

## Drugs approved by CDSCO, India in 2015

K Parushuram Naik<sup>1</sup>, V Sai Lakshmi<sup>2</sup>, J Jyothirmai<sup>3</sup>

<sup>1,2</sup>Assistant Professor, <sup>3</sup>Professor, Department of Pharmacology, Prathima Institute of Medical Sciences, Nagunur, Karimnagar, Telangana, India.

Address for correspondence: Dr. K Parushuram Naik, Assistant Professor, Department of Pharmacology, Prathima Institute of Medical Sciences, Nagunur, Karimnagar, Telangana, India.

Email: kprnaik2k10@gmail.com

S.No	Name Of Drug	Indication	US FDA / Other regulatory approval, with dose and route of administration.	Date of approval.
1	Sofosbuvir Tablet 400 mg. <sup>1</sup>	Chronic Hepatitis C (CHC) in adult.	2013, in combination with ribavirin or with pegylated interferon and ribavirin. One 400 mg tablet, taken orally, once daily with or without food.	13.01.2015
2	Bedaquiline Tablet 100 mg. <sup>2</sup>	Pulmonary tuberculosis due to multi-drug resistant Mycobacterium tuberculosis.	2012, 400 mg once daily for 2 weeks followed by 200 mg 3 times per week (with at least 48 hours between doses) for 22 weeks.	14.01.2015
3	Lixisenatide pre-filled solution for injection 10µg/20 µg. <sup>3</sup>	Type 2 diabetes mellitus. in combination with the following oral antibiotics: -Metformin, a sulphonyl urea, or a combination of these agents. In combination with a basal insulin: alone, in combination with metformin, or in combination with sulphonyl urea.	Not approved by US FDA. Approved by the European Commission, 2013.	15.01.2015
4	Dapagliflozin Tablet 5mg/10mg. <sup>4</sup>	Type-II diabetic mellitus As mono-therapy when diet and exercise alone do not provide adequate glycemic control in patients for whom use of metformin is considered inappropriate due to intolerance. As add-on combination therapy in combination therapy in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycemic control"	2014. 5/10 mg once daily, taken in the morning, with or without food.	25.02.2015

5	Pasireotide solution for injection 0.3mg/0.6mg/0.9mg. <sup>5</sup>	Cushing's disease for whom pituitary surgery is not an option or has not been Curative.	2012. Recommended dosage range is 0.3 mg to 0.9 mg twice a day.	18.03.2015
6	Emphagliflozin Tablet 10mg/10mg. <sup>6</sup>	As an adjunct to diet and exercise to improve glycemic Control in adults with Type 2 diabetes Mellitus	2014. 10 mg once daily, taken in the morning, with or without food.	07.05.2015
7	Gadobutrol solution for injection. <sup>7</sup>	In adult, adolescence and children aged 2 years and older for: 1.contrast enhancement in cranial and spinal magnetic resonance imaging (MRI). 2. Contrast enhancement MRI of other body regions: liver kidneys. 3. Contrast enhancement in Magnetic Resonance Angiography (CE-MRA) 4. For MRI of the breast to assess the presence and extent of malignant breast.	2011. Recommended dose is 0.1 mL/kg body weight (0.1 mmol/kg).	07.05.2015
8	Teneligliptin Tablet 20mg. <sup>8</sup>	Type 2 Diabetes Mellitus as a Monotherapy adjunct to diet and Exercise.	2012. Approved for use in Japan, Korea and India.	18.05.2015
9	Ceritinib 150 mg Hard Gelatin Capsules <sup>9</sup>	Anaplastic lymphoma Kinase (ALK)-positive metastatic non-small cell lung cancers (NSCLC) who have progressed on or are intolerant to crizotinib.	2014. 750 mg orally once daily on an empty stomach (i.e., do not administer within 2 hours of a meal).	13.01.2015
10	Vilazodone Hydrochloride 20mg/40mg and Bulk <sup>10</sup>	Major depressive disorders in adults.	2014. Initial dose 10mg once daily orally, followed by 20mg once daily. The dose may be increased up to 40mg once daily after a minimum of 7 days between dosage increases.	19.08.15
11	Gemigliptin 50mg tablets <sup>11</sup>	As an adjunct to the diet & exercise to improve to improve glycemic control in adults with type-2 diabetes mellitus, as an monotherapy or in combination with metformin in patients with inadequate glycemic control on metformin alone	Korean FDA 2012. 50mg. orally with or without food.	21.08.15
12	Atosiban Acetate Injection 6.75mg/0.9ml and Bulk <sup>12</sup>	Indicated to delay imminent pre-term birth in pregnant adult women with: -Regular uterine contractions of at least 30 Seconds duration at the rate of $\geq 4$ per 30 minutes. -A cervical dilation of 1 to 3 cm (0-3 for nulliparas) and effacement of $\geq 50\%$ . - A gestational age from 24 until 33 Completed weeks a normal foetal heart rate	Not approved by US FDA. Administered IV in three successive stages: an initial bolus dose (6.75 mg), immediately followed by a continuous high dose infusion (loading infusion 300 $\mu\text{g}/\text{min}$ ) of Atosiban 7.5 mg/ml concentrate for solution for infusion during three hours, followed by a lower dose of Atosiban 7.5 mg/ml concentrate for solution for infusion (subsequent infusion 100 $\mu\text{g}/\text{min}$ ) up to 45 hours	16.09.15

