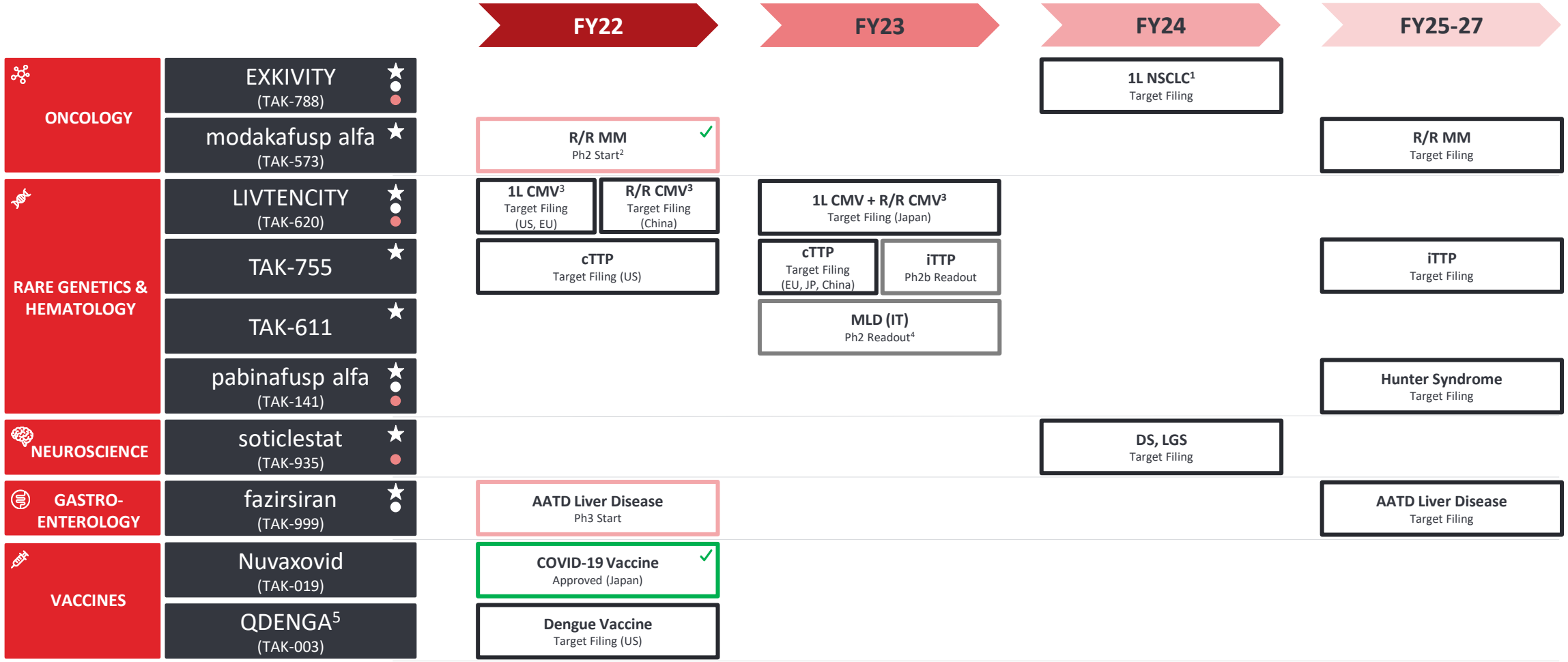
# 10 LATE-STAGE DEVELOPMENT PROGRAMS WITH UPCOMING NME FILING AND EXPANSION OPPORTUNITIES




1. Non-small cell lung cancer with EGFR exon 20 insertion mutations
2. First of a series of Ph1/2 studies started, incl. single agent and multiple combination studies in R/R MM
3. Post-transplant CMV infection/disease
4. Single arm Phase 2, timelines and filing plans will follow the data.
5. QDENGA is the approved brand name of TAK-003 in Indonesia

