

SRNA and Viela Bio Patient Webinar

You can listen to the audio of this podcast at: <https://youtu.be/5IU58hYYg-c>

Viela Bio: [00:00:00] Hello, and welcome. Thank you for joining us tonight. We're excited to introduce you to UPLIZNA, a treatment for adult patients with NMOSD who are anti-aquaporin-4 antibody positive. We wanted to thank SRNA for partnering with Viela Bio to share information about this new treatment for NMOSD. Please note tonight's webinar will be recorded.

[00:00:28] To start, I would like to welcome GG deFiebre. GG, please unmute your microphone and turn on your video now.

GG deFiebre: [00:00:38] Hi everyone. Here we go. Let me start sharing. There we go. Hi everyone. Hopefully everyone can see and hear me. My name is GG deFiebre, and I am the Associate Director of Research and Education at SRNA.

[00:00:54] SRNA is a nonprofit that's focused on support, education, and research of rare neuroimmune disorders, including NMOSD, and you can learn more about us on our website, which is wearesrna.org. Also for some of the, some of you who are able to attend, we are having a one-day virtual symposium this Saturday, where we will have a talk on all of the treatment options available for NMOSD, as well as a session with representatives from Viela Bio.

[00:01:23] We're very excited about Viela Bio's new treatment for those with NMOSD and are very grateful to be able to provide this educational opportunity for our members with them. If you have any questions about SRNA, please reach out to us via our website or via email. So thank you. We're really excited about this.

Viela Bio: [00:01:49] Thank you, GG. Now, I would like to introduce Sheryl Lapidus. Sheryl is Head of Patient Engagement at Viela Bio. Sheryl, please unmute your microphone and share your video now.

Sheryl Lapidus: [00:02:04] Hi everyone. I'm going to... there we go. Hello. GG, thank you so much. And we at Viela Bio would like to extend our sincere thank you to everyone at SRNA for your partnership and co-hosting this opportunity to share information about UPLIZNA. I am the Head of Patient Engagement at Viela Bio, and I have the honor of being able to work with SRNA and the other NMOSD patient advocacy organizations to support patient community.

[00:02:40] You'll be hearing from several people this evening. First off, you'll hear from Dr. Maureen Mealy, who is with the medical affairs department at Viela Bio. She'll be giving you an overview of NMOSD.

[00:02:55] And following Dr. Mealy, you'll hear from Dr. Jeffrey Bennett from the University of Colorado Anschutz Medical Campus Department of Neurology and Ophthalmology.

[00:03:05] Dr. Bennett will be reviewing UPLIZNA, the end momentum trial, and important safety information about it UPLIZNA. Following Dr. Bennett, you'll hear from Sally. Sally is an individual living with NMO, and she's going to share her personal story, as she's been prescribed UPLIZNA. So she'll tell a little bit her own experience.

[00:03:28] And then finally, but certainly not last and least is Denise Butler. Denise is Director of Patient Support Services at Viela Bio, and she'll be sharing information about those patient support services.

[00:03:42] Next slide please. So a little bit about Viela Bio. Our mission at Viela Bio is to improve the lives of those impacted by serious, underserved, inflammatory, and autoimmune diseases. We lead with scientific innovation and are firm believers in cultivating an environment that fosters creativity and collaboration. Next slide please.

[00:04:11] Our philosophy is multifold, to improve access to innovative medicines and focus on underserved patient populations, while promoting a culture of science and giving back to our community. We at Viela Bio always remember to keep the patient at the center of everything that we do. So thank you again for joining us, and we look forward to hopefully getting to know you a little bit better in the future. Thank you.

Viela Bio: [00:04:41] Thank you so much, Sheryl. You will now hear from Dr. Maureen Mealy, Medical Affairs at Viela Bio. Dr. Mealy, please unmute your microphone and turn on your video now.

Dr. Maureen Mealy: [00:04:56] Thank you. I'm so thrilled to be here and speaking with you all today, I'm just going to take really a few minutes to talk about NMOSD. Next slide, please.

[00:05:11] Some of you are the people living with NMOSD, and so you know that this is an autoimmune disease of the central nervous system that preferentially targets the optic nerves and the spinal cord and really can lead to problems with vision, problems with mobility, pain, as well as bowel and bladder dysfunction.

[00:05:34]-And that's just some of the main things that this can cause, but as you all know, this disease really encompasses a lot of aspects of daily life. Now, it's a relapsing disease, and disability accrues with each relapse. And so, we do know from descriptive studies that it really can impact your life.

[00:05:58] And so reducing the risk of relapse is an important component to managing this disease. Next slide please. Now, the prevalence of NMO and its demographics are really evolving as we know more about this disease. Certainly the discovery of the very specific aquaporin-4-IgG helped us to learn more about these, about the prevalence of this disease. But it is still continuing to evolve as practitioners are recognizing it more and as the diagnostic criteria evolves over time. But we do know that this disease disproportionately affects women of color. About nine women are affected for every one man who is affected. And the prevalence has been found to be higher in those of African and Asian descent. And it's women who are really in the primes of their lives.

[00:06:57] The median age of onset is 40 years old. Although it's quite a broad range of patients that can be affected by this disease. As I mentioned, there's a highly specific antibody that was discovered in 2004, the aquaporin-4 antibody. And the patients, about 80% of patients have this antibody who have this disease in the most sensitive of assays that are available. And, this antibody is a pathogenic antibody, and we don't really know why these patients develop antibodies to an otherwise benign protein that exists in all of us.

Viola Bio: [00:07:44] Thank you, Dr. Mealy. Please join me in welcoming Dr. Jeffrey Bennett. Dr. Bennett, you may now unmute your microphone and turn on your video.

