



# Drug Information Bulletin

**Drug Information Centre (DIC)**

*Indian Pharmaceutical Association*

*Bengal Branch*

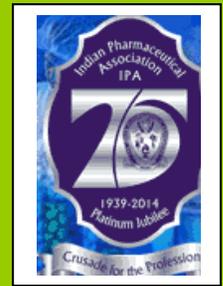
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**Regulatory Affairs Division (RAD), IPA**



**Volume: 08**

**Number: 14**

**12<sup>th</sup> October 2014**

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- **New Drug: Sofosbuvir**
- **Reccommendation for A.P.C.Ray Memorial Gold Medal Award invited on or before 14<sup>th</sup> October 2014**

## Editorial

*Pharmacists of India celebrated 25<sup>th</sup> September as the Pharmacists Day. Pharmacy Council of India has decided that they will celebrate this day as Pharmacists Day in India every year and requested all State Pharmacy Councils, Pharmacy Institutions and professional organizations to celebrate the occasion last year.*

*Pharmacists are one of the three main pillars of the health care systems with Doctors and Nurses. Though Doctors Day and Nurses Day are being celebrated since long back, no Pharmacists day was celebrated. This celebration will be a boost to the pharmacist as a health care provider and certainly recognition to their relentless service to the mankind.*

*IPA, Bengal Branch, has celebrated the day by distributing a badge to the Pharmacists with a request to all fellow Pharmacists to wear this badge during the working hours on 25<sup>th</sup> September. A seminar on "Prevention and Care of Japanese Encephalitis and related Diseases" was also organized on this occasion on 25<sup>th</sup> September 2014 at IPA Auditorium at 6.30 PM.*

*This day was celebrated with great enthusiasm throughout the country. There is information that Pharmacy Council of India, State Pharmacy Councils, IPA branches, Pharmacy Colleges, Hospitals has celebrated the occasion.*

*It may be noted that earlier Her Excellency President of India Mrs. Pratiba Patil has declared that Govt. of India will declare a day as "Pharmacists Day" and will institute an award like- Dr. B.C. Roy Award and Florence Nightingale Award. Hope PCI and Professional organizations of our Country will pursue the matter for its quick implementation.*

*Dr. Subhash C. Mandal  
Editor*

## ***New Drug: Sofosbuvir***

Approved indication: hepatitis C  
Sovaldi (Gilead)  
400 mg tablets  
Australian Medicines Handbook section  
5.4

There are six major types of hepatitis C – genotypes 1–6. In Australia, about half of cases are caused by genotype 1, a third by genotype 3 and 5% by genotype 2. Until recently, standard treatment for chronic hepatitis C infection was with peginterferon and ribavirin. Protease inhibitors boceprevir (Aust Prescr 2012; 35:102-3) and telaprevir (Aust Prescr 2012; 35:128-35) were approved in 2012. Adding either of these to peginterferon and ribavirin seems to improve the response rates in people with genotype 1 disease.

Sofosbuvir is another antiviral drug that can be added to combination treatment for chronic hepatitis C. It is a direct-acting nucleotide polymerase inhibitor. The prodrug is converted to a nucleotide analogue in hepatocytes. This active analogue then binds to RNA polymerase which terminates RNA synthesis and inhibits viral replication.

Sofosbuvir 400 mg/day has been investigated in four pivotal phase III hepatitis C trials (see Table).<sup>1,2</sup> One trial enrolled people with genotypes 1, 4, 5 or 6 and the others enrolled those with genotypes 2 or 3. Some patients in the trials had evidence of liver cirrhosis (15–35%). The primary outcome was the proportion of patients who had achieved a sustained virologic response, defined as undetectable viral RNA 12 weeks after the end of treatment. The highest rate of response to treatment was seen when sofosbuvir was added to peginterferon and ribavirin (90%) in previously

untreated patients with genotypes 1, 4, 5 or 6. Response rates were high with all genotypes although there were only seven people with serotypes 5 or 6.<sup>1</sup> When sofosbuvir was added to ribavirin in patients with genotypes 2 or 3, response rates in genotype 3 infections were considerably lower than those in genotype 2 infections.<sup>1,2</sup> Liver cirrhosis was also associated with lower response rates, particularly in those with genotype 3 disease.

Another trial found that extending sofosbuvir plus ribavirin treatment from 12 to 24 weeks improved response rates in people with genotype 3 infection from 27% (3/11) to 85% (213/250).<sup>3</sup> However, as the trial design was changed during the study, there was no hypothesis testing or statistical comparisons and results were only descriptive. Other trials have found that patients co-infected with HIV<sup>4</sup> and those with hepatocellular carcinoma awaiting liver transplant benefit from treatment with sofosbuvir added to ribavirin.

Treatment discontinuation because of an adverse event occurred in 2% or less of patients taking sofosbuvir-containing regimens. The most common adverse events with sofosbuvir added to ribavirin were fatigue (30–38%), headache (24–30%), nausea (13–22%) and insomnia (15–16%). These events occurred more frequently in patients who were also receiving peginterferon. This was also the case for anaemia and neutropenia.

Absorption is rapid after an oral dose of sofosbuvir with peak plasma concentrations reached after 0.5–2 hours. After metabolism in the liver, most of the dose is excreted in the urine (80%) and faeces (14%). The mean terminal

half-life of the main metabolite is 27 hours.

