A few weeks ago, an event occurred that is ruining my health—daylight savings time (DST). It happens every year, and without exception, it takes me weeks to recover. I love the extra hour of light, but my body has a hard time getting used to it. Apparently, I am not the only one. After we turn the clocks ahead, there is an increase in strokes, heart attacks, and accidents. If I was queen of the world, I would abolish DST. Fortunately for everyone, I am not in control of the world. Also, fortunately for the world, my body gets used to the clock change. However, it is a good opportunity to explore the relationship between sleep and health, especially as it applies to people with liver disease.

The Benefits of Sleep

Getting good quality and quantity of sleep turbo charges your body and mind. A good night’s rest is like hitting the reset button. If you skimp on quantity or quality, you may suffer short- and long-term consequences. Some of the positive effects that sleep provides are:

- Better physical health. Sleep boosts your immune system, and you will likely get sick less often. Plus, you will likely have more energy throughout the day.
- Reduces the risk for serious medical conditions such as type 2 diabetes, high blood pressure and heart disease.

IN THIS ISSUE

| Snapshots                                     | 4 |
| Under The Umbrella                            | 7 |
| Drug Pipeline                                 | 9 |
| What’s Up                                     | 13 |

— Continued on page 2

— By Lucinda K. Porter, RN
• Helps maintain healthy body weight. Sleep is a vital player in your body’s ability to regulate hormones that control your appetite and metabolism. Many of us crave carbohydrates when we are tired.

• Lowers stress and improves your mood.

• Helps you focus and think more creatively. Sleep may ease your ability to solve problems and remember important information.

• Improves relationships. You may find that you are more patient when you have slept well.

• Reduces injuries. When it comes to driving, sleep deprivation is like being intoxicated; sleepy drivers cause thousands of car accidents every year. Well-rested people are more alert, make better decisions, and use better judgement.

Sleep and Liver Disease

According to recent research, most patients with advanced cirrhosis have disturbed sleep, which can reduce quality of life. (Marwan Ghabril, et al., Most Individuals With Advanced Cirrhosis Have Sleep Disturbances, Which Are Associated With Poor Quality of Life, Clinical Gastroenterology and Hepatology, January 2017). Other studies found that patients with cirrhosis have a harder time falling asleep and staying asleep.

Their sleep is of poor quality, and in addition to sleeping less, they feel sleepy during the day.

The reasons that liver patients struggle with insomnia are not fully understood, but we do have some insight into this. The liver has its own clock, and injury to the liver may mess with the clock. Also, the liver helps to regulate hormones, all vital to the body’s sleep-wake cycle. Further, patients with advanced liver disease may suffer from obstructive sleep apnea, which may interfere with sleep quality and quantity.

Tips for Improving Your Sleep

Each of us needs a certain amount of sleep every night, usually between 7 and 9 hours for adults. This is all very well and good, but knowing how much sleep I need does not mean much if I am unable to sleep. As F. Scott Fitzgerald said, “The worst thing in the world is to try to sleep and not to.” So how do we improve
our chances of getting a good night’s sleep? Here are some tips:

- Get expert help. A sleep specialist can evaluate your sleep problems and make necessary recommendations. For instance, if you have sleep apnea, you may need a CPAP machine, mouth guard, or other intervention.

- Turn off all electronic devices several hours before bedtime. Watching TV or working on the computer stimulates the brain to stay awake, making it much harder to fall asleep. Don’t use a mobile device or watch TV in your bedroom.

- Try to go to bed at the same time every night; wake up at the same time in the morning.

- Be sure your sleep environment is comfortable. A cool room, warm blankets, and a comfortable bed and pillow are essential. The room should be dark and quiet.

- Exercise on a regular basis, preferably daily.

- If you nap, keep it short and early in the day.

- Try reading before bedtime, but use a low-watt bulb.

- Do not eat a few hours before bedtime but don’t go to bed hungry. If you eat something, choose food that is light and nutritious. Avoid spicy or greasy food.

- Take a hot bath before retiring.

- If you need sleep aids, talk to your doctor about melatonin or medication that may help you get started on a healthier sleep pattern.

