Exploring One Patient's Journey Living With CML, A Chronic Blood Cancer

(NAPS)—After getting married and having his first child all in the same year, Lee Spiva was excited to start a new chapter in his life. But right when he felt like life had just begun, he was diagnosed with chronic myeloid leukemia (CML), a type of blood cancer in which the body produces an uncontrolled number of abnormal white blood cells.

According to statistics, about 28,900 people are living with CML in the U.S. It is estimated that 5,920 new cases will be diagnosed in 2013. CML occurs when pieces of two different chromosomes break off and attach to each other, creating a chromosome called the Philadelphia chromosome, which contains an abnormal gene called *BCR-ABL*. This gene produces the BCR-ABL protein that signals cells to make too many white blood cells. There is no known reason for the genetic change that causes CML.

CML is classified by one of three phases—chronic, accelerated, and blast. These are defined by the percentage of blast cells (or immature white blood cells) in the blood or bone marrow. Physicians will order tests regularly of a patient's blood or bone marrow to determine the current phase of disease as well as to determine if and how they are responding to therapy.

Fortunately for Lee and many others with CML, there are treatment options available. For people diagnosed with CML and their medical teams, understanding the treatment options and their safety and effectiveness over time may help in determining the treatment plan that is right for them.

Lee describes learning about his diagnosis "as the day his world stopped," but he came to accept his condition and stay positive. "To find out there was a pill like Sprycel®, also known as dasatinib, that I could take once a day to help treat my CML—that was of great comfort to me," said Lee. "My medical team was also of great support as they helped motivate and teach me more about the importance of tracking treatment goals."

Sprycel is a prescription medicine used to treat adults who have newly diagnosed Philadelphia chromosome–positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. The effectiveness of Sprycel in these patients is based on a study that measured two types of response to treatment (cytogenetic and molecular) by 1 year. The study is ongoing to find out how Sprycel works over a longer period of time. Sprycel is also indicated for adults with Ph+ CML who are no longer benefitting from, or did not tolerate, other treatment including Gleevec® (imatinib mesylate).

Recently, the U.S. product labeling for Sprycel was updated by the U.S. Food and Drug Administration to include longer-term efficacy and safety information in both patients with newly diagnosed Philadelphia chromosome-positive (Ph+) CML in chronic phase (CP) as well as patients who are resistant or intolerant to Gleevec® (imatinib mesylate). The data added to the Sprycel U.S. labeling are among the longest follow-up data of current CML treatment options.

For people diagnosed with chronic myeloid leukemia, learning more about the disease and treatment options can help them navigate their journey.

Information added to the Sprycel® (dasatinib) label in the first-line CP Ph+ CML setting is based on three-year data from DASISION (Dasatinib versus Imatinib Study in Treatment-Naïve CML Patients), an open-label, randomized, Phase 3 international trial. The safety and efficacy evaluation in this trial is ongoing. Information was also added to the Sprycel labeling for CP Ph+ CML patients with resistance or intolerance to prior imatinib therapy is based on five-year data from Study CA180-034, a Phase 3 open-label, dose-optimization trial.

Sprycel may cause serious side effects, including low blood cell counts, bleeding, fluid retention, heart problems, and pulmonary arterial hypertension. Other common side effects of Sprycel include diarrhea, headache, cough, skin rash, fever, nausea, tiredness, vomiting, muscle pain, weakness, and infections. This is not a complete list of all side effects recorded in clinical studies with Sprycel. Tell your healthcare provider if you have any side effects while taking Sprycel.

Please see additional Important Safety Information for Sprycel below.

Talk to your healthcare provider about any questions you may have about your health or Sprycel. To learn more about Sprycel as well as Lee's story, visit "Sprycel Journeys," at www.Sprycel.com.

SPRYCEL® (dasatinib)
IMPORTANT SAFETY INFORMATION FOR PATIENTS

Important Safety Information about SPRYCEL

It is not known if SPRYCEL is safe and effective in children younger than 18 years old.

Before you take SPRYCEL, tell your healthcare provider if you:

- have problems with your immune system
- have liver problems
- have heart problems
- are lactose intolerant
- have any other medical conditions
- are pregnant or planning to become pregnant. SPRYCEL may harm your unborn baby. Women should not become pregnant while taking SPRYCEL. Talk to your healthcare provider right away if you are pregnant or plan to become pregnant
- are breast-feeding or plan to breast-feed. It is not known if SPRYCEL passes into your breast milk or if it can harm your baby. You and your healthcare provider should decide if you will take SPRYCEL® (dasatinib) or breast-feed. You should not do both

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, antacids, and herbal supplements.

