Epclusa (Sofosbuvir 400 mg + Velpatasvir 100 mg)

April 13, 2017 By Greg Jefferys

Background

Epclusa is made by GILEAD, the same company that manufactures Sovaldi (Sofosbuvir 400 mg) and Harvoni (Sofosbuvir 400 mg + Ledipasvir 90 mg).

Whilst Harvoni was, and still is, the optimum treatment for Hep C genotype 1 it is not the best treatment for all other forms of Hepatitis C, which, up until the release of Epclusa, were best treated by the combination of Sofosbuvir 400 mg + Daclatasvir 60 mg.

Because Hep C genotype 1 represents about 50% of all Hep C infections GILEAD had a large part of the market covered with Harvoni however it was missing out on profits from the other half of the market and GILEAD is all about profits.

So GILEAD put in a lot of work to find a drug combination based around Sofosbuvir that would work against all genotypes of Hep C.

That mission was completed with the arrival of Epclusa.

Whilst Epclusa is not any better for treating G1 than Harvoni it is equal to, or better than, Sofosbuvir + Daclatasvir for treating the other genotypes.

Early research suggests that it is slightly better than Sof+ Dac for treating genotype 3, though this is not conclusive at the time of writing.

However the big advantage of Epclusa is that a person does not need to know their genotype of Hep C to begin treating the virus because Epclusa will treat all genotypes.

For a lot of people this is a big saving in money terms because the test for genotype generally costs at least US$260, or more.

Of course like all GILEAD products Epclusa is grossly overpriced and out of the reach of most people who need treatment for chronic Hepatitis C.

Like all GILEAD products the aim is to sell Epclusa at a price that maximises profits and minimises access, so Epclusa is only affordable to people with top level health insurance or living in wealthy countries that can afford to include it in their National Health Services.

For the other 150 million people with Hep C generic Epclusa is the option.

Generic Epclusa

Bangladesh

The first generic Epclusa was made in Bangladesh using APIs of Sofosbuvir and Velpatasvir imported from China.

These two generic versions of Epclusa were made by Beacon Industries (SOFOSVEL) and Incepta (PANOVIR)

However whilst these products appear to be effective there is an issue with the drug Velpatasvir. Like the Ledipasvir used in Harvoni Velpatasvir is very difficult for the body to absorb.

That is to say Velpatasvir is essentially insoluble.

This is the opposite of Sofosbuvir, which is very soluble.

To improve the absorption of Velpatasvir GILEAD developed a technology that mixes the very small particles of Velpatasvir with some other chemicals that make it easier for the body to absorb and utilise Velpatasvir.

So with the Bangladesh generics I do not know, and have not been able to find out, if they have been able to figure out how to do this with their generic Epclusa.

Generic Epclusa from India

When Epclusa was released in the USA and Europe once again India entered into negotiations with GILEAD. This time to produce a licensed generic version of Epclusa. Because part of the license agreement is that the Indian manufacturers will have access to all of GILEAD's intellectual property, including the technology for improving absorption of Velpatasvir, this means that the Indian generic Epclusa is identical to the GILEAD branded Epclusa.

As with Harvoni two Indian pharmaceutical companies are making the generic Epclusa, these are Natco and Hetero Pharmaceuticals.

Whilst both of these companies finalised licensing agreements with GILEAD to manufacture generic Epclusa late in 2016 the India government has been a little tardy in granting these companies permission to sell generic Epclusa in India.

This permission finally came through in April 2017 and the release date for the generic Epclusa to be available for sale in India is expected in mid to late April 2017.

At this point in time the price is not known but it is expected to be somewhere around US$1,000 to

US$1,200 for a 12 week treatment.

How Effective is Epclusa?

One of GILEAD's strongest attributes is its skill in sales and marketing.

Indeed, like all of Big Pharma, GILEAD spends more on marketing than it does on research.

As a result of GILEAD's promotion of Epclusa it is widely considered the new wonder drug for Hepatitis C however in reality Epclusa is no more effective than Harvoni against Hepatitis C genotype 1 and no more effective against the other genotypes of Hepatitis C than Sofosbuvir + Daclatasvir. The one possible exception to this might be Hep C genotype 3. There is some suggestion that Sofosbuvir + Velpatasvir (Epclusa) may be slightly better for treating G3 than Sof + Daclatasvir but there is not enough research data to be sure of this at the moment.

So if you have genotype 1 there is no real advantage in using Epclusa over Harvoni.

If you have G2 than Sof+ Dac will be just as effective as Sof+Velpatasvir.

For G3 Sof+ Velpatasvir is probably worth doing instead of Sof+ Dac but it is still worth considering doing 24 weeks instead of the recommended 12 weeks treatment.

BUT… if you do not know what genotype of Hepatitis C you have and if you would have problems finding the US$260 or more for the genotype test then Epclusa is a very good idea, though treating with Sofosbuvir + Daclatasvir would give the same results.

Another good reason for using Epclusa is that about 10% of people with Hepatitis C are infected with more than one genotype. By using Epclusa all genotypes will be treated. Though, again, treating with Sofosbuvir + Daclatasvir would give the same results.

I hope this is helpful to people.

A Footnote from Dr James Freeman

Once upon a time, a company called Pharmasett was working on a new Hepatitis C drug, a Direct Acting Antiviral called PSI-7977, an NS5B inhibitor, which was later re-named GS-7977 when Gilead Sciences bought Pharmasett. This is the drug we know today as Sovaldi (Sofosbuvir).

Back when Sofosbuvir was PSI-7977 Pharmasett were working with BMS (Bristol Myer Squib) and combining Sofosbuvir with their NS5A inhibitor called Daclatasvir, a combination that would have created an affordable pan-genotypic treatment for everyone with Hepatitis C.

However when Gilead purchased Pharmasett they severed that relationship with BMS so instead of the pan-genotypic Darvoni, we got the Genotype 1 focused Harvoni using the non pan-genotypic NS5A inhibitor Ledipasvir which Gilead owned.

Because Gilead owned Sofosbuvir and because Daclatasvir by itself was not a viable treatment this was a commercial decision that helped no-one except Gilead and it allowed Gilead to take all the profits and delayed the release of a single dose pan-genotypic treatment for 3 years.

The pricing of Sovaldi at $84,00 and Harvoni at $94,000 in effect valued the NS5A (Daclatasvir) part at $10,000 (BMS charge about $50,000) meaning relatively few people (outside the world of generics) got access to the powerful drug combination of Sofosbuvir + Daclatasvir.

This strategy worked very well for Gilead’s profits but, for GT3 F4 patients - not well at all. It also left GT2 patients taking Sofosbuvir + Ribavirin when they could have been taking the equally (if not more) effective treatment of Sofosbuvir + Daclatasvir, which of course skips the Ribavirin side effects.

In the mean time with the release of generic single dose Sofosbuvir + Daclatsvir treatments such as Darvoni it became very obvious that a pan-genotype treatment was the best way to go and from that need arises Epclusa.

Is it a better treatment than Sofosbuvir + Daclatasvir? That is a question that only time will answer.

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