UPDATES

Health notices · Monday 9 November

3 notices from the agencies today, in plain words, each with the original linked.

FDA approves PALBOCICLIB (Ibrance) for certain breast cancers

FDA · Approval

If you have advanced or metastatic breast cancer, the US Food and Drug Administration (FDA) has approved PALBOCICLIB (Ibrance) for certain tumors based on hormone receptor and HER2 status.

PALBOCICLIB is a kinase inhibitor, which is a medicine that blocks signals inside cancer cells. The approval covers use with other breast cancer medicines in specific combinations and settings described in the label.

This may change what options your care team can offer for HR-positive, HER2-negative disease, including cases linked to a PIK3CA change, or for HR-positive, HER2-positive disease as maintenance after initial treatment.

Read the original notice

FDA approved pramipexole dihydrochloride extended-release for Parkinson's disease

FDA · Approval

If you have Parkinson's disease, the US Food and Drug Administration has approved pramipexole dihydrochloride extended-release tablets.

This medicine is a "dopamine agonist," meaning it works on dopamine, a chemical involved in movement control.

If you're considering treatment options, the approval means this specific tablet form is now indicated for Parkinson's disease.

Read the original notice

FDA approves Evoxac for dry mouth in Sjögren's syndrome

FDA · Approval

If you have Sjögren's syndrome and get symptoms of dry mouth, the FDA has approved Evoxac (cevimeline).

Sjögren's syndrome is a condition that can lead to reduced moisture in the body, including dry mouth.

What may be different for you tomorrow is that this medicine is now an available option to help with dry mouth symptoms.

Read the original notice

Where this comes from

- FDA approves PALBOCICLIB (Ibrance) for certain breast cancers

  US Food and Drug Administration - Drugs@FDA · https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=220444
- FDA approved pramipexole dihydrochloride extended-release for Parkinson's disease

  US Food and Drug Administration - Drugs@FDA · https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=090764
- FDA approves Evoxac for dry mouth in Sjögren's syndrome

  US Food and Drug Administration - Drugs@FDA · https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=221183