○ US Breakthrough and/or EU PRIME designations in at least one indication

● Japan SAKIGAKE and/or China Breakthrough designations in at least one indication

☆ Orphan drug designations in at least one indication

Approved

Proof-of-concept/ Ph2 study readout

Study start

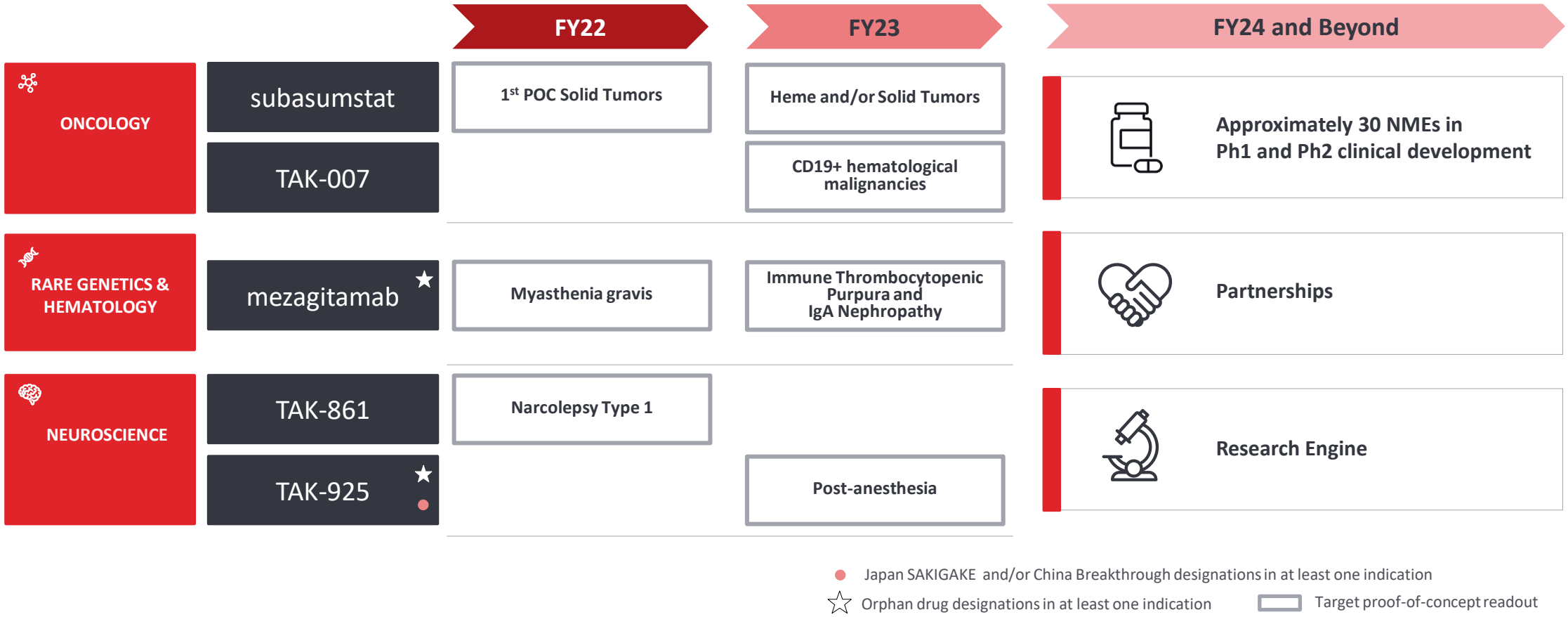
Target Filing, anticipated year of filing for regulatory approval

✓ Milestone achieved

Late-stage program: Program in or expected to be in potential pivotal trial or having achieved proof-of-concept.

All timelines are approximate estimates as of October 27, 2022, are subject to change and are subject to clinical and regulatory success. Table only shows selected R&D milestones and is not comprehensive. For full glossary of abbreviations please refer to appendix.

