Transcript Details

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MSperceptions: Candid HCP/Patient Clinical Conversations about MS

Announcer
Welcome to ReachMD. This medical industry feature titled “MS perceptions, Candid HCP and Patient Clinical Conversations About MS” is sponsored by Biogen. This program is intended for US healthcare professionals. Continue listening for Important Safety Information, including **Boxed Warning**, and see full Prescribing Information at TYSABRI.com.

Dr. Jacqueline Nicholas
Hi, I'm Dr. Jacqueline Nicholas, and I'm the System Chief of MS and Neuroimmunology for the OhioHealth Multiple Sclerosis Center. Today, I'm excited to be talking with Kim, a TYSABRI patient ambassador, about some of the discussions a patient and their care team have when deciding to start a high efficacy, disease modifying therapy for relapsing multiple sclerosis and adults like TYSABRI.

Kim
Hi, my name's Kim. It's so nice to speak with you today. I just wanted to give you a quick background on me. I'm a mom of three kids. I've been a nurse for 25 years, I recently became a nurse practitioner. But today I'm here truly just to talk about being a relapsing MS patient. And I was diagnosed with MS in March of 2015, so I've been living with MS for nearly seven years, and I've been on TYSABRI since April of 2015.

Dr. Jacqueline Nicholas
Thanks for sharing. Kim, as you know, newly diagnosed patients often have many questions about starting treatment and TYSABRI may be the first treatment for many of these newly diagnosed individuals. Interestingly, in one in three patients who start TYSABRI, they have actually never been on a prior disease-modifying therapy. I'd really like to hear more about your experience after your diagnosis and what your individual treatment goals were, and how you ultimately decided to start treatment with TYSABRI.

Kim
Well, after I was diagnosed with MS, I thought to myself, what are my goals with treatment? And I truly had three goals that were important to me, and that was fewer relapses, reducing development of any new lesions, and delaying the progression of any physical disability. Those were my treatment goals and that supported my ultimate goal, which was truly to maintain my current level of physical ability. I knew that delaying disability early was key, and I wanted a treatment that would do just that.

So before meeting with my provider to discuss all these treatment options that we have, they checked my lab work, which included John Cunningham's virus, also known as JCV test. And that's used to assess risk for developing PML while on therapy. My lab work revealed that I was JCV negative. So that was information that could factor into my decision. During the treatment process, my neurologist and I laid out all the benefits of treatment, such as success with delaying disability and risks of different treatment options. Ultimately, my neurologist and I decided to start treatment with TYSABRI because I truly wanted a proven effective aggressive treatment plan from day one. Based on my goals, the watch and wait approach just wasn't an option for me.

Dr. Jacqueline Nicholas
That makes a lot of sense. In my practice, speaking with patients about treatment options for MS is very individualized. During our treatment decision process, we discuss a lot of factors, and these include the individual's disease severity, their individual preferences, goals, lifestyle. As you can imagine, the mode of administration of the treatment is really important. I want to make sure that's going to fit well into my patient's lifestyle, their individual risk tolerance, the amount of monitoring that may be required for that individual disease modifying therapy in terms of labs and MRIs, as well as ideas behind family planning, pregnancy, and age. For patients with highly active disease, I often use highly effective disease-modifying therapies as first line treatment.

And some of the characteristics I consider when making this choice are risk tolerability and monitoring needs. My patients who choose to start treatment with TYSABRI often do so for many reasons; these typically include its high efficacy, its tolerability, infrequent administration, the ease of monitoring, and the absence of immune cell depletion. My patients have found these considerations in addition to high efficacy, especially important when thinking about TYSABRI. So I'm curious, Kim, when you decided to start TYSABRI, did you have any question or concerns?

Kim
Once I decided to start treatment with TYSABRI, I did have some lingering questions. Like how was it going to make me feel? Would I get sick or have a reaction? How was it going to affect my lab work or my liver? My neurologist answered the concerns I had by discussing that risk profile of TYSABRI.