Especially tell your healthcare provider if you take:

- **medicines that increase the amount of SPRYCEL in your bloodstream, such as:** Nizoral® (ketoconazole), Sporanox® (itraconazole), Norvir® (ritonavir), Reyataz® (atazanavir sulfate), Crixivan® (indinavir), Viracept® (nelfinavir), Nefazodone (serzone®, nefadar), Invirase® (saquinavir), Ketek® (telithromycin), E-mycin® (erythromycin), and Biaxin® (clarithromycin).
- **medicines that decrease the amount of SPRYCEL in your bloodstream, such as:** Decadron® (dexamethasone), Dilantin® (phenytoin), Tegretol® (carbamazepine), Rimactane® (rifampin), and Luminal® (phenobarbital).
- **medicines whose blood levels might change by taking SPRYCEL, such as:** Sandimmune® (cyclosporine), Alfenta® (alfentanil), Fentanyl® (fentanyl), Orap® (pimozide), Rapamune® (sirolimus), Prograf® (tacrolimus), and Ergomar® (ergotamine).

SPRYCEL is best absorbed from your stomach into your bloodstream in the presence of stomach acid. You should avoid taking medicines that reduce stomach acid, such as: Tagamet® (cimetidine), Pepcid® (famotidine), Zantac® (ranitidine), Prilosec® (omeprazole), Protonix® (pantoprazole sodium), Nexium® (esomeprazole), AciphHex® (rabeprazole), and Prevacid® (lansoprazole).

Medicines that neutralize stomach acid, such as Maalox® (aluminum hydroxide/magnesium hydroxide), Tums® (calcium carbonate), or Rolaids® (calcium carbonate and magnesia), may be taken up to 2 hours before or 2 hours after SPRYCEL.

Since SPRYCEL therapy may cause bleeding, tell your healthcare provider if you are using blood thinner medicine, such as Coumadin® (warfarin sodium) or aspirin.

Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

Take SPRYCEL exactly as prescribed by your healthcare provider

- Take SPRYCEL with or without food. Try to take SPRYCEL at the same time each day
- Swallow SPRYCEL tablets whole with water. Do not break, cut, or crush the tablets
- You should not drink grapefruit juice while taking SPRYCEL
- If you miss a dose of SPRYCEL, take your next scheduled dose at its regular time. Do not take two doses at the same time

SPRYCEL may cause serious side effects, including:

- **Low Blood Cell Counts:** SPRYCEL may cause low red blood cell counts (anemia), low white blood cell counts (neutropenia), and low platelet counts (thrombocytopenia). Your healthcare provider will do blood tests to check your blood cell counts regularly during your treatment with SPRYCEL® (dasatinib). Call your healthcare provider right away if you have a fever or any signs of an infection while taking SPRYCEL
- **Bleeding:** SPRYCEL may cause severe bleeding that can lead to death. Call your healthcare provider right away if you have:
  - o unusual bleeding or bruising of your skin
  - o bright red or dark, tar-like stools
  - o a decrease in your level of consciousness, headache, or change in speech
- **Your body may hold too much fluid (fluid retention):** In severe cases, fluid may build up in the lining of your lungs, the sac around your heart, or your stomach cavity. Call your healthcare provider right away if you get any of these symptoms during treatment with SPRYCEL:
  - o swelling all over your body
  - o weight gain
  - o shortness of breath and cough
- **Heart problems:** SPRYCEL may cause an abnormal heart rate, heart problems, or a heart attack that can lead to death. Your healthcare provider will monitor the potassium and magnesium levels in your blood and your heart function
- **Pulmonary Arterial Hypertension (PAH):** SPRYCEL may cause high blood pressure in the vessels of your lungs. PAH may happen at any time during your treatment with SPRYCEL. Your healthcare provider should check your heart and lungs before and during your treatment with SPRYCEL. Call your healthcare provider right away if you have shortness of breath, tiredness, or swelling all over your body (fluid retention)

Other common side effects of SPRYCEL therapy include: diarrhea, headache, cough, skin rash, fever, nausea, tiredness, vomiting, muscle pain, weakness, and infections.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all of the possible side effects of SPRYCEL. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please read the Patient Information in the full Prescribing Information http://packageinserts.bms.com/pi/pi_sprycel.pdf.

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