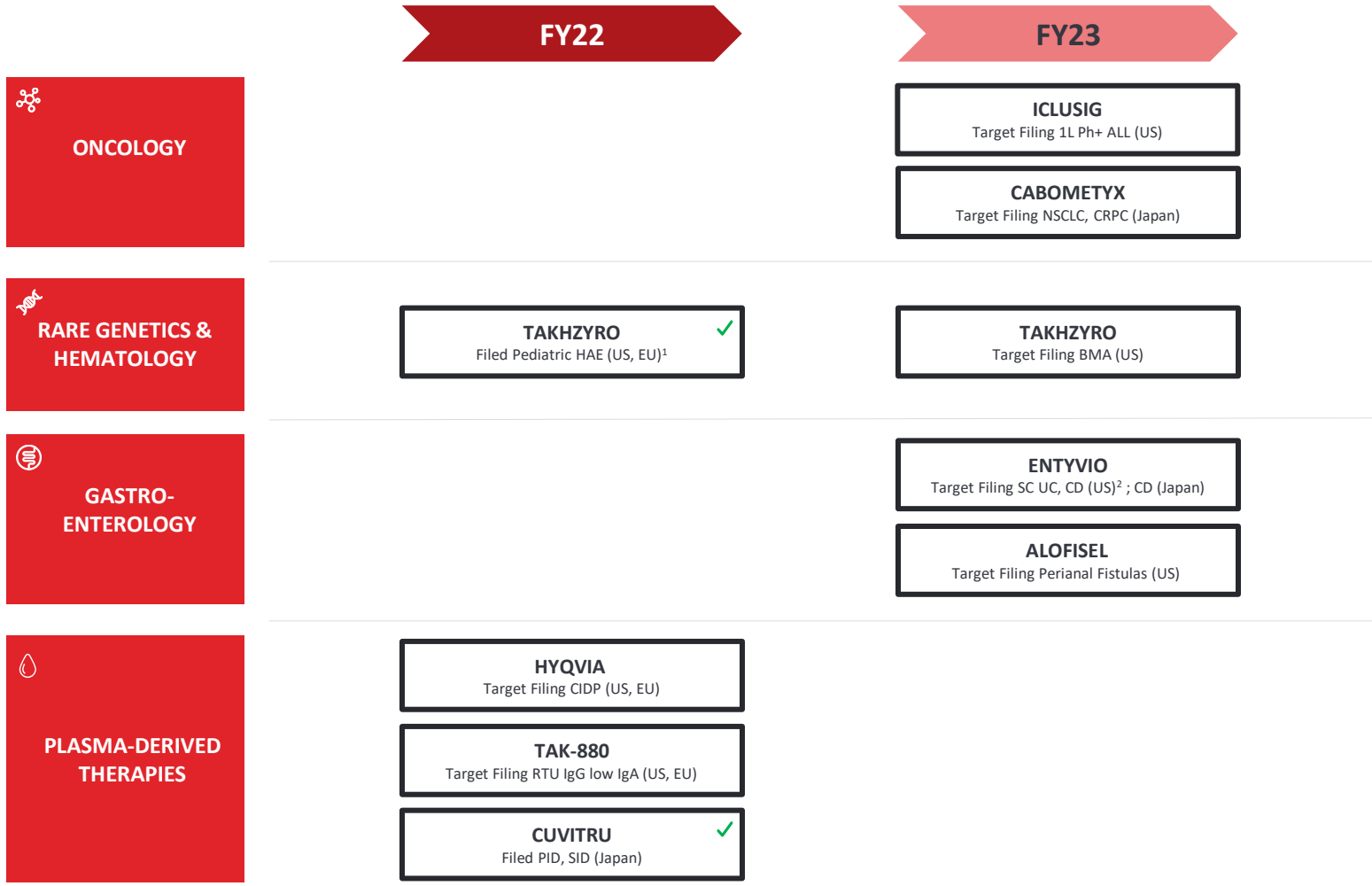
# KEY PROOF-OF-CONCEPT READOUTS IN FY22/23 EXPECTED TO ADD TO LATE-STAGE PIPELINE AND GLOBAL FILINGS IN MID/LATE 2020'S




