have a 50% or higher percent derivation score when compared to the brand name: “oxeladin” (50%)

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
Elusanes	Deslodyna, Ladose, Seldono, Adenosan, Elas	None	None

LIVMARLI (maralixibat)	
EMA Approval Date	**14 October 2022**
Agency Product Number	EMEA/H/C/005857
Company	Mirum Pharmaceuticals International B.V.
Therapeutic Class	Alagille Syndrome
Pharmacological Class	Selective inhibitor of the ileal bile acid transporter
Indication	Treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 2 months of age and older.
Dosage Strength(s)	9.5 mg/mL
Dosage Form	Oral solution
Route	Oral
Product Use Comments	• The usual dose is weight based, 190 mcg/kg or 380 mcg/kg, and should be taken 30 minutes before the first meal of the day.
Active Ingredient Comments	• First EMA approved treatment for cholestatic pruritis due to ALGS; previous therapies based on prescriber's clinical experience not efficacy • The -ixibat stem for "ileal bile acid transporter (IBAT) inhibitors, bile acid reabsorption inhibitors" was first published in March 2019 by INN as an addendum to the 2018 Stem Book. USAN has previously used the stem "ibat".
Brand Name Comments	• The invented name suffix, "marli", is similar to the first 6 letters of the non-proprietary name, "marali". • Nineteen (19) names identified in article 57 public database with high orthographic similarity. • Percent Derivation (PD) results identified the following international nonproprietary names (INNs) that have a 50% or higher percent derivation score when compared to the brand name: “arlipoic” (50%)

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
None	Velmari, Climara, Liprimar, Rivatril, Livial, Livormac, Variliv, Imraldi, Marelim, Rimal, Rival, Silimarin, Silimarit, Simalvia, Lamivir, Givlaari, Amplival, Varilrix, Lariam	None	Livormac

SPEVIGO (spesolimab)	
EMA Approval Date	**9 December 2022**
Agency Product Number	EMEA/H/C/005874
Company	Boehringer Ingelheim International GmbH
Therapeutic Class	Immunomodulator
Pharmacological Class	Monoclonal antibody (interleukin-36 receptor antagonist)
Indication	Treatment of flares in adult patients with generalised pustular psoriasis (GPP) as monotherapy.
Dosage Strength(s)	450 mg
Dosage Form	Concentrate for solution for infusion
Route	Intravenous infusion
Product Use Comments	• First in class treatment option approved for GPP • Given "conditional authorization" meaning that the EMA has decided that the benefits of Spevigo outweigh the potential, but the company will have to provide additional evidence after authorization
Active Ingredient Comments	• None
Brand Name Comments	• Invented name prefix connotes the active ingredient, spesolimab. • This product is used in the treatment of "generalized pustular psoriasis **flares**" and therefore reference to the English word "vigor" is an interesting association with this brand name. According to Webster's Dictionary, "vigor" is a *sudden* brief burst of bright flame or light or to burn with *a sudden* intensity. • Similar sounding name, "Sitavig" is a buccal tablet formulation of acyclovir available in 50 mg which has the same starting letter, "S" and letter string "VIG" but no overlapping characteristics.

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
Spezato	Pevison, Isopeg, Pevisone	Spezato, Sitavig	Spezato

ZYNLONTA (loncastuximab tesirine)

EMA Approval Date	**20 December 2022**
Agency Product Number	EMEA/H/C/005685
Company	ADC Therapeutics (NL) B.V.
Therapeutic Class	Anti-Neoplastic
Pharmacological Class	Antibody Drug Conjugate (CD19-directed monoclonal antibody and alkylating agent)
Indication	Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL), after two or more lines of systemic therapy.
Dosage Strength(s)	10 mg
Dosage Form	Powder for concentrate for solution for infusion
Route	Intravenous infusion
Product Use Comments	• EPAR not published
Active Ingredient Comments	• None
Brand Name Comments	• The “lon” infix evokes the antibody component (loncastuximab) while the suffix “ta” may imply the drug conjugate (tesirine)

Name Safety Tools Chart

Highly Similar (Combined POCA 70% -100%)	Orthographic (writing) Similarity 75% - 100%	Phonetic (sound) Similarity 75%-100%	Word Construction Analysis (WCA) Point Range 6-10
Zylanza	Zylanza, Zyrona, Lonata	None	Zynteglo