Dr. Jacqueline Nicholas
Your concerns are very similar to what I've heard from my patients. Sometimes my patients tell me they're worried that when they start a disease modifying therapy, that they might feel different or even feel worse. And sometimes people express concerns about safety. We discuss PML and other risks with TYSABRI. When discussing PML, I describe how JC virus serum antibody testing can be used to safely monitor individual PML risk. It doesn't matter if patients are JC virus positive or negative. Patients can begin TYSABRI with a low risk of PML, which is less than 1%. Adding in more frequent MRI monitoring can be beneficial in safety monitoring. We talk a lot about these factors and I inform my patients that those on TYSABRI often have a very positive experience in the infusion center. When it comes to concerns about safety, I think it's really important to have a conversation about the benefits as well as the risks.

With TYSABRI, I do describe it as a highly effective therapy in terms of reducing relapses, delaying disability progression, and reducing the risk of new lesions on MRI. When we look at the data from the two-year AFFIRM pivotal trial, 83% of patients taking TYSABRI had no sustained disability progression for 12 weeks compared to only 71% with placebo. The same study also showed that there was a 67% relative reduction in the annualized relapse rate with TYSABRI versus placebo. And 97% of TYSABRI treated patients showed full suppression of Gad-enhancing activity, meaning suppression of contrast enhancing lesions versus only 72% with placebo.

Quality of life is another very important point to discuss with my patients when we're talking about selecting an MS disease modifying therapy. I share my clinical experience with patients going on TYSABRI and the effect it may have on their quality of life. We also talk about the mechanism of action. TYSABRI binds to white blood cells, and this prevents the white blood cells from entering into the central nervous system, but it does not actually deplete or destroy these white blood cells. We talk about how this is beneficial as we need our white blood cells to help fight infection. Kim, after you decided to start TYSABRI, what were the next steps to getting started?

Kim
So next steps in logistics of starting TYSABRI were made easier with the help of my provider, for sure, Biogen's financial and support services, and my infusion site, honestly. When I was dealing with insurance authorization delays, my provider knew exactly what to do, enrolled me in Biogen's free drug program for my first dose, and that way there was no delay in starting treatment with TYSABRI. Not only did Biogen's free drug program assist me financially, but their support services worked with me in my infusion center to ensure TYSABRI would be available for my very first dose. And I know some TYSABRI patients receive treatment in dedicated infusion centers.

I received my monthly infusion right at my doctor's office, like in an exam room. So the care team at my doctor's office was very familiar with TYSABRI and they were able to assist me in completing all the paperwork to get started. Now my infusion site has really become a home away from home, and the nurse who does my one-hour infusion is now a friend. I actually look forward to seeing her every four weeks and we usually get to catch up on our life events. And then while I'm there, I just check emails, pay bills, make some phone calls, anything else that I'm actually behind on I get done while I'm there getting my infusion. So it's actually quite helpful.

Dr. Jacqueline Nicholas
It's great to hear that you've had such a great experience with your infusions and that it's fitting into your busy work schedule and home life. The process of getting started for you sounds like it was very easy and that's very similar to what I hear with my patients. This really is one of the benefits. It's important because it reduces the time to start treatment, which may lower the risk of relapse over time. We rarely in my experience ever have an issue with patients being turned down for TYSABRI. It's also wonderful to hear that you've developed such a close relationship with your care team. Many of my patients describe the same feelings in regards to their care team.

Interestingly, there was a recent update to the TYSABRI administration instructions that have actually made it easier. Once you've received your 12th infusion, if you have not experienced any reactions, your provider may decide to shorten or even skip the observation period altogether. So Kim, how has TYSABRI impacted use in starting treatment?

Kim

Although I would absolutely love a life without infusions and MRIs and neurologists and just MS altogether, TYSABRI's a manageable treatment for me and my lifestyle. I'm still able to work full time. I care for my three children, I stay active, continue to do all the things that I love.

Dr. Jacqueline Nicholas
That's great. Thank you so much for sharing your experience. As a physician, minimizing patients' risk of relapse is important to me, too. The feedback I typically receive from patients who start TYSABRI is that they really like the high degree of disease control and how easily the treatment regimen fits into their lifestyle. Another aspect of TYSABRI that my patients appreciate is the ease of monitoring compared to some of the other treatment options. JC virus monitoring is typically performed every six months at the time of their infusion appointment. And I explained that this monitoring is really important to help keep them safe, and it's actually free through Biogen Support Program, even free for providers who may decide to test more frequently. What has it been like for you in terms of your monitoring experience while on TYSABRI?

