This month’s HCV Drugs column includes information about a variety of studies recently published in the *New England Journal of Medicine* (NEJM)—AbbVie’s 3D drug combination to treat genotype 1, and Gilead’s sofosbuvir, ledipasvir with and without ribavirin to treat genotype 1 and sofosbuvir plus ribavirin to treat genotypes 2 and 3. In addition, there were applications for marketing of AbbVie’s 3D combination in the European Union and Janssen’s supplemental application to the FDA for marketing approval of Sovaldi and Olysio for genotype 1 in the U.S.

Finally, there is a short recap of the results of a study presented at the Digestive Disease Week conference to treat HCV genotype 4.

A summary of the information from the NEJM will also be included in the Drugs in Development section of the HCSP Fact Sheets on our website. Additional EASL conference coverage will also be available in our blog.

### ABBVIE

**PEARL III & IV:**

In an article in the *New England Journal of Medicine* (NEJM) the results of the PEARL-III and PEARL-IV studies were reported. The studies included HCV genotype 1a (305) and 1b (419) patients without cirrhosis who were treated with ABT-450/r, ombitasvir, dasabuvir with and without ribavirin for 12 weeks.

**Patient Population:**

The patients were somewhat similar between the arms:

- **Genotype 1a**—male 63-70%; White 83-86%; age 51yo; fibrosis F0/F1–63 to 64%, F2–7 to 21%, F3–16 to 19%.
- **Genotype 1b**—male 41-51%; White 94%; age 48-49yo; fibrosis F0/F1–68 to 71%, F2–18 to 23%, F3–10 to 11%.

Overall cure rates were 90 to 99% (see Table 1 on page 5 which includes results from all of AbbVie’s Phase 3 clinical trials).

The majority of the side effects were mild. The most common side effects in all the studies were headache and fatigue. Two patients in the study discontinued therapy due to side effects.

The authors of the study noted that the cure rates were higher in the ribavirin containing arm of the group of patients with HCV genotype 1a—90 % vs. 97% in the ribavirin containing arm. In the HCV genotype 1b arms there was no difference in the ribavirin vs. no ribavirin arms—99-100%.

**Comments:**

AbbVie has completed their Phase 3 studies and submitted their data to the Food and Drug Administration (FDA) for approval. It is likely that the AbbVie 3D (without ribavirin) combination for a treatment period of 12 weeks will be approved by the FDA to treat HCV genotype 1b. The 3D combination will also be approved to treat HCV genotype 1a, but it is unclear if the approval will stipulate that ribavirin will be necessary. A 7% difference in cure

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**HEALTHWISE: Hepatitis C & Liver Cancer (HCC)** .......................................................... 3

CONTINUED ON PAGE 5
Important note: This month’s HCV Snapshots features selected abstracts from the May 2014 meeting of Digestive Disease Week. The research presented here came from conference posters and presentations, representing part of a picture. There are multiple factors that influence treatment outcomes such as the number of patients in the study, patient demographics (weight, age, ethnicity), and study design (inclusion criteria, placebo vs. open label, etc.) to name a few. Unless and until these studies are published in peer-reviewed journals, these data and conclusions are considered preliminary.


This study gathered data from medical records and estimated the liver disease stage of 227,563 Veterans Administration patients with chronic hepatitis C infection (HCV). Using these data, they forecasted the outcomes if:

1. Patients received no treatment (NT)
   • Projected deaths in 2014 = 958; 2019 = 1490; 2024 = 1800

2. Patients were treated with pegylated interferon and ribavirin (PR)
   • Projected deaths in 2014 decreased 7.1%; in 2019 decreased 8%; 2024 decreased 8.9%

3. Patients were treated with pegylated interferon, ribavirin, and a protease inhibitor (PRPI)
   • Projected deaths in 2014 decreased 10.9%; in 2019 decreased 12.3%; 2024 decreased 13.7%

4. Patients were treated with new all oral hepatitis medications expected to be released in 2014, such as sofosbuvir and ledipasvir.
   • Projected deaths in 2014 decreased 50.2%; in 2019 decreased 56.7%; 2024 decreased 63.1%

The Bottom Line: All oral hepatitis C therapies are anticipated to save lives, and provide other positive health outcomes.

Editorial Comment: Hepatitis C-related deaths may be underreported. Hepatitis C patients are at increased risk of premature death from other medical conditions such as heart disease, stroke, and cancer. Since these factors are not captured in this analysis, the potential benefits of new hepatitis C treatments may be greater than what is reported here.