13	Ibrutinib Hard gelatin Capsule 140mg. <sup>13</sup>	Mantle cell lymphoma (MCL) who have received at least one prior therapy. Chronic Lymphocytic leukemia (CLL) who have received at least one prior therapy. Chronic lymphocytic leukemia with 17p deletion.	2013. MCL: 560 mg taken orally once daily (four 140 mg capsules once daily). CLL and WM: 420 mg taken orally once daily (three 140 mg capsules once daily).	07.10.2015
14	Ledipasvir (90mg)+ Sofosbuvir (400mg) Tablet. <sup>14</sup>	Chronic hepatitis C (CHC) Genotype 1 infection in adults.	2014. One tablet (90 mg of Ledipasvir and 400 mg of Sofosbuvir) taken orally once daily with or without food.	08.12.2015
15	Daclatasvir Dihydrochloride Tablet 30mg/60mg. <sup>15</sup>	For use with Sofosbuvir for the treatment of patient with chronic hepatitis C virus (HCV) genotype 3 infection	2015. 60 mg taken orally once daily with or without food in combination with Sofosbuvir.	14.12.2015
16	Enzalutamide 40 mg soft Capsule. <sup>16</sup>	Adults with metastatic castration resistant prostate cancer whose disease has progressed on or after Docetaxel therapy.	2012. 160 mg (four 40 mg capsules) administered orally once daily.	18. 12 .2015

## REFERENCES

1. <http://www.fda.gov/ForPatients/Illness/HepatitisBC/ucm377920.htm>.
2. <https://www.sirturo.com/sites/default/files/pdf/sirturo-pi.pdf>
3. [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/EPAR\\_-\\_Product\\_Information/human/002445/WC500140401.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002445/WC500140401.pdf)
4. [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/202293s003lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/202293s003lbl.pdf)
5. <https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/signifor.pdf>
6. [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/204629s000lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/204629s000lbl.pdf)
7. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2011/201277s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/201277s000lbl.pdf)
8. <http://docs.boehringer-ingenelheim.com/Prescribing%20Information/Pis/Jentaduetto/Jentaduetto.pdf>
9. <https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/zykadia.pdf>
10. [http://www.allergan.com/assets/pdf/viibryd\\_pi](http://www.allergan.com/assets/pdf/viibryd_pi)
11. <http://link.springer.com/article/10.1007/s12272-013-0171-x>
12. [https://www.old.health.gov.il/units/pharmacy/trufot/alonim/atosiban\\_dr\\_1329380162642.pdf](https://www.old.health.gov.il/units/pharmacy/trufot/alonim/atosiban_dr_1329380162642.pdf)
13. [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/205552s002lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/205552s002lbl.pdf)
14. [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/205834s000lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205834s000lbl.pdf)
15. [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/206843Orig1s000lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/206843Orig1s000lbl.pdf)
16. [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2012/203415lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/203415lbl.pdf)

**Please cite this article as:** Parushuram Naik,Sai Lakshmi, Jyothirmai. Drugs Approved by CDSCO, India in 2015. Perspectives in medical research 2016;4:2:67-69.

**Sources of Support:** Nil,Conflict of interest:None declared