Health relies on a foundation of good sleep. When I sleep well, I eat better, think better, and move better. I feel like I am queen of the world. We don’t need science to tell us why sleep is important. Shakespeare knew that, as sleep figures prominently in many of his plays. This quote from Shakespeare’s Macbeth says in a few words what it took me an entire article to write:

Sleep that knits up the ravel’d sleeve of care,
The death of each day’s life, sore labour’s bath,
Balm of hurt minds, great nature’s second course,
Chief nourisher in life’s feast.

Resources:
American Academy of Sleep Medicine www.sleepeducation.com
American Sleep Association www.sleepassociation.org
The National Sleep Foundation www.sleepfoundation.org
The Sleep Revolution: Transforming Your Life, One Night at a Time by Arianna Huffington

Lucinda K. Porter, RN, is a long-time contributor to the HCV Advocate and author of “Free from Hepatitis C” and “Hepatitis C One Step at a Time.” She blogs at www.LucindaPorterRN.com and HepMag.com
Study Aims and Results
The study aim was to find out if Zepatier was safe and effective in people with various forms of inherited blood disorders*. The trial enrolled 159 patients and was conducted in 31 sites from around the world. All of the patients in the Immediate Treatment Group (n=107 patients) were treated with Zepatier for 12 weeks. There were two groups—an Immediate Treatment Group who received Zepatier right away and the Deferred Treatment Group who received a placebo (sugar pill) for 12 weeks followed by a 4-week follow-up period. The placebo group only provided safety information. After the 4-week period the placebo group was given Zepatier treatment for 12 weeks. The goal or primary end point of the study was sustained virological response (SVR) or cure 12-weeks after the end of treatment and to compare the safety of the two groups—that is the immediate treatment group and the Deferred Group.

The patient characteristics in the Immediate Treatment Group were mostly genotype 1 and evenly divided between genotype 1a and 1b, treatment naïve and treatment experienced. The patients were mostly White and mostly F0-F2 (no fibrosis to early fibrosis).

Conclusion
The cure rates for the Immediate Treatment Group was 93.5% (100 of 107 patients); 6 patients relapsed; 1 patient was lost to follow-up. Breaking down the cure rate by inherited blood disorder—sickle cell anemia (94.7%-18 of 19 pts); β-thalassemia (97.6% 40 of 41 pts); hemophilia A/B or von Willebrand disease (89.4% 42 of 47 pts).

Serious adverse events were reported in 2.8% (3 pts) of the Immediate Treatment Group who received Zepatier and 11.5% (6 pts) in the Deferred Group who received the placebo drug.

Editorial Comments
This is great information for people with inherited blood disorders—high cure rates and low side effect profile. Now we can hopefully cure everyone with inherited blood disorders.

*Inherited blood disorders:

Sickle cell anemia—a disease of red blood cells that are shaped like crescent moons or sickles that get stuck in small blood vessels. This can slow or block blood flow and decrease the flow of oxygen to the body. This can lead to anemia and severe pain.

β-thalassemia is a blood disorder that causes the body to make less hemoglobin. This means there is less oxygen being carried to cells and throughout the body. Beta thalassemia can cause mild to severe anemia.

Hemophilia A is the most common type of hemophilia. It affects males and causes increased bleeding.

Hemophilia B is the second most common type of hemophilia. It affects males and also causes increased bleeding.

Von Willebrand disease (VWD) is a genetic disorder caused by a missing or defective clotting protein.

Check out the HCSP Fact Sheet: Bleeding Disorders for more information on some of these disorders. http://hcvadvocate.org/hepatitis/factsheets_pdf/Bleeding_Disorders.pdf
Study Aims and Results
The authors analyzed the hepatitis C treatment uptake in the Veterans Administration from January 01, 1999 through December 31, 2015. This would include treatment with interferon-based regimes including the use of it with ribavirin and sofosbuvir, through direct-acting antiviral medications—specifically simeprevir + sofosbuvir, Harvoni (ledipasvir + sofosbuvir), and Viekira Pak (paritaprevir + ombitasvir + ritonavir + dasabuvir).