There has been a campaign to screen Baby Boomers (those born from 1945-1965) for hepatitis C, hoping to find undiagnosed patients who might otherwise fall through the cracks. It has been estimated that birth year screening will identify 800,000 Baby Boomers with hepatitis C who might not otherwise be diagnosed. However, there isn’t strong data on actual hepatitis C diagnosis in communities. This study, conducted in Olmsted County, Minnesota, looked at blood samples of residents born from 1954 through 1976.

The Bottom Line: The prevalence of hepatitis C in this rural Midwestern was similar to national data, confirming that the majority of those with hepatitis C are not yet diagnosed, including the majority of hepatitis C patients who are younger, between ages 30 and 49.

Editorial Comment: Hepatitis C is a growing problem in our youth, and younger adults. Those who are 30 to 49 may be overlooked. This study emphasizes the need to screen everyone, not just Baby Boomers. In addition to birth year screening, we also need to ramp up risk-based screening.

This year, four friends were diagnosed with liver cancer. One died in February. Two are not expected to live long. One is doing well after surgery. None of these friends has hepatitis B or C, although one has a history of hepatitis C, and was cured more than ten years ago.

The World Health Organization (WHO) just announced that liver cancer has moved in to second place as the most common cause of cancer deaths in the world. Second only to lung cancer, liver cancer is responsible for more than 9% of cancer deaths. The combined number of deaths from liver cancer and cirrhosis is 1.75 million annually.

In the February 11, 2014 online American Journal of Gastroenterology, Sean Altekruse and colleagues reported that U.S. liver cancer mortality rates increased with age in all racial/ethnic groups. Washington DC, Louisiana, Mississippi, and Texas have the most liver cancer deaths. North Dakota has the lowest liver cancer mortality rates, followed by Idaho and Utah.

There are two categories of liver cancer—primary and secondary. Primary liver cancer starts in the liver. Cancerous tumors are called malignant hepatomas, the most common of which is hepatocellular carcinoma (HCC). Secondary liver cancer is more common in the U.S. Also known as metastatic cancer, it starts in another part of the body and spreads to the liver. Colorectal cancer is famous for this, with roughly half of all cases metastasizing to the liver. Because blood filters through the liver, it is a prime target for metastasis.

Cirrhosis is linked to more than 80% of all HCC. Anything that leads to cirrhosis increases liver cancer risk. Alcohol abuse, chemicals, drugs, parasites, viruses, and autoimmune conditions may all lead to cirrhosis. Although the majority of primary liver cancers begin with cirrhosis, the majority of those with cirrhosis will never get liver cancer.

Hepatitis B and C are the most common risk factors for HCC. Areas that have a high prevalence of HBV have high liver cancer rates. Hepatitis C is the next leading cause of liver cancer. In addition to age, (greater than 60 years old), male gender, and a family history of liver cancer, other risk factors for HCC are:

- Long-term, heavy alcohol consumption
- Tobacco use
- Obesity or poor diet
- Diabetes
- Use of anabolic steroids or male hormones
- Certain inherited diseases, such as hemochromatosis (excess iron storage)
- Ingestion of arsenic, such as in drinking water
- Exposure to certain industrial chemicals
- Aflatoxins (a poison produced by a fungus sometimes found

“...We used to think that hepatitis C without cirrhosis was not a risk factor. However, a study conducted by a team headed by Anna Lok at the University of Michigan, identified HCC in a significant number of HCV patients with advanced fibrosis but no cirrhosis.”
on peanuts, corn, grains and nuts. In the U.S., most commercially available grains and nuts are safe.)

**Signs and Symptoms**

One of the reasons that liver cancer is particularly life threatening has to do with the liver itself. With over 500 functions, this resilient organ doesn’t complain. Other parts of the body let us know when there is trouble. The liver quietly goes about its work and may not let you know there is a problem until the damage is extensive. That’s why those with chronic hepatitis C might live with the virus for decades before realizing that they have it.

The symptoms of liver cancer are similar to other health problems, such as gall bladder disease. However, since the symptoms of liver cancer usually don’t show themselves until the later stages of cancer, it is critical that patients consult their medical providers as soon as they are even mildly symptomatic. Wait too long and the tumor may grow too large to treat effectively.