Kim
I'm very diligent with my lab work, my MRIs, my follow-up appointments, and being enrolled in the TOUCH Prescribing Program helps with monitoring my JC virus status, which is checked every six months. Since I'm not able to get my JCV test at the same time as my infusion, I have my JCV testing and other blood work done locally, which is just convenient for me. But should the day come that I'm no longer JCV negative, that doesn't necessarily mean I would choose to be done with TYSABRI, it just means having a different conversation with my neurologist or the risk versus benefit, and maybe some closer monitoring.

Dr. Jacqueline Nicholas
Kim, thank you so much for sharing your insights and your experience in starting TYSABRI. Monitoring through the TOUCH Prescribing Program is incredibly helpful to both me and my patients as well. One of the first steps I take after a patient chooses to start TYSABRI is to sign them up with TOUCH. It actually streamlines the process of safety monitoring and helps me to continue to estimate my patient's potential risk while on TYSABRI. As you know, in addition to TOUCH, Biogen also provides support services. Have you had an impact on your treatment journey with some of the Biogen Support Services available?

Kim
Biogen Support Services is always there along the way on my treatment journey. Personally, I have had multiple insurance changes over the years; Biogen Support Services, such as their financial support, have always been there to help me with my insurance transitions and preventing any disruption in treatment. And whenever I have a question, Biogen Support Services assists me in getting in touch with the right person to help.

Dr. Jacqueline Nicholas
That's great. Do you have any final last words of advice to offer patients who are considering starting TYSABRI?

Kim
My final word of advice for anyone who's thinking about starting TYSABRI is to discuss all your treatment options and choose what works best for you.

Dr. Jacqueline Nicholas
Thanks, Kim. That is excellent advice. And for my fellow healthcare providers listening, I would advise them to share with their patients the same information I provided today about TYSABRI's high efficacy, its impact on quality of life, immune mechanism, its lack of cell depletion, and ease of administration.

Announcer
TYSABRI HCP Indication and Important Safety Information.

Indication: TYSABRI, natalizumab, is indicated as monotherapy for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease, in adults. TYSABRI increases the risk of PML. When initiating and continuing treatment with TYSABRI, physicians should consider whether the expected benefit of TYSABRI is sufficient to offset this risk.

Important safety information. Warning: Progressive Multifocal L eukoencephalopathy, PML. TYSABRI, natalizumab, increases the risk of PML, an opportunistic viral infection of the brain that usually leads to death or severe disability. Risk factors for the development of PML include the presence of anti-JCV antibodies, duration of therapy, and prior use of immunosuppressants. These factors should be considered in the context of expected benefit when initiating and continuing treatment with TYSABRI. Healthcare professionals should monitor patients on TYSABRI for any new sign or symptom that may be suggestive of PML.

TYSABRI dosing should be withheld immediately at the first sign or symptom suggestive of PML. For diagnosis, an evaluation including a gadolinium-enhanced MRI scan of the brain and, when indicated, cerebrospinal fluid analysis for JC viral DNA are recommended.

Because of the risk of PML, TYSABRI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy, REMS, called the TOUCH Prescribing Program.

Infection by the JC Virus (JCV) is required for the development of PML

There are no known interventions that can reliably prevent PML or that can adequately treat PML if it occurs

Postmarketing data suggest that the risk of developing PML may be associated with relative levels of serum anti-JCV antibody compared to a calibrator as measured by ELISA (often described as an anti-JCV antibody index value)

MRI findings may be apparent before clinical signs or symptoms suggestive of PML. Monitoring with MRI for signs that may be consistent with PML may be useful, and any suspicious findings should lead to further investigation to allow for an early diagnosis of PML, if present. Consider monitoring patients at high risk for PML more frequently. Lower PML-related mortality and morbidity have been reported following TYSABRI discontinuation in patients with PML who were initially asymptomatic compared to patients with PML who had characteristic clinical signs and symptoms at diagnosis