The analysis included 105,369 patients in the Veterans Affairs national healthcare system and reported on the number of patients treated and the sustained virological response (SVR) or cure rates.

Conclusion
TreatmenUptake
During the interferon mono-therapy treatment years—2001—the treatment rates were 2,726 but increased to 6,679 the year after pegylated interferon was approved in 2002. Treatment peaked in the pegylated interferon era in 2002 but continued to decline until 2010. There was a modest increase to 4,900 in 2011 with the approval of pegylated interferon, ribavirin and boceprevir or telaprevir. But by 2013 the treatment fell to 2,609—the lowest since 2000.

The introduction of sofosbuvir and simeprevir at the end of 2013 greatly increased the treatment uptake to 9,180 followed by an even larger treatment increase in 2015 to 31,028 with the introduction of Harvoni and Viekira Pak.

Cure Rates
From 1999 to 2001 the cure rates were under 25% in the interferon era and increased to 22-37% from 2001 to 2010 during the pegylated interferon era. The pegylated interferon, ribavirin plus boceprevir or telaprevir era of 2011-2013 had high cure rates of 50%. Next came the use of simeprevir plus sofosbuvir that increased the cure rates up to 80.4% in 2014. The next big increase came with the use of Harvoni and Viekira Pak in 2015 with 90.5% cure rates—an all-time high. The dramatic increase in cure rates was even more incredible when you look at the most difficult-to-treat populations from the meager beginnings of the interferon era to the Harvoni/Viekira Pak era:
• Cirrhotic patients—11.0% to 87%
• Decompensated patients—14.6% to 85.2%
• Treatment-experienced patients—16.4% to 89.3%
• Genotype 1 patients—1.3% to 91.7%

Editorial Comments
It’s easy to forget how far we have come in the advancement of the treatments in such a short period. The paper also gives us a good idea of the how well hepatitis C drugs work in real world situations. It doesn’t mirror, however, the number of people who have been treated in the real world. The VA has a mandate to treat every Veteran with hepatitis C and has been funded by the Congress. That’s as it should be. But should everyone with hepatitis C have the right to be treated and cured? That should be a resounding YES!

“But should everyone with hepatitis C have the right to be treated and cured?”
Human immunodeficiency virus–infected and uninfected adults with non–genotype 3 hepatitis C virus have less hepatic steatosis than adults with neither infection—JC Price et al.


Study Aims and Results
The study looked at the rate of steatosis (fatty liver) in a group of 356 adults. The study group included 107 healthy people and compared them to 57 hepatitis C mono-infected patients, 70 people co-infected with HIV and hepatitis C and 122 with HIV mono-infected patients. People with HCV genotype 3 infection were excluded from the study because of the relationship between fatty liver and genotype 3— it is believed that HCV genotype 3 causes fatty liver.

The people in the study were evaluated for fatty liver disease using magnetic resonance imaging (MRI) and spectroscopy.

Conclusion
The highest rate of fatty liver was in the people who were uninfected (33%) followed by people who were HIV mono-infected (28%), HCV mono-infected (19%) and HIV/HCV co-infected (11%).

Editorial Comments
It’s interesting that the people with the lowest rates of fatty liver were people co-infected with HIV and hepatitis C followed by those with HIV and HCV mono-infection. It's pure speculation but there must be some interaction between the viruses and how fat is metabolized in the liver.

It would be helpful if a study would be conducted that would shine a light on how people who were cured of hepatitis C and if it effects the development of fatty liver. This could help advise people who are cured on lifestyle and medical issues.

“It’s pure speculation but there must be some interaction between the viruses and how fat is metabolized in the liver.”

Alan Franciscus is the Executive Director of the Hepatitis C Support Project and the Editor-in-Chief of the HCV Advocate Website.
The damage that hepatitis C does to the liver is something that everyone who contracts it will experience. Beyond that there are a lot of things that can be different from person to person and even from one gender to another. We are going to take some time in this article to look at a few ways hepatitis C affects women specifically. Some of these facts you may already know and some may even be surprising. If you have some of your own facts or would like to share your experiences please comment below or send us an email!