**Symptoms of liver cancer:**

- Pain or discomfort in the upper right side of the abdomen
- Lump on right side or heavy feeling in abdomen
- Pain in the back or right shoulder
- Appetite loss or feeling full after a small meal
- Unexplained weight loss
- Bloated or swollen belly
- Unexplained fatigue or weakness
- Fever
- Bruising, bleeding
- Nausea or vomiting
- Jaundice (yellow skin and eyes)
- Dark, tea-colored urine
- Pale, clay-colored stools
- Tremors, confusion, disorientation

**Screening**

For those at risk, regular HCC screening is critical. Surveillance is recommended for those with family history of liver cancer, people with cirrhosis, Africans, Asians and Pacific Islanders, people with hepatitis B or C, and those at high risk.

We used to think that hepatitis C without cirrhosis was not a risk factor. However, a study conducted by a team headed by Anna Lok at the University of Michigan, identified HCC in a significant number of HCV patients with advanced fibrosis but no cirrhosis.

We also thought that a sustained virologic response (SVR) to hepatitis C treatment ensured safety from hepatitis C’s risk of cirrhosis or liver cancer. However, a study presented by Thierry Poynard at the 2013 Liver Meeting showed that hepatitis C patients who had previously developed significant fibrosis, could still continue to be at risk for fibrosis/cirrhosis and liver cancer despite an SVR. Another small study presented by Savino Bruno and colleagues at the 2014 European Association for the Study of the Liver (EASL) showed that an SVR did not reduce HCC risk. However, the numbers of subjects in the study were too few to make strong conclusions.

Screening helps. In a paper published in the April 2014 Hepatology, Abbas Mourad and team reported that HCC screening improves survival rate. The current screening recommendation for hepatitis C patients with advanced fibrosis is every 6 months. Fortunately, although HCC rates are increasing, so are the treatment options and success rates. Early screening leads to higher survival rates.

**Prevention**

Everything that prevents hepatitis or cirrhosis reduces liver cancer risk. Children are now routinely immunized against hepatitis A and B. Other ways to reduce HCC risk are to maintain a normal weight, quit smoking, and avoid anabolic steroid use. Abstaining from alcohol is recommended for those with liver disease. For those whose health allows it, moderate use of alcohol does not appear to raise the HCC risk.

Many international studies have examined the relationship between coffee drinking and the risk of primary liver cancer. Patients with chronic hepatitis C...
Drugs in Development

AbbVie-Phase 3 Clinical Trial Results

<table>
<thead>
<tr>
<th>Study name/ Treatment Period</th>
<th>Ribavirin Y/N</th>
<th>TX Naïve/ Experienced</th>
<th>Number of Patients</th>
<th>Cure Rates Overall</th>
<th>Cure Rates Genotype 1a</th>
<th>Cure Rates Genotype 1b</th>
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<td>SAPPHIRE-1</td>
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<td>95%</td>
<td>98%</td>
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<tr>
<td>TURQUOISE-II</td>
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<td>89%</td>
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<tr>
<td></td>
<td>yes</td>
<td>both</td>
<td>172</td>
<td>96%</td>
<td>99%</td>
<td>100%</td>
</tr>
</tbody>
</table>

AbbVie table adapted from: Doi:10.1056/NEJMoa1402338

rates between the arms with and without ribavirin is not statistically different (at least in my opinion).

At any rate it is likely that the FDA will approve these ‘breakthrough therapies’ by the end of 2014 or the beginning of 2015.

AbbVie also announced that it had applied to the European Medicines Agency (EMA) for marketing approval of their 3D combination. It was also noted that the 3D combination had been granted Accelerated Assessment designation that will speed up the review process.

Note: Please see HCSP Fact Sheet Drugs in Development: Phase 3–AbbVie’s 3 Drug Combination Therapy for more information about the phase 3 studies.

GILEAD

ION-3

There were three medications used in the study:

- Sovaldi (sofosbuvir) – polymerase inhibitor, 400 mg
- Ledipasvir – NS5A inhibitor, 90 mg
- Ribavirin – dosed twice a day based on body weight

Patient Population

A total of 647 treatment naïve patients without cirrhosis were randomly assigned to 3 treatment arms:

- **Arm 1**: Sovaldi (sofosbuvir) and ledipasvir (215 pts) treated for 8 weeks,
- **Arm 2**: Sovaldi, ledipasvir, ribavirin (216 pts) treated for 8 weeks,
- **Arm 3**: Sovaldi and ledipasvir (216 pts) treated for 12 weeks

CONTINUED ON PAGE 7
Snapsots

Of the more than 52,000 participants in the National Household and Nutrition Examination Survey 2001-2010, 502 (1.3%) tested positive for past or current HCV infection. After participants were notified of test results, and encouraged to pursue further care, a follow-up interview was conducted. Approximately 50% of the participants had not known they were HCV+ prior to notification. Roughly 80% pursued medical follow-up.

