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DRUG DISCOVERY

FDA approved drugs - October 2012

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1. SYNRIBO (OMACETAXINE MEPESUCCINATE)

1.1. Company

Teva Pharmaceuticals; Approved by October 2012

1.2. Treatment Area

Chronic or accelerated phase chronic myeloid leukemia

1.3. General Information

Synribo (omacetaxine mepesuccinate) is a cephalotaxine ester. It is specifically approved for the treatment of adults with chronic or accelerated phase chronic myeloid leukemia with resistance and/or intolerance to two or more tyrosine kinase inhibitors. It is supplied as a solution for subcutaneous administration. The recommended dosage is 1.25 mg/m2 administered subcutaneously twice daily for 7 consecutive days every 28 days, over a 28-day cycle. Treatment should continue as long as patients are clinically benefiting from therapy.

1.4. Mechanism of Action

Synribo (omacetaxine mepesuccinate) is a protein synthesis inhibitor and is independent of direct Bcr-Abl binding. Omacetaxine mepesuccinate binds to the A-site cleft in the peptidyl-transferase center of the large ribosomal subunit from a strain of archaeabacteria. In vitro, omacetaxine mepesuccinate reduced protein levels of the Bcr-Abl oncoprotein and Mcl-1, an anti-apoptotic Bcl-2 family member.

1.5. Side Effects

Adverse events associated with the use of Synribo include: Thrombocytopenia, anemia , neutropenia , diarrhea , nausea , fatigue , asthenia , injection site reaction , pyrexia , infection , lymphopenia

2. FYCOMPA (PERAMPANEL)

2.1. Company

Eisai; Approved by October 2012

2.2. Treatment Area

Partial-onset seizures with or without secondarily generalized seizures

2.3. General Information

Fycompa (perampanel) is a selective AMPA-type glutamate receptor antagonist. The AMPA receptor is widely present most excitatory neuronal synapses and plays a role in a large number of central nervous system diseases. Fycompa is specifically 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. Fycompa is supplied as a tablet for oral administration. **In the absence of enzyme-inducing anti-epileptic drugs** the recommended dose is 2 mg once daily taken orally at bedtime. **In the presence of enzyme-inducing anti-epileptic drugs, t**he recommended is 4 mg and patients should be monitored closely for response.

2.4. Mechanism of Action

Fycompa (perampanel) is a non-competitive antagonist of the ionotropic a-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid (AMPA) glutamate receptor on post-synaptic neurons. Glutamate is the primary excitatory neurotransmitter in the central nervous system and is implicated in a number of neurological disorders caused by neuronal over excitation.

2.5. Side Effects

Adverse events associated with the use of Fycompa include: Dizziness, somnolence , fatigue , irritability , falls , nausea , weight gain , vertigo , ataxia , gait disturbance , balance disorder

3. OXTELLAR XR (OXCARBAZEPINE EXTENDED RELEASE)

3.1. Company

Supernus Pharmaceuticals ; Approved by October 2012

3.2. Treatment Area

Partial seizures in adults and in children 6 years to 17 years of age

Brithvi V,
FDA approved drugs – October 2012,
Drug discovery, 2012, 2(6), 33-35,

3.3. General Information
Oxtellar XR is an extended release, once daily formulation of oxcarbazepine, a currently approved anti-epileptic drug. Oxtellar XR is specifically indicated as adjunctive therapy of partial seizures in adults and in children 6 years to 17 years of age. It is supplied as a tablet for oral administration. It should be administered as a single daily dose taken on an empty stomach. The tablets should be swallowed whole. The recommended daily dose to **a**dults is 1,200 mg to 2,400 mg per day, given once daily.

3.4. Mechanism of Action
Oxtellar XR is a currently approved anti-epileptic drug. Oxcarbazepine produces blockade of voltage-sensitive sodium channels, resulting in stabilization of hyperexcited neural membranes, inhibition of repetitive neuronal firing, and diminution of propagation of synaptic impulses. These actions are thought to be important in the prevention of seizure spread in the intact brain. In addition, increased potassium conductance and modulation of high-voltage activated calcium channels may contribute to the anticonvulsant effects of the drug.