1. Women are more likely to “clear” hepatitis C than men. This means that women’s immune systems not only fight off hepatitis C more often than men but that they will cure themselves twice as often! This is pretty amazing. We don’t exactly know why this happens but it’s definitely something that is unique to women who are exposed to hepatitis C.

2. Maybe you knew that women cure themselves of hepatitis C twice as often as men. I bet you didn’t know that hepatitis C progresses more slowly in women than men! It’s true, not only do women fend off hepatitis C twice as often as men, they are able to wrangle it in with the lasso of their immune system and slow it down to a cool country pace if they do contract it. Now that’s what I call pretty impressive.

3. If you’re as smart as I know you are, you’ve likely guessed that women are less likely to die from hepatitis C than men. This makes a lot of sense after reading the first two facts. More likely to fight off hepatitis C + hepatitis C progressing more slowly = less likelihood that women will die from hepatitis C related complications. Things like alcohol and substances can accelerate the progression of hepatitis C. This is important because alcohol especially affects women more so than men. The number of drinks that women can have before the liver becomes damaged are fewer than men and...
this is an important thing to keep in mind! The reason for this is because even though damage to a women’s liver progresses more slowly while living with hepatitis C, consuming alcohol can accelerate that process. Always do what you can to help your body out and stay healthy!

4. Pregnancy is often filled with nervousness and excitement. A hepatitis C diagnosis can add negative emotions or fear during a time that should be filled with celebration. Transmission of hepatitis C from mother to child is called vertical transmission. This happens at a rate of 4-6% and although it’s rare being aware of your status before and during pregnancy is really important! If you have always wanted children and you find yourself with a hepatitis C diagnosis don’t think that you suddenly can’t fulfill those dreams, because you can! Make sure to talk with your doctor about treatment and any concerns you may have. They’ll help guide you through the process so that both you and your baby will be healthy, safe and happy!

5. I think many people experience stigma in some way or another. Whether it’s because of our skin color, gender, sexual identity, sexual orientation, socioeconomic status, country of origin or simply our beliefs. Illness and disease are often ways that people stigmatize others and hepatitis C is no exception. For pregnant women, or women of childbearing age, this stigma can be more biting because many people associate hepatitis C transmission with injection drug use. In my experience this leads to people labeling women as “bad mothers” or “irresponsible” and leads to less women being open and asking for a hepatitis C test because they are afraid of what will happen. If you’ve ever had an experience like this I want you to know that not everyone sees you that way or will treat you that way. There are a lot of great doctors, healthcare providers and community healthcare workers that are only interested in improving your mental, emotional and physical health. If you ever feel like you can’t be open and honest with your doctor about your health, or wanting a test, then you owe it to yourself to find one with whom you can. And always remember, you can beat this, you’re literally designed to fight hepatitis C better than most!

If you’ve been told that you have hepatitis C, successfully been cured or are afraid you have it then you either knew this information or find it comforting. Or maybe you just find it interesting and useful! If you want to learn more about hepatitis C and women check out these three great resources on the HCV Advocate website written by Lucinda K. Porter!

1. An Overview of Women and HCV
2. Being a Positive Mother
3. Guide: Women and Hepatitis C

Matthew Zielske is the Training Manager for the Hepatitis C Support Project’s Train-the-Trainer workshop. He has a Master’s in Communication with a focus on health communication and health literacy. You can read his blog at www.umbrellaway.org
HCV Advocate
Monthly Pipeline Update

A brief overview of how this pipeline is laid out:

**Date:** The Pipeline will be updated on a monthly basis and will be included with the HCV Advocate Newsletter.

**Genotype (s):** This lists the drugs or combination of drugs and the particular genotype or genotypes that the drug is active against.

**Comments:** This section will list the study results. Within this section, I will list the genotype(s) being studied and the phase of the study with a brief recap of the study.

