The Pharmacist Activist

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Editorial

A Christmas Letter

Editor's note: The following letter (author unknown), intended to be a communication from Jesus Christ regarding the celebration of his birth, includes a message that can be of value for each of us, regardless of our personal faith.

Dear children,

It has come to my attention that many of you are upset that folks are taking my name out of the season. Maybe you have forgotten that I wasn't actually born during this time of the year and that it was some of your predecessors who decided to celebrate my birthday on what was actually a time of pagan festival. Although, I do appreciate being remembered anytime.

How I personally feel about this celebration can probably be most easily understood by those of you who have been blessed with children of your own. I don't care what you call the day. If you want to celebrate my birth, just get along and love one another.

Now, having said that, let me go on:

If it bothers you that the town in which you live doesn't allow a scene depicting my birth, then just get rid of a couple of Santas and snowmen and put a small Nativity scene on your own front lawn. If all of my followers did that there wouldn't be any need for such a scene on the town square because there would be many of them all around town.

Stop worrying about the fact that people are calling the tree a holiday tree instead of a Christmas tree. It was I who made all trees. You can and may remember me any time you see any tree. Decorate a grapevine if you wish. I actually spoke of that one in a teaching explaining who I am in relation to you and what each of our tasks are. If you have forgotten that one, look it up in John 15: 1-8.

If you want to give me a present in remembrance of my birth, here is my wish list. Choose something from it.

1. Instead of writing protest letters objecting to the way my birthday is being celebrated, write letters of love and hope to soldiers away from home. They are terribly afraid and lonely this time of year. I know—they tell me all the time.

2. Visit someone in a nursing home. You don't have to know them personally. They just need to know that someone cares about them.

3. Instead of writing George complaining about the wording on the cards his staff sent out this year, why don't you write and tell him you'll be praying for him and his family this year.

4. Instead of giving your children a lot of gifts you can't afford and they don't need, spend time with them. Tell them the story of my birth, and why I came to live with you down here. Hold them in your arms and remind them that I love them.

5. Pick someone that has hurt you in the past and forgive him or her.

6. Did you know that someone in your town will attempt to take his own life this season because he feels so alone and helpless? Since you don't know who that person is, try giving everyone you meet

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News, Information and Career Opportunities
NEWS - Line PUBLISHING

(Christmas Cont.)

a warm smile—it could make the difference. Also, you might consider supporting the local Hot-Line; they talk with people like that every day.

7. Instead of nitpicking about what the retailers in your town call the holiday, be patient with the people who work there. Give them a warm smile and a kind word. Even if they aren't allowed to wish you a "Merry Christmas," that doesn't keep you from wishing them one. Then stop shopping there on Sunday. If the store didn't make so much money on that day, they would close and let their employees spend the day at home with their families.

8. If you really want to make a difference, support a missionary, especially one who takes my love and good news to those who have never heard my name. You may already know someone like that.

9. Here's a good one. There are individuals and whole families in your town who not only will have no "Christmas" tree, but will also not have any presents to give or receive. If you don't know them (and I suspect you don't) buy some food and a few gifts and give them to the Marines, the Salvation Army or some other charity which believes in me and they will make the delivery for you.

10. Finally, if you want to make a statement about your belief in and loyalty to me, then behave like a Christian. Don't do things in secret that you wouldn't do in my presence. Let people know by your actions that you are one of mine.

P.S. Don't forget; I am God and can take care of myself. Just love me and do what I have told you to do. I'll take care of all the rest. Check out the list above and get to work. Time is short. I'll help you, but the ball is now in your court. And do have a most blessed Christmas with all those whom you love and, remember, I love you.

A Gift of Life

Pharmacist Jim Wilson is President of Wilson Health Information, LLC of New Hope, Pennsylvania. I was one of the recipients of a communication he just sent to family members and friends and, with his permission, I have included most of his message below:

"I am pleased to let you know that on December 1st, I have received the greatest gift of life, a liver transplant. After four unsuccessful attempts, number five was a perfect fit and I was back home in about a week! I want to thank all of you, my friends, colleagues, and family for your prayers and support during this difficult journey… Also, I would encourage all of you to sign your transplant option on your motor vehicle registration as soon as possible and make your wishes known. The life you save may just be the one person you wished you would have been able to do more to help."