3.5. Side Effects
Adverse events associated with the use of Oxtellar XR include: dizziness, somnolence, headache, balance disorder, tremor, vomiting, diplopia, asthenia, fatigue

4. ABRAXANE (PACLITAXEL PROTEIN-BOUND PARTICLES FOR INJECTABLE SUSPENSION)
4.1. Company
Celgene; Approved by October 2012

4.2. Treatment Area
Non-small cell lung cancer

4.3. General Information
Abraxane (paclitaxel protein-bound particles for injectable suspension) is an intravenous nanoparticle, albumin-bound formulation of paclitaxel, a cancer chemotherapy that is protein-stable and Cremophor-free. It was designed to deliver a greater amount of chemotherapy to cancer cells with fewer side effects. It is specifically indicated for the first-line treatment of locally advanced or metastatic non-small cell lung cancer, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy. It is supplied as a solution for intravenous injection. The recommended dose is 100 mg/m2 administered as an intravenous infusion over 30 minutes on Days 1, 8, and 15 of each 21-day cycle.

4.4. Mechanism of Action
Abraxane is a microtubule inhibitor that promotes the assembly of microtubules from tubulin dimers and stabilizes microtubules by preventing depolymerization. This stability results in the inhibition of the normal dynamic reorganization of the microtubule network that is essential for vital interphase and mitotic cellular functions. Paclitaxel induces abnormal arrays (or bundles) of microtubules throughout the cell cycle and multiple asters of microtubules during mitosis.

4.5. Side Effects
Adverse events associated with the use of Abraxane include: anemia , neutropenia , thrombocytopenia , alopecia , peripheral neuropathy , nausea , fatigue

5. CYSTARAN (CYSTEAMINE HYDROCHLORIDE)
5.1. Company
Sigma Tau Pharmaceuticals; Approved by October 2012

5.2. Treatment Area
Corneal cystine crystal accumulation due to cystinosis

5.3. General Information
Cystaran (cysteamine hydrochloride) is a cystine-depleting agent which lowers the cystine content of cells in patients with cystinosis, a rare genetic disorder. Cystine is a naturally occuring amino acid. Cystinosis causes an accumulation cystine within cells; the cystine eventually forms crystals that build up and damage the cells. Cystaran is specifically approved for the treatment of corneal cystine crystal accumulation in adults and children with cystinosis. Cystaran is supplied as an ophthalmic solution for topical administration. The recommended dose one drop in each eye, every waking hour. The solution should be discarded after one week of use.

5.4. Mechanism of Action
Cystaran (cysteamine hydrochloride) acts as a cystine-depleting agent by converting cystine to cysteine and cysteine-cysteamine mixed disulfides and reduces corneal cystine crystal accumulation.

5.5. Side Effects
Adverse effects associated with the use of Cystaran include: sensitivity to light, redness, eye pain and irritation, headache, visual field defects

6. JETREA (OCRIPLASMIN)
6.1. Company
Thrombogenics; Approved by October 2012

6.2. Treatment Area
Symptomatic vitreomacular adhesion

6.3. General Information
Jetrea (ocriplasmin) is an alpha-2 antiplasmin reducer. It is a truncated form of the natural human protein plasmin, an enzyme that dissolves protein formations that are crucial to blood clot (thrombus) formation. It is specifically indicated for the treatment ofsymptomatic vitreomacular adhesion. It is supplied as a solution for intravitreal injection. The recommended dose is 0.125 mg (0.1 mL of the diluted solution) administered by intravitreal injection to the affected eye once as a single dose.

Brithvi V,
FDA approved drugs – October 2012,
Drug discovery, 2012, 2(6), 33-35,

6.4. Mechanism of Action

Jetrea (ocriplasmin) has proteolytic activity against protein components of the vitreous body and the vitreoretinal interface, thereby dissolving the protein matrix responsible for the vitreomacular adhesion.

6.5. Side Effects

Adverse events associated with the use of Jetrea include: vitreous floaters, conjunctival hemorrhage, eye pain, photopsia, blurred vision, macular hole, reduced visual acuity, visual impairment, retinal edema.

Brithvi V,
FDA approved drugs – October 2012,
Drug discovery, 2012, 2(6), 33-35,