You will note that many of the drugs or combinations of drugs are pan-genotypic—that is they work on many or most of the HCV genotypes. **Note:** There is more detailed information about the drugs in development in our newsletter (http://hcvadvocate.org/publications/newsletter/2016-2/) and our blog (http://hepatitisc.hcvadvocate.org/) and in the HJCV Advocate Hepatitis C Drug Pipeline & Conference Coverage Site hcvdrugs.com

If you are interested in finding out about clinical trials visit HCV Advocate Clinical Trial Reference Guide (http://hcvclinical.hcvadvocate.org/) for a list of trials that are currently recruiting patients.

<table>
<thead>
<tr>
<th>AbbVie</th>
<th>Genotype(s): 1, 2, 3, 4, 5, 6 (Pan-genotypic)</th>
</tr>
</thead>
</table>

**COMMENTS:**
The combination of glecaprevir (ABT-493) plus pibrentasvir (ABT-530) to treat genotype 1, 3, 4, 5, 6 for a treatment duration of 8 weeks. The sustained virological results (SVR12/cure) released on 11/12/2016 are listed below:

<table>
<thead>
<tr>
<th>Study Name</th>
<th>Patient Population</th>
<th>Treatment Duration</th>
<th>Treatment Regimen</th>
<th>SVR&lt;sub&gt;12&lt;/sub&gt; Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENDURANCE-1</td>
<td>GT1 without cirrhosis, new to treatment or not cured with previous IFN-based treatments (pegIFN +/- RBV or SOF/RBV +/- pegIFN), and patients co-infected with HIV-1</td>
<td>8 week</td>
<td>G/P</td>
<td>99% (348 of 351 pts)</td>
</tr>
<tr>
<td>ENDURANCE-3</td>
<td>GT3 without cirrhosis, new to treatment</td>
<td>8 week</td>
<td>G/P</td>
<td>95% (149 of 157 pts)</td>
</tr>
<tr>
<td>SURVEYOR-2 (Part 4)</td>
<td>GT2, 4, 5, or 6 without cirrhosis, new to treatment or not cured with previous IFN-based treatments (pegIFN, SOF/RBV or pegIFN/SOF)</td>
<td>8 week</td>
<td>G/P</td>
<td>97% (196 of 203 pts)</td>
</tr>
</tbody>
</table>

*pegINF = pegylated interferon; RBV = ribavirin; SOF = sofosbuvir; This combination was granted Breakthrough Therapy designation by the Food and Drug Administration (FDA) for those with HCV genotype 1 who had failed a previous course of therapy that contained a NS5A inhibitor. In December 2016 AbbVie applied to the FDA to market and treat all HCV genotypes with the combination listed above. On February 02, 2017 the FDA granted AbbVie Priority review for this combination.
### Gilead – Sofosbuvir, Valpatasvir& Voxilaprevir (GS-9857)

#### Genotype(s) 1,2,3,4,6, (Pan-genotypic)

**COMMENTS:**

Gilead released the results of four phase 3 studies (POLARIS) of the triple combination of sofosbuvir (polymerase inhibitor), velpatasvir (NS5A inhibitor), and voxilaprevir (protease inhibitor). The study included 1,056 patients who received the triple combination (sofosbuvir (SOF), velpatasvir (VEL), plus voxilaprevir (VOX)—611 were treatment naïve and 455 were treatment experienced.

_Note: I am only listing the results from the triple therapy below – you will note that the percentage and numbers include all the patients treated. For a complete breakdown of all treatment regimens see November 2016 newsletter: http://hcvadvocate.org/news/NewsUpdates_pdf/Advocate_2016/advocate1116.pdf_