Proof-of-concept (POC): Achieving proof-of-concept means obtaining clinical data sufficient to initiate pivotal trials or late-stage development.
A "readout(s)" for a clinical trial occurs when Takeda has (1) received the relevant clinical data, (2) completed any necessary analysis and review of such clinical data, and (3) in instances where it is required or otherwise common convention or practice, consulted with applicable regulatory authorities regarding such clinical data.
Where a readout is indicated for a class of related indications (e.g., solid tumors) involving multiple POC clinical trials, such readout occurs upon the earlier of (1) the first achievement of POC in an indication in such class, or (2) the conclusion of all of the POC clinical trials in such class.

All timelines are approximate estimates as of October 27, 2022, are subject to change and are subject to clinical and regulatory success. Table only shows selected R&D milestones and is not comprehensive. For full glossary of abbreviations please refer to appendix.

# EXPECTED LCM MILESTONES FOR OUR GROWTH & LAUNCH AND OTHER KEY PRODUCTS IN MAJOR REGIONS




Approved  Study readout  Target Filing  ✓ Milestone achieved

1. TAKHZYRO pediatric HAE filed the US, pending filing in the EU
2. ENTYVIO SC for UC in the US will be a resubmission after receiving FDA CRL in 2019

All timelines are approximate estimates as of October 27, 2022, are subject to change and are subject to clinical and regulatory success. Table only shows selected R&D milestones and is not comprehensive. For full glossary of abbreviations please refer to appendix.