Appendix I. Definitions

Active Ingredient Comments	**Dosage Strength(s)**
Notes on the non-proprietary name or drug class	How much of the active ingredient is present in each dosage
Application	**Drugs@FDA**
Submission Classification that provides a way of categorizing new drug applications, e.g., "Type 1" applications are for "New Molecular Entities"	A searchable database for information about FDA approved brand name and generic drugs and therapeutic biological products
Brand Name Comments	**FDA Approval Date**
Notes on the product's proprietary name	The date the product was officially approved for use by the FDA
Combined POCA Score 70% -100%	**Indication**
Name pair has high overall similarity. This score is calculated by averaging the two individual scores (Orthographic and Phonetic)	The patient population and disease state for which the product is approved for use
Company	**Orthographic Similarity 75% - 100%**
Sponsor of the New Drug Application	Name pair has high similarity when written (script and/or print)
Discontinued	**Pharmacological Class**
Products listed in Drugs@FDA as "discontinued" are approved products that have never been marketed, have been discontinued from marketing, are for military use, are for export only, or have had their approvals withdrawn for reasons other than safety or efficacy after being discontinued from marketing	Drug classification based on chemical definition, clinical pharmacology/mechanism of action, and/or USAN/INN stem, e.g., beta-adrenergic antagonist
Dosage Form	**Phonetic Similarity 75%-100%**
The physical form in which a drug is produced and dispensed, such as a tablet, a capsule, or an injectable	Name pair has high similarity when spoken

Appendix I. Definitions (Continued)

POCA	Word Construction Analysis (WCA)
The Phonetic and Orthographic Computer Analysis (POCA) program is a software tool that uses an advanced algorithm to determine the orthographic and phonetic similarity between two drug names. The FDA POCA System compares a name pair (new brand name vs. existing product name) and the output is a value from 0 to 100%. The higher the value, the more similar a name pair. The FDA POCA System output shows similarity when written called orthographic similarity or POCA-O, similarity when spoken called phonetic or phonologic similarity or POCA-P, and a Combined Score that considers orthographic and phonetic similarity. Threshold values are identified by the FDA to help categorize similarity as low (0%-54%), moderate (55%-69%) and highly similar (70%-100%).	Word Construction Analysis (WCA) is a name safety testing tool developed by SafeMark and currently used in SafeMark Model name safety testing during the similarity review of a proprietary (brand) name. The WCA output scale of 0-10 is used to determine what name pairs should be further evaluated using a Name Pair Analysis (NPA) where overlapping characteristics are compared between the proposed or new product and the identified products. Considerations such as market availability, status of the product (Rx, OTC, Medical Device), and setting of use for the product are also included in a Name Pair Analysis. This is not an absolute threshold and is one tool used in name safety testing.
Product Use Comments	**WCA Point Range 6-10**
Notes on the prescribing, dispensing, administration, or safety of the product	A WCA point value is assigned to a name pair ranges from 0 to 10 and a higher number indicates more similarity between the name pairs. Points are assigned based on the FDA Combined and Individual Orthographic and Phonetic POCA scores, starting letter comparison, Prefix and Suffix Comparison and overall character count between the name pair. A cited name with a WCA value of 6-10 is considered relevant in the similarity analysis.
Route of Administration	
A way of administering a drug to a site in a patient	
RxNorm	
Provides normalized names for clinical drugs and links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software, including those of First Databank, Micromedex, and Gold Standard Drug Database	
Therapeutic Class	
Drug classification based on the indication or by the pathology it is used to treat (therapeutic use), e.g., anti-hypertensive agent	

Appendix I. Definitions (Continued)

C/O	MD
Name was identified as a chemical, food/food additive, medical/scientific term, or otherwise not a marketable product	Product is for office use or is provided directly from a physician
D/C	**N/F**
Brand name listed on Drugs@FDA as Discontinued or otherwise found to be not marketed	Product availability or marketing status could not be reliably verified or was Not Found
Dev	**OTC**
Product was found to be classified as a device	Over the Counter (non-prescription, FDA defines over the counter (OTC) drugs as safe and effective for use by the general public without a doctor's prescription)
DS	**Rx**
Dietary Supplement. Dietary supplements include such ingredients as vitamins, minerals, herbs, amino acids, and enzymes	A prescription drug product requires a doctor's authorization to purchase
Dx	**UA**
Diagnostic product	This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA
Hp	**V**
Homeopathic product. Homeopathic products have not been evaluated by the FDA for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective	Vaccine used for prophylaxis of a disease state or condition
INT	**Vet**
Identified as an international or non-US brand name	Veterinary product (Rx, OTC, or unapproved) for use in animals