PML has been reported after discontinuation of TYSABRI in patients who did not have findings suggestive of PML at the time of discontinuation. Patients should continue to be monitored for any new signs or symptoms that may be suggestive of PML for at least 6 months after discontinuation of TYSABRI

Adverse events that may occur during plasma exchange (PLEX) include clearance of other medications and volume shifts, which have the potential to lead to hypotension or pulmonary edema. Although PLEX has not been prospectively studied in TYSABRI-treated patients with PML, it has been used in such patients in the postmarketing setting to remove TYSABRI more quickly from the circulation. There is no evidence that PLEX has any benefit in the treatment of opportunistic infections such as PML

JCV infection of granule cell neurons in the cerebellum, i.e., JCV granule cell neuronopathy (GCN), with symptoms similar to PML, has been reported in patients treated with TYSABRI. JCV GCN can occur with or without concomitant PML and can cause cerebellar dysfunction. Diagnosis and management of JCV GCN should follow guidance provided for PML

Immune reconstitution inflammatory syndrome (IRIS) has been reported in the majority of TYSABRI-treated patients who developed PML and subsequently discontinued TYSABRI. In almost all cases, IRIS occurred after PLEX was used to eliminate circulating TYSABRI. It presents as a clinical decline in the patient's condition after TYSABRI removal (and, in some cases, after apparent clinical improvement) that may be rapid, can lead to serious neurological complications or death, and is often associated with characteristic changes in the MRI. TYSABRI has not been associated with IRIS in patients discontinuing treatment with TYSABRI for reasons unrelated to PML. In TYSABRI-treated patients with PML, IRIS has been reported within days to several weeks after PLEX. Monitoring for development of IRIS and appropriate treatment of the associated inflammation should be undertaken

Contraindications

TYSABRI is contraindicated in patients who have or have had PML

TYSABRI is contraindicated in patients who have had a hypersensitivity reaction to TYSABRI

TYSABRI TOUCH Prescribing Program

Because of the risk of PML, TYSABRI is available only through a restricted distribution program under a REMS called the TOUCH® Prescribing Program

Patients must be enrolled in the TOUCH Prescribing Program, read the Medication Guide, understand the risks associated with TYSABRI, and complete and sign the Patient-Prescriber Enrollment Form

Herpes Infections – Encephalitis, Meningitis and Acute Retinal Necrosis

TYSABRI increases the risk of developing encephalitis and meningitis caused by herpes simplex and varicella zoster viruses

Serious, life-threatening, and sometimes fatal cases have been reported in the postmarketing setting in multiple sclerosis patients receiving TYSABRI

The duration of treatment with TYSABRI prior to onset ranged from a few months to several years

Monitor patients receiving TYSABRI for signs and symptoms of meningitis and encephalitis. If herpes encephalitis or meningitis occurs,

TYSABRI should be discontinued, and appropriate treatment for herpes encephalitis/meningitis should be administered

Patients being administered TYSABRI are at a higher risk of acute retinal necrosis (ARN), a fulminant viral infection of the retina caused by the family of herpes viruses. Patients with eye symptoms such as decreased visual acuity, redness or eye pain should be referred for retinal screening as serious cases of ARN can lead to blindness of one or both eyes

Following clinical diagnosis of ARN, consider discontinuation of TYSABRI

Hepatotoxicity

Clinically significant liver injury, including acute liver failure requiring transplant, has been reported in patients treated with TYSABRI in the postmarketing setting

Signs of liver injury, including markedly elevated serum hepatic enzymes and elevated total bilirubin, occurred as early as six days after the first dose; signs of liver injury have also been reported for the first time after multiple doses

TYSABRI should be discontinued in patients with jaundice or other evidence of significant liver injury (e.g., laboratory evidence)

Hypersensitivity/Antibody Formation

Hypersensitivity reactions have occurred in patients receiving TYSABRI, including serious systemic reactions (e.g., anaphylaxis) which occurred at an incidence of <1%

Reactions usually occur within 2 hours of the start of the infusion. Symptoms associated with these reactions can include urticaria, dizziness, fever, rash, rigors, pruritus, nausea, flushing, hypotension, dyspnea, and chest pain