The Bottom Line: The majority of patients who screen positive for HCV infection do pursue further HCV-related care. Lack of health insurance was the main reason when further medical care was not pursued.

Editorial Comment: The hope here is that health care coverage expansion will increase access to HCV medical care. Also noteworthy is that the median age of the HCV+ participants was 49, which means that quite a few were born after 1965, the limit of the age-based testing recommendation.


This study used data from the 2012 U.S. National Health and Wellness Survey. Of the 71,157 respondents, 0.9% reported chronic HCV, 1.3% reported congestive heart failure (CHF), 2.8% reported myocardial infarction (MI or heart attack), 5% reported chronic obstructive pulmonary disease (COPD), 10.9% reported diabetes, 14.9% reported depression, and 17.3% reported osteoarthritis (OA).

The Bottom Line: Compared to the other six medical conditions, HCV patients were second only to depression in the mental quality of life component of the survey. HCV patients were third on physical quality of life. A quarter of the HCV patients worked full-time, but reported loss of productivity at work and missed work.

Editorial Comment: Although hepatitis C is largely invisible and silent, it has the power to do significant damage.

The HCV Advocate monthly newsletter is going paperless! This will help to reduce our expenses and help the environment. Beginning in June we will not be accepting any new subscriptions, but any current paid subscriptions will be honored until the subscription expires.

We hope that you will take advantage of printing out the newsletter for family, friends and others.

Below are some suggestions for obtaining free copies:

- Ask family and/or friends to print out copies for you.
- Go to your local library and print it off from www.hcvadvocate.org.
- Ask your doctor or nurse to print it off for you.
- Provide copies for your support group or ask someone in the support group to print it off for you. It is also a good idea for members to alternate the printing among the members.
- Advocates—please consider printing off the newsletter to provide copies to people at high risk of hepatitis C—prisons, jails, homeless, people who inject drugs or any other populations that you advocate and provide services for.
Drugs in Development  FROM PAGE 5

### Genotype 1 – ledipasvir, sofosbuvir with and without ribavirin

<table>
<thead>
<tr>
<th>Study name/Treatment Period</th>
<th>Ribavirin Y/N</th>
<th>Number of Patients</th>
<th>Cure Rates Overall</th>
<th>Cure Rates Genotype 1a</th>
<th>Cure Rates Genotype 1b</th>
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</thead>
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<td>98%</td>
<td>100%</td>
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<tr>
<td>12 weeks yes</td>
<td>217</td>
<td>97%</td>
<td>97%</td>
<td>99%</td>
<td></td>
</tr>
<tr>
<td>24 weeks no</td>
<td>217</td>
<td>98%</td>
<td>98%</td>
<td>97%</td>
<td></td>
</tr>
<tr>
<td>24 weeks yes</td>
<td>217</td>
<td>99%</td>
<td>99%</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td><strong>ION-2: Treatment Experienced</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
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<td>109</td>
<td>94%</td>
<td>95%</td>
<td>87%</td>
<td></td>
</tr>
<tr>
<td>12 weeks yes</td>
<td>111</td>
<td>96%</td>
<td>95%</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>24 weeks no</td>
<td>109</td>
<td>99%</td>
<td>99%</td>
<td>100%</td>
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</tr>
<tr>
<td>24 weeks yes</td>
<td>111</td>
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<td><strong>ION-3: Treatment Naïve</strong></td>
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<td>8 weeks yes</td>
<td>216</td>
<td>93%</td>
<td>92%</td>
<td>95%</td>
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<tr>
<td>12 weeks no</td>
<td>216</td>
<td>95%</td>
<td>95%</td>
<td>98%</td>
<td></td>
</tr>
</tbody>
</table>

Gilead table adapted from: Doi:10.1056/NEJMoa1402338

**Note:** Sofosbuvir and ledipasvir are co-formulated into one pill, taken once a day. Ribavirin is dosed twice a day.

The patient population was similar across all treatment arms: male (54% - 60%), mean age (51-53 yo), White (76% - 81%), genotype 1a (80%), genotype 1b (20%), F0-F2 (50-59%), and F-3 (13%).

The overall cure rates were 93 to 95%. The table above lists the drug combination and treatment duration for all of the ION studies.

**Side Effects:**

Fatigue, headache and nausea were the most common side effects especially in the ribavirin containing group. There were 3 treatment discontinuations, but there were no treatment discontinuations in the 8-week sofosbuvir/ledipasvir (no ribavirin).

