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INFORMED CONSENT FOR TREATMENT WITH XELJANZ, OLUMIANT and RINVOQ

Xeljanz Olumiant and Rinvoq have been approved by the Food and Drug Administration (FDA) for the treatment of moderately to severely active Rheumatoid Arthritis (RA) in those who have had an inadequate response to Methotrexate. This class of drugs blocks the JAK (Janus Kinase) pathway. This blockade may result in decreased joint pain and swelling (inflammation).

WARNINGS:

Xeljanz/Olumiant and Rinvoq may decrease immune system function (immunosuppression), which can result in serious infections including invasive fungal infections or worsening of an existing infection. Deaths from serious infections have been reported in patients receiving Xeljanz/Olumiant or Rinvoq.

Before starting treatment, tell your doctor if you:

- have HIV
- have tuberculosis (TB), or have been in close contact with someone with TB
- were born in, lived in, or traveled to countries where there is more risk for getting TB. Ask your doctor if you are not sure.
- live or have lived in certain parts of the country (such as the Ohio and Mississippi River valleys) where there is an increased risk for getting certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, blastomycosis). These infections may develop or become more severe if you take Xeljanz/Olumiant or Rinvoq. If you do not know if you have lived in an area where histoplasmosis, coccidioidomycosis, or blastomycosis is common, ask your doctor.
- have or have had hepatitis B

Before starting treatment, your doctor will arrange for you to have a tuberculosis skin or blood test done to check for tuberculosis that may not be causing any symptoms (latent tuberculosis). If you have been diagnosed with tuberculosis, anti-tuberculosis medicines must be started before you start Xeljanz/Olumiant or Rinvoq therapy. This will reduce the likelihood of a serious tuberculosis infection. You also will be tested for Hepatitis B.

Tell your doctor if you have been diagnosed as having an infection, are on antibiotics or if you are prone to recurrent infections. Tell your doctor immediately if you have any complaints that might indicate an infection. These include but are not limited to pink eye, ear pain or drainage, sinus pain or drainage, sore throat, hoarse voice, cough, difficulty breathing, fevers, chills, sweats, vomiting, abdominal pain, diarrhea, burning with urination, increased frequency of urination, vaginal discharge, and cuts or wounds that are red, swollen or draining pus. **You should not receive Xeljanz/Olumiant or Rinvoq while you have an infection or while you are on antibiotics.** Treatment can be restarted once you have completed your antibiotic course and your infection has resolved.

Tell your doctor if you have a planned surgery, as you will need to stop Xeljanz/Olumiant or Rinvoq temporarily around the time of your surgery.

PRECAUTIONS:

Serious side effects have happened in patients taking Xeljanz including:

-Certain Types of Cancer. There have been cases of certain types of cancer in people taking Xeljanz. People with RA, especially more serious RA, may have a higher chance for getting a kind of cancer called lymphoma. Other cancers have been observed.

-Gastrointestinal perforations have been reported in clinical trials usually in patients with diverticulitis. Tell your doctor if you have been diagnosed with diverticulitis.

-Hepatic: Xeljanz should not be used with severe liver impairment

-Hematologic: Blood clots in the lungs (pulmonary embolism, PE), veins of the legs (deep vein thrombosis, DVT) and arteries (arterial thrombosis) have happened more often in patients with rheumatoid arthritis who are 50 years of age and older and with at least 1 heart disease (cardiovascular) risk factor taking a higher than recommended dose

Laboratory Testing: Treatment with Xeljanz/Olumiant or Rinvoq may result in decrease white blood cell levels, hemoglobin levels. These will be followed regularly. Let your doctor know if you notice bruising or paleness. Some patients have had increases in cholesterol level (LDL), these will be followed periodically. Liver enzymes have sometimes been elevated with treatment and will be followed.

Vaccinations: You should not receive live vaccines (for eg. polio, smallpox) while on a JAK inhibitor, without speaking with your doctor. The injected flu vaccine and pneumonia vaccine can be safely administered while on Xeljanz/Olumiant or Rinvoq. The nasal spray version of the flu vaccine is a live vaccine and should not be administered while on this class of drugs. Let your doctor know if someone in your household has received or will receive a live virus vaccine. Please discuss the shingles vaccine with your doctor.

Pregnancy and Breastfeeding: Tell your doctor if you are pregnant, planning to become pregnant, or breastfeeding. Xeljanz/Olumiant and Rinvoq have not been studied in pregnant or nursing women.

Medication Interactions: Tell your doctor about all the medicines you take including prescription and nonprescription medicines, vitamins, and herbal supplements. Your doctor will tell you if it is okay to take your other medicines while taking a JAK inhibitor

• Let your doctor know if you are on fluconazole or ketoconazole.

You should not take Xeljanz/Olumiant or Rinvoq while you are taking any other biologic medication – these include Enbrel, Humira, Remicade, Kineret, Orencia and Rituxan.

ADVERSE REACTIONS:

The most common side effects are respiratory infections, sinusitis, headache, diarrhea, and high blood pressure.

MEDICATION ADMINISTRATION:

Xeljanz is administered either as a pill once or twice per day (may be reduced with kidney or liver impairment).

Olumiant is administered as a pill once a day.

Rinvoq is administered as a pill once a day.

You will see your physician in follow-up to monitor your progress and response to the Xeljanz. Also, please call us if you experience any side effects, and we will be available to you 24 hours a day if you experience any problems.

EMERGENCY CONTACTS:

In case of emergency, you can contact our office at (503) 297-3384 from 8:00 am to 5:00 pm Monday – Friday, or after hours dial the above number to page your physician or call 911 or go to the emergency room.

I certify that I have read and understand this consent form and agree to receive oral Xeljanz/ Olumiant /Rinvoq (circle one). I have had an opportunity to discuss this treatment with my physician and ask questions regarding the treatment. I will be given a signed copy of this form for my records.

Patient signature

Date