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Genotype</th>
<th>Treatment</th>
<th>Duration</th>
<th>SVR12 Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>POLARIS-1</td>
<td>NS5A inhibitor-experienced</td>
<td>1, 2, 3, 4, 5, 6</td>
<td>SOF/VEL/VOX</td>
<td>12 Weeks</td>
<td>96% (253/263)</td>
</tr>
<tr>
<td></td>
<td>41 percent (172/415) had cirrhosis</td>
<td></td>
<td>Placebo</td>
<td>12 Weeks</td>
<td>0% (0/152)</td>
</tr>
<tr>
<td>POLARIS-4</td>
<td>DAA-experienced (No NS5A inhibitor)</td>
<td>1, 2, 3, 4</td>
<td>SOF/VEL/VOX</td>
<td>12 Weeks</td>
<td>97% (177/182)</td>
</tr>
<tr>
<td></td>
<td>46 percent (153/333) had cirrhosis</td>
<td></td>
<td>SOF/VEL</td>
<td>12 Weeks</td>
<td>90% (136/151)</td>
</tr>
<tr>
<td>POLARIS-2</td>
<td>DAA-naïve</td>
<td>1, 2, 3, 4, 5, 6</td>
<td>SOF/VEL/VOX</td>
<td>8 Weeks</td>
<td>95% (476/501)</td>
</tr>
<tr>
<td></td>
<td>18 percent (174/941) had cirrhosis</td>
<td></td>
<td>SOF/VEL</td>
<td>12 Weeks</td>
<td>98% (432/440)</td>
</tr>
<tr>
<td>POLARIS-3</td>
<td>DAA-naïve</td>
<td>3</td>
<td>SOF/VEL/VOX</td>
<td>8 Weeks</td>
<td>96% (106/110)</td>
</tr>
<tr>
<td></td>
<td>All had cirrhosis</td>
<td></td>
<td>SOF/VEL</td>
<td>12 Weeks</td>
<td>96% (105/109)</td>
</tr>
</tbody>
</table>

The side effects were similar between the placebo (sugar pills) group, sofosbuvir plus velpatasvir, and the sofosbuvir, velpatasvir plus voxilaprevir groups. The most common side effects were headache, fatigue, diarrhea and nausea. Only one patient in the entire study discontinued therapy due to side effects.

This combination was granted Breakthrough Therapy designation by the Food and Drug Administration (FDA) for those with HCV genotype 1 who had failed a previous course of therapy that contained a NS5A inhibitor.

In December 2016 Gilead applied to the FDA to market and treat all HCV genotypes with the combination listed above—combined into one pill taken once-a-day.
Janssen (Achillion/Alios) | Genotype(s) 1,2,3,4,5,6 (Pan-genotypic)

**COMMENTS:**

- **Genotype 1 – Phase 1:** In a small study of samatasvir, it was found to be safe and have antiviral properties against genotype 1, 2, 3 and 4. There is now a phase 2 study of samatasvir plus Olysio (simeprevir) in treatment-naïve patients with genotype 1b or 4.

- **Genotype 1 – Phase 2a Study** Janssen (Alios Pharma) has initiated a of AL-335, odalasvir, and simeprevir to treat HCV genotype 1 treatment-naïve patients. There will be 60 patients divided into three treatment arms who are treated for 4, 6 or 8 weeks. The results were listed in the October 2016 HCV Advocate newsletter. ([http://hcvadvocate.org/news/NewsUpdates_pdf/Advocate_2016/advocate1016.pdf](http://hcvadvocate.org/news/NewsUpdates_pdf/Advocate_2016/advocate1016.pdf))

- **Genotype 1 – Phase 2 Study:** ACH-3422 and Odalasvir (ACH-3102) and Sovaprevir are in studies with various combinations. Recently, Johnson & Johnson Innovation – JJDC, INC (Janssen) made an investment in Achillion for co-development and distribution.

- **Genotype 1 – Phase 2 Study:** Odalasvir plus sofosbuvir (used as a proxy drug) to treat genotype 1 patients for 6 weeks achieved 100% (12 of 12 patients) cure rates. A proxy drug is a drug used to stand in for another drug. Sofosbuvir is a polymerase inhibitor so it is assumed that odalasvir plus a polymerase inhibitor that is being developed by Achillion will produce similar cure rates.