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Editor's Note: All issues of The Pharmacist Activist are available without charge at www.pharmacistactivist.com.

New Drug Review

Telbivudine (Tyzeka)

New Drug Comparison Rating (NDCR) = 3

(no or minor advantages/ disadvantages, or advantages and disadvantages of similar importance)

in a scale of 1 to 5, with 5 being the highest rating

Indications:

Treatment of chronic hepatitis B virus (HBV) infection in adult patients with evidence of viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease.

Comparative drugs:

Adefovir dipivoxil (Hepsera), entecavir (Baraclude), lamivudine (Epivir HBV).

Advantages:

- May be more effective in reducing viral load (compared with lamivudine and adefovir)
- Is not likely to reduce the effectiveness of antiviral agents used to treat HIV infection in patients who are co-infected with HBV and HIV (compared with lamivudine and adefovir)
- Is in Pregnancy Category B (comparative drugs are in Category C)

Disadvantages:

- May be more likely to cause musculoskeletal effects (e.g., myopathy)
- Not indicated in patients less than 16 years of age (compared with lamivudine that is indicated for use in children as young as 2 years of age)

Conclusions:

Telbivudine was compared with lamivudine in the pivotal study (GLOBE) that was the primary basis for its approval. The one-year results of this study demonstrated a therapeutic response in approximately 75% of the patients treated with each of the two drugs. The recently-presented second-year results of this study identified a higher therapeutic response rate in the patients treated with telbivudine. In other studies, telbivudine has been reported to decrease viral load to a greater extent than lamivudine and adefovir. Telbivudine has not been directly compared with entecavir, a recently-marketed (2005) antiviral agent that has been effective in some patients with chronic HBV infection that has become resistant to lamivudine. There have not been well-controlled studies of telbivudine in patients with chronic HBV infections that have become resistant to any of the other antiviral agents.

Telbivudine is well tolerated by most patients; however, it appears more likely than the other orally administered antiviral agents for HBV infection to cause musculoskeletal effects (e.g., myopathy) in conjunction with increases in creatine kinase (CK) values. It is classified in Pregnancy Category B whereas the comparative drugs are in Category C. Lamivudine is the only one of the four agents that has been studied in pediatric patients, and it is indicated for use in children as young as 2 years of age. Lactic acidosis and severe hepatomegaly with steatosis have been infrequently associated with the use of nucleoside analogues, and these possibilities are the subject of a "black box" warning in the labeling for telbivudine, as well as in the labeling for adefovir, entecavir, and lamivudine. Unlike adefovir and lamivudine, but like entecavir, telbivudine is not active against HIV and its concurrent use with HIV nucleoside reverse transcriptase inhibitors (NRTIs) is not likely to reduce the efficacy of any of the antiviral agents.

Like the comparative drugs, telbivudine is administered once a day. The interval between doses should be adjusted in patients with a creatinine clearance less than 50 mL/minute.

Telbivudine is a useful addition to the relatively small group of orally administered antiviral agents that are of value in the treatment of chronic HBV infection. It may be more effective than lamivudine and adefovir; however, it has not been demonstrated to be more effective than entecavir and appears more likely than the other agents to cause musculoskeletal adverse events.

Discussion

Approximately 1.25 million Americans have chronic hepatitis B virus (HBV) infection. Many patients experience a worsening of the infection, resulting in cirrhosis of the liver, liver cancer, and death.

Although vaccines have been developed to provide immunization against HBV, there has only been partial success in the treatment of chronic HBV infection. The infection cannot be cured, and there are only a limited number of treatment options available. Interferon alfa-2b (Intron A) was the first drug approved for the treatment of chronic HBV infection but its effectiveness is limited, it must be administered parenterally, and most patients experience adverse events. Peginterferon alfa-2a (Pegasys) is also indicated for the treatment of chronic HBV infection. Lamivudine (Epivir HBV) was initially approved for the treatment of HIV infection/AIDS and, subsequently, for chronic HBV infection. It is administered orally and is better tolerated than the interferons; however, many patients have developed resistance to its use. Additional orally administered agents, adefovir dipivoxil (Hepsera) and entecavir (Baraclude), were marketed in 2002 and 2005, respectively, and their anti-HBV activity includes some isolates that are resistant to lamivudine.

