Newly published EPARs:

The EPAR (European public assessment report) is the main document where the EMA publishes detailed information on the medicines assessed by the CHMP. Below is a list of the EPARs for recently approved products that have been made available on the EMA homepage:

Ebvallo (tabelecleucel) is indicated as monotherapy for treatment of adult and paediatric patients 2 years of age and older with relapsed or refractory Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD) who have received at least one prior therapy. For solid organ transplant patients, prior therapy includes chemotherapy unless chemotherapy is inappropriate. Ebvallo is an advanced therapy medicinal product (ATMP) composed of allogeneic T-cells, selected for their specific immunological function (lysis of EBV+ targets) and sufficient human leukocyte antigen (HLA) similarity between donor and recipient. Although limited to a niche indication, the use of allogenic T-cells is a new, previously unauthorized mode of action for the immunotherapy of cancer. EPAR Ebvallo.

Eladynos (abaloparatide) is indicated for the treatment of osteoporosis in postmenopausal women at increased risk of fracture. EPAR Eladynos.

Locametz (gozetotide), after radiolabelling with gallium-68, is indicated for the detection of prostate-specific membrane antigen (PSMA)-positive lesions with positron emission tomography in adults with prostate cancer (PCa) in the following clinical settings:

- Primary staging of patients with high-risk PCa prior to primary curative therapy,
- Suspected PCa recurrence in patients with increasing levels of serum prostate-specific antigen (PSA) after primary curative therapy,
- Identification of patients with PSMA-positive progressive metastatic castration-resistant prostate cancer (mCRPC) for whom PSMA-targeted therapy is indicated.

EPAR Locametz.

Mycapssa (octreotide) is indicated for maintenance treatment in adult patients with acromegaly who have responded to and tolerated treatment with somatostatin analogues. EPAR Mycapssa.

Pluvicto [*lutetium-177 vipivotide tetraxetan]*, *in combination with androgen deprivation therapy with or without androgen receptor pathway inhibition is indicated for the treatment of adult patients with progressive PSMA-positive mCRPC who have been treated with androgen receptor pathway inhibition and taxane-based chemotherapy.* While PSMA has been used in the diagnostic of prostate cancer for several years, Pluvicto is the first cancer treatment targeting PSMA that received a positive CHMP opinion. EPAR Pluvicto.

Zynlonta (loncastuximab tesirine), as monotherapy, is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma and high-grade B-cell lymphoma, after two or more lines of systemic therapy. EPAR Zynlonta.

Links, in order or appearance:

https://www.ema.europa.eu/documents/assessment-report/ebvallo-epar-public-assessment-report_en.pdf

https://www.ema.europa.eu/documents/assessment-report/eladynos-epar-public-assessment-report_en.pdf

https://www.ema.europa.eu/documents/assessment-report/locametz-epar-public-assessment-report_en.pdf

https://www.ema.europa.eu/documents/assessment-report/mycapssa-epar-public-assessment-report_en.pdf

https://www.ema.europa.eu/documents/assessment-report/pluvicto-epar-public-assessment-report_en.pdf

https://www.ema.europa.eu/documents/assessment-report/zynlonta-epar-public-assessment-report_en.pdf