Good News for World Hepatitis Day

July 29, 2013 By Margaret Dudley

Another World Hepatitis Day is upon us! And I wanted to share the some 'good news' with you all and to offer hope for all who suffer with Hepatitis C.

On May 22nd, I began treatment in a clinical trial being conducted by Gilead Sciences. I am genotype 3a and have never received treatment before now. My liver biopsy from 12/07/11 indicated Stage 2, Grade 3. The clinical trial I am participating in is a Phase 2 trial with sofosbuvir (formerly GS-7977) and GS-5816, which is Gilead's newest NS5A inhibitor and is pan-genotypic (which means it is effective in all genotypes). Hopefully, this is their 'answer' to Bristol-Myers' daclatasvir. This is a Phase 2 trial for 12 weeks; 140 participants including genotypes 1, 2, and 3; without toxic interferon OR toxic ribavirin.

My baseline viral load (VL) was 6,530,000; AST 47; ALT 58. My VL became 'UNDETECTABLE' sometime between week 4 and week 6 of treatment and was still 'Undetectable' after my 8th week of treatment. My AST is down to 20 and my ALT 13. They have not been in the normal range in years.
The side effects have been absolutely minimal. The first couple of weeks, I had a few fleeting headaches and some nausea, but that has all subsided now. I now have energy that I didn't expect to ever have again. My thinking seems to be clearer, the depression has lifted and my spirit is soaring. Before starting treatment, I was constantly and utterly fatigued, bloated, nauseated, and just generally miserable. My family and friends cannot believe the difference in the way I now look and feel in such a short time and neither can I.

If the virus stays 'undetected' until Nov. 14th, then I will be officially considered cured. Praying this will be the case, not only for me but the other 140 people who are in this trial as well, because this would mean new and real hope for the HCV community and their families if this combination turns out to be 100% effective like the combination of sofosbuvir and Bristol's daclatasvir.

Although, we all worked extremely hard (each and every one of you) for over a year to try and 'encourage' the collaboration between Gilead Sciences and Bristol-Myers with our petition (over 20,000 people signed), we now know that because of 'financial reasons' (to put it kindly) it was just not meant to be. But we should not think our hard work was completely to no avail, because I truly believe that our voices were heard not only by 'big pharma' but by God Himself... and God willing, we will soon have access to what we have prayed and lobbied for this last two years --- safe and effective treatment for all genotypes WITHOUT toxic interferon or ribavirin!

My prayer is that GS-5816 is truly Gilead's answer for Bristol's daclatasvir, and that soon all will have access to a cure that is safer, more effective, with minimal side effects and is effective in ALL genotypes, co-infected, hemophiliacs, cirrhotics, relapsers, null responders, etc.! If the results from this phase 2 trial are as amazing as the sofosbuvir/daclatasvir trials were, then Gilead plans to initiate a phase 3 trial immediately (from what was mentioned in their 2Q investor meeting). And since both of these drugs are

owned by Gilead, we won’t experience what we went through in the Gilead/Bristol situation.

Yesterday was World Hepatitis Day and I pray that by World Hepatitis Day 2014, the whole WORLD will have something to truly celebrate - life without Hep C!

(Note: It also appears Gilead may be applying for FDA approval of the fixed dose combination of sofosbuvir and ledipasvir in the 2nd quarter of 2014 which is great for genotype 1!)

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