Telbivudine (Tyzeka-Idenix; Novartis) is a thymidine nucleoside analogue that is phosphorylated to its active triphosphate form that inhibits HBV DNA polymerase (reverse transcriptase) and HBV replication. It is indicated for the treatment of chronic HBV infection in adult patients with evidence of viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease.

The approval of telbivudine was based primarily on the one-year results of a pivotal study (GLOBE) in which it was compared with lamivudine. In HBeAg-positive patients, 75% of the telbivudine patients and 67% of the lamivudine patients had a therapeutic response, and, in the HBeAg-negative patients, 75% of the telbivudine patients and 77% of the lamivudine patients had a therapeutic response.

The second-year results of the GLOBE study have been recently presented and show that the primary endpoint continued to be met after two years of therapy in 64% of HBeAg-positive patients treated with telbivudine and in 48% of those treated with lamivudine. In the HBeAg-negative patients, a therapeutic response was attained in 78% and 66% of the patients treated with telbivudine and lamivudine, respectively. In other studies, telbivudine has been reported to decrease viral load to a greater extent than lamivudine and adefovir; however, there have been no well-controlled studies of telbivudine in patients with established lamivudine-resistant or adefovir-resistant HBV infection.

Most patients in the clinical studies tolerated telbivudine well. Lactic acidosis and severe hepatomegaly with steatosis have been infrequently associated with the use of nucleoside analogues, and these possibilities are the subject of a "black box" warning in the labeling for the new drug, as well as in the labeling for lamivudine, adefovir, and entecavir.

The most frequently experienced adverse events by patients treated with telbivudine include upper respiratory tract infection (14%), fatigue and malaise (12%), abdominal pain (12%), nasopharyngitis (11%), and headache (11%). Treatment discontinuation rates for adverse events, clinical disease progression, or lack of efficacy were 0.6% for telbivudine and 2% for lamivudine.

Some patients treated with telbivudine have experienced myopathy in conjunction with increases in creatine kinase (CK) values. Patients should be advised to promptly report any unexplained muscle aches, pain, tenderness, or weakness. Treatment should be interrupted if myopathy is suspected, and discontinued if myopathy is diagnosed. It is not known if the risk of myopathy is increased by the concurrent use of other agents that have been associated with the occurrence of myopathy such as the statins (e.g., atorvastatin [Lipitor]).

Telbivudine is classified in Pregnancy Category B. If it is to be used in a woman who is pregnant, the patient should be registered in the Antiretroviral Pregnancy Registry (1-800-258-4263). Although it is not known whether telbivudine is excreted in human milk, mothers should be instructed not to breastfeed if they are being treated with the drug. The effectiveness and safety of telbivudine in patients under 16 years of age have not been established.

Unlike lamivudine and adefovir, but like entecavir, telbivudine does not exhibit activity against HIV. The concurrent use of telbivudine with HIV nucleoside reverse transcriptase inhibitors (NRTIs) is not likely to reduce the efficacy of any of the antiviral agents.

The absorption of telbivudine is not affected by food and it may be administered without regard to meals. It is not metabolized and is eliminated as unchanged drug, primarily by urinary excretion.

The recommended dosage of telbivudine is 600 mg once a day. The dosage interval should be adjusted in patients with a creatinine clearance of less than 50 mL/minute. A dose of 600 mg should be administered once every 48 hours in patients with a creatinine clearance of 30-49 mL/minute, every 72 hours in patients with a creatinine clearance less than 30 mL/minute (not requiring dialysis), and every 96 hours in patients with end-stage renal disease.

There have been reports of severe acute exacerbations of HBV infection in some patients who have discontinued therapy with anti-hepatitis B medications, including telbivudine. Hepatic function should be closely monitored for at least several months in patients who discontinue telbivudine treatment.

Telbivudine film-coated tablets are supplied in a 600 mg-potency.

Daniel A. Hussar