- **Genotypes 1 through 6–Phase 2b Study:** Odalasvir, AL-335, and simeprevir in treatment-naïve and treatment-experienced patients with and without cirrhosis. The trial will enroll 400 patients for six or eight weeks. The study will include four arms with different combinations of drugs. The trial began in June 2016 and will end in July 2017.
### Merck

**Genotype(s):** 1, 2, 3, 4, 5, 6 (Pan-genotypic)

**COMMENTS:**

- **Phase 2- AASLD 2016:**
  
  **C-Crest:** The trial was a phase 2 study of a 3-drug co-formulation of MK-3682 (polymerase inhibitor), grazoprevir (protease inhibitor) plus ruzasvir (NS5A inhibitor) with and without ribavirin to treat HCV genotypes 1, 2 and 3. The treatment period was 8, 12 or 16 weeks. In the people who were previously treated with pegylated interferon plus ribavirin the SVR12/cure rates were 95% to 100% in genotype 1a, 1b and 3. In people with genotype 2 the cure rate was 87% in the 8-week group and a 100% rate in the 12 week group and 96% to 98% in the 16 week groups. There was very little difference in cure rates between the groups who had cirrhosis, and who did/did not receive ribavirin.

  **C-Surge:** An on-going phase 2 study to treat people with genotype 1 who had failed a previous course of a direct-acting antiviral therapy (Harvoni or Zepatier) using MK-3682, grazoprevir and ruzasvir with and without ribavirin. In the group that received ribavirin the treatment duration was 16 weeks; in the group that did not receive ribavirin the treatment duration was 24 weeks. The SVR 8 results were 98% in the 16 week group that received ribavirin and 100% in the 24 week group that did not receive ribavirin.

### Regulus

**Genotype(s):** 1, 2, 3, 4, 6

**COMMENTS:**

**Regulus Therapeutic Inc.**

The study included 79 treatment-naive genotype 1 and 4 patients. RG-101 is a GalNAc-conjugated anti-miR targeting miR-122, a host factor for HCV infection. It is an injectable medication given at Day 1 and Day 29 plus 4 weeks of a once-a-day direct-acting antiviral medication –Harvoni (27 patients), Olysio (27 patients), Daklinza (25 patients). Regulus issued a press release on June 7, 2016 that reported through 24 weeks of follow-up an additional 4 patients relapsed.

<table>
<thead>
<tr>
<th>Time Since Treatment Completion</th>
<th>RG-101 + Harvoni</th>
<th>RG-101 + Olysio</th>
<th>RG-101 + Daklinza</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 12</td>
<td>27/27 pts (100%)</td>
<td>26/27 pts (96.3%)</td>
<td>22/24 pts (91.7%)*</td>
</tr>
<tr>
<td>Week 16</td>
<td>21/21 pts (100%)</td>
<td>19/20 pts (95.0%)</td>
<td>20/22 pts (90.9%)</td>
</tr>
<tr>
<td>Week 20</td>
<td>14/14 pts (100%)</td>
<td>13/15 pts (86.7%)</td>
<td>13/13 pts (100%)</td>
</tr>
<tr>
<td>Week 24</td>
<td>10/10 pts (100%)</td>
<td>8/10 pts (80.0%)</td>
<td>8/9 pts (88.9%)</td>
</tr>
</tbody>
</table>

*One patient missed the Week 12 visit. Viral load results for this patient at week 8 and 16 were collected and indicate that the patient was a responder at both time points. This trial is on clinical hold due to safety concerns.*
WHAT’S UP!
Check out the following New and Updated fact sheets

HCSP FACTS: THE KIDNEYS
CLICK TO DOWNLOAD

HCSP FACTS: BLEEDING DISORDERS
CLICK TO DOWNLOAD

HARM REDUCTION: COTTON FEVER
CLICK TO DOWNLOAD

HARM REDUCTION: ABSCESS
CLICK TO DOWNLOAD

HARM REDUCTION: OVERDOSE
CLICK TO DOWNLOAD

The HCV Advocate offers information about various forms of intervention in order to serve our community. By providing information about any form of medication, treatment, therapy or diet we are neither promoting nor recommending use, but simply offering information in the belief that the best decision is an educated one.

Reprint permission is granted and encouraged with credit to the Hepatitis C Support Project.

2 http://hcvadvocate.org/hepatitis/factsheets_pdf/Bleeding_Disorders.pdf