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DRUG DISCOVERY

# FDA approved drugs – March 2013

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## 1. OSPHENA (OSPEMIFENE)

### 1.1. Company
Shionogi; Approved by March 2013

### 1.2. Treatment Area
Dyspareunia and vulvar and vaginal atrophy due to menopause

### 1.3. General Information
Osphena (ospemifene) is an estrogen agonist/antagonist with tissue selective effects. It binds to estrogen receptors, resulting in the activation of estrogenic pathways in some tissues and the blockade of estrogenic pathways in other tissues. It is specifically indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause. It is supplied as a tablet for oral administration. The recommended dose is one 60 mg tablet with food once daily. Use of Osphena should be for the shortest duration consistent with treatment goals and risks. For postmenopausal woman with a uterus, the addition of a progestin should be considered to reduce the risk of endometrial cancer. A woman without a uterus does not need a progestin.

### 1.4. Mechanism of Action
Osphena (ospemifene biological actions are mediated through binding to estrogen receptors. This binding results in activation of estrogenic pathways in some tissues (agonism) and blockade of estrogenic pathways in others (antagonism).

### 1.5. Side Effects
Adverse events associated with the use of Osphena include: hot flush, vaginal discharge, muscle spasms, genital discharge, hyperhidrosis.

## 2. TECFIDERA (DIMETHYL FUMARATE)

### 2.1. Company
Biogen Idec; Approved by March 2013

### 2.2. Treatment Area
relapsing multiple sclerosis

### 2.3. General Information
Tecfidera is specifically indicated for the treatment of adults with relapsing forms of multiple sclerosis. It is supplied as a delayed-release capsule for oral administration. The recommended initial dose is 120 mg twice a day orally. After 7 days, the dose should be increased to the maintenance dose of 240 mg twice a day orally. It should be swallowed whole and intact. It can be taken with or without food.

### 2.4. Mechanism of Action
Tecfidera (dimethyl fumarate) is an oral, small molecule immune modulator. The mechanism by which dimethyl fumarate exerts its therapeutic effect in multiple sclerosis is unknown. DMF and the metabolite, monomethyl fumarate (MMF), have been shown to activate the Nuclear factor (erythroid-derived 2)-like 2 (Nrf2) pathway in vitro and in vivo in animals and humans. The Nrf2 pathway is involved in the cellular response to oxidative stress. MMF has been identified as a nicotinic acid receptor agonist in vitro.

### 2.5. Side Effects
Adverse events associated with the use of Tecfidera include: flushing, abdominal pain, diarrhea, nausea



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http://www.discovery.org.in/dd.htm