# GLOSSARY OF ABBREVIATIONS

**Regional Abbreviations:**
CN: China; EU: Europe; JP: Japan; US: United States of America

| | |
|---|---|
| **AATD** | α1-antitrypsin deficiency |
| **ADC** | antibody drug conjugate |
| **ADHD** | attention deficit hyperactivity disorder |
| **AHA** | acquired hemophilia A |
| **ALK** | anaplastic lymphoma kinase |
| **ALCL** | anaplastic large-cell lymphoma |
| **ALL** | acute lymphocytic leukemia |
| **AML** | acute myeloid leukemia |
| **ASCT** | autologous stem cell transplant |
| **ARD** | acid-related diseases |
| **AVA** | Advanced Vial Access |
| **BBB** | blood brain barrier |
| **BLA** | biologics license application |
| **BMA** | bradykinin mediated angioedema |
| **BTD** | breakthrough therapy designation |
| **CAR-T** | chimeric antigen receptor-T |
| **CD** | Crohn's disease |
| **CHMP** | Committee for Medicinal Products for Human Use |
| **CIDP** | chronic inflammatory demyelinating polyradiculoneuropathy |
| **CLL** | chronic lymphocytic leukemia |
| **CML** | chronic myeloid leukemia |
| **CMV** | cytomegalovirus |
| **CNS** | central nervous system |
| **CPF** | complex perianal fistulas |
| **CRL** | complete response letter |
| **CRPC** | Castrate-resistant prostate cancer |
| **CTCL** | cutaneous T-cell lymphoma |
| **cTTP** | congenital thrombotic thrombocytopenic purpura |
| **DEE** | developmental and epileptic encephalopathies |
| **DLBCL** | diffuse large B-cell lymphoma |
| **DOAC** | direct oral anti-coagulation |
| **DS** | Dravet syndrome |
| **DU** | duodenal ulcer |
| **Dx** | Diagnosis |
| **EE H** | erosive esophagitis healing |
| **EE M** | erosive esophagitis maintenance |
| **EGFR** | epidermal growth factor receptor |
| **EMA** | European Medicines Agency |
| **FDA** | the U.S. Food & Drug Administration |
| **FL** | front line |
| **FSI** | first subject in |
| **FY** | fiscal year |
| **GERD** | gastroesophageal reflux disease |
| **GI** | gastrointestinal |
| **GU** | gastric ulcer |
| **GvHD** | graft versus host disease |
| **HAE** | hereditary angioedema |
| **H2H** | head-to-head |
| **HemA** | hemophilia A |
| **HL** | Hodgkin lymphoma |
| **HSCT** | hematopoietic stem cell transplant |
| **IBD** | inflammatory bowel disease |
| **IgAN** | immunoglobulin A nephropathy |
| **IH** | idiopathic hypersomnia |
| **INCAT** | Inflammatory Neuropathy Cause and Treatment disability score |
| **IND** | investigational new drug |
| **iNHL** | indolent non-Hodgkin's lymphoma |
| **ITP** | Immune thrombocytopenic purpura |
| **iTTP** | immune thrombotic thrombocytopenic purpura |
| **IV** | intravenous |
| **iPSC** | induced pluripotent stem cells |
| **L-ASA** | low dose aspirin |
| **LSD** | lysosomal storage disorder |
| **LCM** | lifecycle management |
| **LGS** | Lennox-Gastaut syndrome |
| **mAb** | monoclonal antibody |
| **MAOB** | monoamine oxidase B |
| **MDD** | major depressive disorder |
| **MG** | myasthenia gravis |
| **MLD** | metachromatic leukodystrophy |
| **MM** | multiple myeloma |
| **MMN** | multifocal motor neuropathy |
| **NBE** | New Biological Entity |
| **NCE** | New Chemical Entity |
| **ND** | newly diagnosed |
| **NDA** | new drug application |
| **Neg** | Negative |
| **NERD** | non-erosive reflux disease |
| **NHL** | non-Hodgkin lymphoma |
| **NK** | natural killer |
| **NME** | new molecular entity |
| **NMPA** | National Medical Products Administration |
| **NSCLC** | non-small cell lung cancer |
| **NSCT** | non stem cell transplant |
| **NT1 or 2** | narcolepsy Type 1 or 2 |
| **ORR** | overall response rate |
| **OSA** | obstructive sleep apnea |
| **PARP** | poly (ADP-ribose) polymerase |
| **PAS** | prior approval supplement |
| **PCAB** | potassium competitive acid blocker |
| **PCD** | protein C deficiency |
| **PEX** | plasma exchange |
| **Ph+ ALL** | Philadelphia chromosome-positive acute lymphoblastic leukemia |
| **PID** | primary immunodeficiency |
| **PK** | pharmacokinetics |
| **PMDA** | Japan's Pharmaceuticals and Medical Devices Agency |
| **POC** | proof of concept |
| **POGD** | post-operative gastrointestinal dysfunction |
| **PONV** | postoperative nausea and vomiting |
| **PRIME** | Priority medicines scheme by EMA |
| **PTCL** | peripheral T-cell lymphoma |
| **PTH** | parathyroid hormone |
| **R/R** | relapsed/refractory |
| **RCC** | renal cell cancer |
| **RTK** | receptor tyrosine kinase |
| **RTU** | ready to use |
| **sALCL** | systemic anaplastic large cell lymphoma |
| **SBS** | short bowel syndrome |
| **SC** | subcutaneous formulation |
| **SCD** | sickle cell disease |
| **SCT** | stem cell transplant |
| **SID** | secondary immunodeficiency |
| **SLE** | systemic lupus erythematosus |
| **sq** | squamous |
| **STING** | stimulator of interferon genes |
| **SUMO** | small ubiquitin-related modifier |
| **TCE** | T-cell engager |
| **TESD** | treatment emergent sexual dysfunction |
| **TKI** | tyrosine kinase inhibitor |
| **TREM2** | triggering receptor expressed on myeloid cells 2 |
| **UC** | ulcerative colitis |
| **VCD** | virologically confirmed dengue |
| **vWD** | von Willebrand disease |
| **VWF** | von Willebrand factor |