If a hypersensitivity reaction occurs, discontinue administration of TYSABRI and initiate appropriate therapy. Patients who experience a hypersensitivity reaction should not be re-treated with TYSABRI

Hypersensitivity reactions were more frequent in patients with antibodies to TYSABRI compared with patients who did not develop antibodies to TYSABRI in both MS and CD studies

Patients who receive TYSABRI for a short exposure (1 to 2 infusions) followed by an extended period without treatment are at higher risk of developing anti-natalizumab antibodies and/or hypersensitivity reactions on re-exposure, compared to patients who received regularly scheduled treatment

Immunosuppression/Infections

The immune system effects of TYSABRI may increase the risk for infections

In Study MS1, certain types of infections—including pneumonias and urinary tract infections (including serious cases), gastroenteritis, vaginal infections, tooth infections, tonsillitis, and herpes infections—occurred more often in TYSABRI-treated patients than in placebo-treated patients. One opportunistic infection, a cryptosporidial gastroenteritis with a prolonged course, was observed in a patient who received TYSABRI in Study MS1

In Studies MS1 and MS2, an increase in infections was seen in patients concurrently receiving short courses of corticosteroids. However, the increase in infections in TYSABRI-treated patients who received steroids was similar to the increase in placebo-treated patients who received steroids

In a long-term safety study of patients, opportunistic infections (pulmonary mycobacterium avium intracellulare, aspergilloma, cryptococcal fungemia and meningitis, and Candida pneumonia) have been observed in <1% of TYSABRI-treated patients

Concurrent use of antineoplastic, immunosuppressant, or immunomodulating agents may further increase the risk of infections over the risk observed with use of TYSABRI alone

In Studies MS1 and MS2, the rate of any type of infection was approximately 1.5 per patient-year in both TYSABRI-treated patients and placebo-treated patients

In Study MS1, the incidence of serious infections was approximately 3% in TYSABRI-treated patients and in placebo-treated patients. Most patients did not interrupt treatment with TYSABRI during infections

Laboratory Test Abnormalities

In clinical trials, TYSABRI was observed to induce increases in circulating lymphocytes, monocytes, eosinophils, basophils, and nucleated red blood cells. Observed changes persisted during TYSABRI exposure, but were reversible, returning to baseline levels

usually within 16 weeks after the last dose. Elevations of neutrophils were not observed. TYSABRI induces mild decreases in hemoglobin levels (mean decrease of 0.6 g/dL) that are frequently transient

Thrombocytopenia

Cases of thrombocytopenia, including immune thrombocytopenic purpura (ITP), have been reported with the use of TYSABRI in the postmarketing setting. Symptoms of thrombocytopenia may include easy bruising, abnormal bleeding, and petechiae. Delay in the diagnosis and treatment of thrombocytopenia may lead to serious and life-threatening sequelae. If thrombocytopenia is suspected, TYSABRI should be discontinued

Cases of neonatal thrombocytopenia, at times associated with anemia, have been reported in newborns with in utero exposure to TYSABRI. A CBC should be obtained in neonates with in utero exposure to TYSABRI

Adverse Reactions

The most common adverse reactions reported at an incidence of ≥10% with TYSABRI and ≥2% difference with placebo were headache (38% vs 33%), fatigue (27% vs 21%), infusion reactions (24% vs 18%), urinary tract infections (21% vs 17%), arthralgia (19% vs 14%), depression (19% vs 16%), pain in extremity (16% vs 14%), rash (12% vs 9%), gastroenteritis (11% vs 9%), and vaginitis (10% vs 6%)

The most frequently reported serious adverse reactions in Study MS1 were infections (3.2% vs 2.6% placebo), including urinary tract infection (0.8% vs 0.3%) and pneumonia (0.6% vs 0%), acute hypersensitivity reactions (1.1% vs 0.3%, including anaphylaxis/anaphylactoid reaction [0.8% vs 0%]), depression (1.0% vs 1.0%, including suicidal ideation or attempt [0.6% vs 0.3%]), and cholelithiasis (1.0% vs 0.3%)

Based on animal data, TYSABRI may cause fetal harm. TYSABRI should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus

Please see full Prescribing Information, including **Boxed Warning**.

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