**Comments:**

The overall cure rates were similar among the three groups of treatment-naïve patients without cirrhosis. The researchers concluded that “no additional benefit was associated with the inclusion of ribavirin in the regimen or with the extension of the duration of treatment to 12 weeks.” But it is important to know that this study only included treatment-naïve patients and excluded people with cirrhosis—people who are treatment-experienced and who have cirrhosis may require longer treatment duration.

**Valence:**

The VALENCE study was recently published in the New England Journal of Medicine. It is the same study data that was submitted to the Food and Drug Administration (FDA) for marketing approval in 2013. The information from the FDA on this study is already listed on our HCSP Fact Sheet Genotypes 2 and 3: Sovaldi (Sofosbuvir) plus Ribavirin Therapy.

This article is a short recap of the results. There were a total of 419 patients—genotype 2 (73 pts); genotype 3 (261 pts). The genotype 2 patients were treated for 12 weeks; genotype 3 for 12 weeks (11 pts) and 24 weeks (250 pts). **Note:** there was a total of
85 patients (genotypes 2 & 3) who were in the placebo arms.

The cure rates by genotype and treatment duration are listed below:

- **Genotype 2** (12 weeks) – 93% cure rate
- **Genotype 3** (12 weeks) – 27% cure rate
- **Genotype 3** (24 weeks) – 85% cure rate

The most common side effects were headache, fatigue, and pruritus (itching).

**Comments:**

It is not a surprise that the treatment duration for genotype 3 was pushed to 24 weeks since 12 weeks of treatment cure rates were so low. The 24-week treatment duration was more than 3 times higher than 12 weeks and it’s an interferon-free therapy.

**Note:** Please see HCSP Fact Sheet *Drugs in Development: Genotype 1 – Sofosbuvir/ Ledipasvir* for more information about the phase 3 studies.

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**BMS**

Bristol-Myers Squibb has an extensive drug development portfolio with their HCV inhibitors daclatasvir, asunaprevir and BMS-791325 (BMS “triple therapy”) as well as combinations of their HCV drugs with drugs from other pharmaceutical companies such as sofosbuvir (Gilead), and simeprevir (Janssen). The combinations are being tested in HCV genotypes 1, 2, 3 and 4. These studies include monoinfected people and those coinfected with HIV.

BMS has submitted their data to the Food and Drug Administration for approval of the triple therapy for the treatment of genotype 1b. BMS is also conducting studies with other HCV drugs and will seek regulatory approval for a wide range of indications, both with their drugs, and with combinations of their drugs with HCV drugs from other companies.

At the recent Digestive Disease Conference there was data presented on the combination of daclatasvir, asunaprevir and BMS-791325 to treat HCV genotype 4. Genotype 4 worldwide is prevalent in Egypt, other parts of Africa, and the Middle East. In the United States genotype 4 is usually found in immigrant populations.

There was a total of 21 patients in the study. Twenty-one patients received the triple combination therapy with their HCV inhibitors daclatasvir, asunaprevir and BMS-791325 (BMS “triple therapy”) as well as combinations of their HCV drugs with drugs from other pharmaceutical companies such as sofosbuvir (Gilead), and simeprevir (Janssen). The combinations are being tested in HCV genotypes 1, 2, 3 and 4. These studies include monoinfected people and those coinfected with HIV.

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and advanced liver disease who drink three or more cups of coffee per day have a 53% lower risk of liver disease progression than non-coffee drinkers, according to a new study led by Neal Freedman, Ph.D., MPH, from the National Cancer Institute (NCI). Reduction of disease progression may help to prevent HCC.

No herbs or dietary supplements have been proven to prevent HCC. Varieties of supplements are being tested in clinical trials. The National Cancer Institute and the National Institute of Nursing Research are studying milk thistle for cancer prevention. A large 2007 Chinese study using a variety of dietary supplements for liver cancer prevention yielded disappointing results. Although liver cancer mortality remained unchanged, the incidence of cancer was lower for those under age 55 who took combinations of retinol and zinc or riboflavin and niacin.

Taking care of our health is the best weapon against all cancer. Exercise, maintaining a normal body weight and healthy eating habits are essential. Regular screening for those at risk for HCC and other forms of cancer is critical. Although HCC is a serious, potentially life-threatening form of cancer, we are not completely helpless against it. If you are at risk for HCC, talk to your healthcare provider. Although the liver is a silent organ, we never have to stay quiet about our health.

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. Her blog is www.LucindaPorterRN.com.

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