Sofosbuvir is a substrate of P glycoprotein so potent inducers of this transporter, such as rifampicin and St John's wort, should be avoided as they may decrease sofosbuvir's therapeutic effect. Other drugs that may reduce sofosbuvir exposure and are not recommended include modafinil, carbamazepine, phenytoin, phenobarbitone and tipranavir in combination with ritonavir.

Sofosbuvir should always be used in a combination regimen. As ribavirin is teratogenic, adequate contraception must be used during and for six months after treatment in men and women.

Sofosbuvir is effective and well tolerated when added to current therapy for people with chronic hepatitis C. The main predictors of response are viral genotype and liver cirrhosis. Response rates in people with genotype 3 infection are lower than with other genotypes and these people may need to take treatment for longer. Sofosbuvir also provides an alternative for people who have relapsed,

cannot tolerate or do not want to take interferon-containing regimens.

#### REFERENCES:

1. Lawitz E, Mangia A, Wyles D, Rodriguez-Torres M, Hassanein T, Gordon SC, et al. Sofosbuvir for previously untreated chronic hepatitis C infection. *N Engl J Med* 2013;368:1878-87.
2. Jacobson IM, Gordon SC, Kowdley KV, Yoshida EM, Rodriguez-Torres M, Sulkowski MS, et al. Sofosbuvir for hepatitis C genotype 2 or 3 in patients without treatment options. *N Engl J Med* 2013;368:1867-77 .
3. Zeuzem S, Dusheiko GM, Salupere R, Mangia A, Flisiak R, Hyland RH, et al. Sofosbuvir and ribavirin in HCV genotypes 2 and 3. *N Engl J Med* 2014;370:1993-2001.
4. Sulkowski MS, Naggie S, Lalezari J, Fessel WJ, Mounzer K, Shuhart M, et al. Sofosbuvir and ribavirin for hepatitis C in patients with HIV coinfection. *JAMA* 2014;312:353-61.

*Reference: Aust Prescr* 2014;37:172-79

### **2<sup>nd</sup> National Pharmacists Day Celebrated on 25<sup>th</sup> September 2014**

by:

**IPA Bengal Branch**

#### **Programmes:**

- Public Awareness programme "KYM"
- Wishing quick recovery to Hospital Patients
- Seminar on " Prevention and Care of Japanese Encephalitis and related Diseases":

Venue: IPA Auditorium

Speaker: Dr. Anjan Adhikari

### **Platinum Jubilee Celebration of IPA cum NPW celebration 15<sup>th</sup> – 23<sup>rd</sup> November 2014**

**Organized by:** IPA Bengal Branch

#### **Platinum Jubilee Celebration**

**Inauguration:** 15<sup>th</sup> November 2014

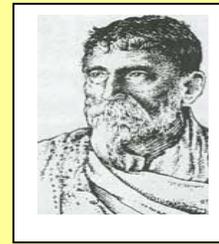
**National Workshop:** 16<sup>th</sup> November 2014

#### **National Pharmacy Week Celebration**

- Inauguration: Concurrently with Platinum Jubilee Celebration
- Different programmes throughout the week

**Recommendations for Acharya P. C. Ray Memorial Gold Medal Award, 2014 invited on or before 15<sup>th</sup> October 2014:**

The Indian Pharmaceutical Association, Bengal Branch gives annually gold medal on the occasion of celebration of National Pharmacy Week during 3<sup>rd</sup> week of November of each year to perpetuate the memory of great national figure Acharya P.C.Ray, the pioneer designer of Pharmaceutical Industry in our country since 1962.



IPA, Bengal Branch Executive Committee select the awardee amongst the Pharmaceutical Scientists, Teachers, Pharma Regulators, Hospital Pharmacists, Community Pharmacist, Administrators, etc. for outstanding contribution in their respective field and for overall development of the profession of pharmacy.

Any member of IPA can recommend name of the person with their detailed Bio-data and Two Page summary of the Bio data for 2014 award, which may be sent by 15<sup>th</sup> October 2014 to:

**The Hony. Secretary,**  
Indian Pharmaceutical Association, Bengal Branch,  
22 B Panchanontola Road,  
Kolkata – 700029  
e-mail: [ipabengal@gmail.com](mailto:ipabengal@gmail.com)

**N.B.: Biodata should include the following points-**

1. Date of Birth.
2. Qualification.
3. Experiences in the selected field.
4. Achievements in advancement of sciences/Administration/relevant field.
5.
  - a. Whether member of IPA? If yes, how many years?
  - b. Whether member of allied pharmaceutical profession other than IPA? If yes, how many years?
6. Services rendered (in years) on the executive Council of IPA Centre or any of its Branches in the capacity as:
  - a. President/Vice President / Hony. Secretary/Treasurer/Editor of Official Publication of IPA.
  - b. Executive Council Member.
7. Recognition/Award received from other professional organizations including industry/trade associations.
8. Award/Recognition/Honour received from international/national Govt. authorities or prestigious institution/organization by way of award or membership of their constituted body/committee other than sl. No. 6 above.
9. Performance in growth/ improvement of any of the field of pharmacy and shown creditable leadership in the chosen field.
10. Involvement and outstanding achievements in professional development in national/international arena.
11. Notable achievements in any other field or profession excluding pharmacy for which the nominee is nominated for the award including social welfare activities with Govt. and Non Govt. organizations.