Dr. Jeffrey Bennett: [00:07:59] Good afternoon or good evening everyone. I'm Jeffrey Bennett from the University of Colorado Anschutz Medical Center. And in the next few slides, I'm going to review some of the clinical trial results, mechanism of action, prescription information and safety information for UPLIZNA. UPLIZNA is an FDA approved treatment for aquaporin-4 autoantibody seropositive neuromyelitis optica spectrum disorder, or what I'm going to abbreviate as NMOSD. As noted in the Kaplan–Meier plot of relapse risk on the left of this slide, UPLIZNA reduced the risk of NMOSD attack by 78%. Almost about 90% of NMOSD patients treated with UPLIZNA were relapse free at 28 weeks versus 58% of patients treated with placebo. Hospitalizations related to NMOSD attacks were reduced almost five-fold from 50% in placebo treated patients to 11% in UPLIZNA treated patients.

[00:09:13] UPLIZNA works by depleting B lymphocytes, or B cells, thereby modulating the immune response. The exact mechanism by which B cell depletion exerts its beneficial effects in the treatment of NMOSD is unknown but may involve one or more of several mechanisms, including decreased production of aquaporin-4 autoantibodies, inflammatory messenger secretion that is decreased from B cells to other immune cells, or in general, the reduction of immune cell activation. Despite its beneficial effect on the autoimmune response in NMOSD, UPLIZNA treatment did not increase the risk for infection. Side effects or even serious adverse events were not more frequent in UPLIZNA treated patients versus those treated with placebo. The most common reported adverse events, as shown on the slide, include urinary tract infection, joint pain, headache, and back pain. Infusion-related reactions were infrequent in treated patients and occurred in less than 10% of treated individuals.

[00:10:31] The UPLIZNA N-MOMentum trial was the largest randomized double-blind placebo controlled clinical study in NMOSD and enrolled 230 NMOSD patients in over 25 countries. UPLIZNA was studied in both aquaporin-4 seropositive and seronegative patients as monotherapy. That is, no other immune suppressive therapy was allowed during this treatment trial. The amount of seronegative patients that were enrolled were rather minimal, and therefore the results and the approval are concentrated on the aquaporin-4-IgG seropositive patients.

[00:11:14] UPLIZNA is a therapeutic monoclonal antibody that is infused intravenously over the course of 90 minutes. The initial treatment is comprised of two doses of 300 milligrams administered two weeks apart. Subsequent doses of medication are administered once every six months thereafter.

[00:11:37] Whether you were recently diagnosed with NMOSD, have established disease and suffered a recent attack, or even relapse-free on one of several unapproved therapies, it is prudent to have a conversation with your doctor about whether UPLIZNA can benefit the care of your NMOSD. Your physician will be able to review other important issues about UPLIZNA treatment and overall care of your NMOSD. And it's always important to remember not only to talk with your physician about your general care, but any other subtle symptoms such as those on the right that might relate to undercover disease activity.

[00:12:22] To review, UPLIZNA is a novel monoclonal antibody treatment approved for the treatment of NMOSD that is aquaporin-4 seropositive. Patients with active hepatitis B and active or untreated tuberculosis should not receive UPLIZNA. Your doctor will test you for hepatitis B and TB prior to initiating treatment. Before treatment, patients should receive any required vaccinations, and if pregnancy is possible, use some form of active birth control. It is currently unknown whether UPLIZNA can harm a developing baby. UPLIZNA may pass into breast milk, and therefore any infusions scheduled in breastfeeding mothers should be monitored and rescheduled appropriately.

[00:13:12] During UPLIZNA treatment, patients should engage with their prescribing physician and inform them of any adverse events or changes in medication while on therapy. Yearly, patients will be tested to ensure that they have not been infected with hepatitis B or experienced hepatitis B viral action.

[00:13:33] Actions such as progressive multifocal leukoencephalopathy, a reactivation of latent viral infection with JC virus, may occur with UPLIZNA. While PML has not been reported to date in a plasma treated patients, PML has been infrequently reported in patients treated with other B cell depleting therapies. Symptoms include weakness, confusion, loss of coordination, or changes in personality and could be confused with an NMOSD attack. As a reminder, UPLIZNA is delivered intravenously in concert with additional medications to minimize infusion related reactions. The first dose is given as two infusions two weeks apart, and then subsequent infusions are delivered once every six months.

[00:14:26] Possible side effects include infusion related reactions, urinary tract infection, headache, and joint pain. Blood counts will be routinely monitored in treated patients to assess therapeutic efficacy and to test for safety. Thank you very much for your attention.

Vielabio: [00:14:47] Thank you, Dr. Bennett. As a note, the full safety information and prescribing information for UPLIZNA is available for download in the file section on the bottom, right of your screen. To download, please click on the document name. Next, please join me in welcoming Sally.

Sally: [00:15:07] Thank you for having me here today to share my story with you. In 2016, I started to get a strange pain in my right arm and hand, and it felt like a combination of numbness and shooting pain. At first, I thought I had a pinched nerve, so I went to my primary care physician and to try and figure out what was wrong. Following an MRI, ER doctors determined that I had suffered from a stroke.

[00:15:40] And that didn't make sense to me at the time, because I was a healthy, active person, regularly hiking and doing regular physical activity. So I was surprised at that. After the stroke diagnosis, I met with the neurologist and requested a full MRI to also include my cervical spine since the pain was in my arm. The MRI showed lesions of my cervical spine and I was diagnosed with MS. As the numbness continued to worsen, the neurologist referred me to an NMO center of excellence to determine the specific type of MS and treatment options. The neurologist confirmed that the lesions were still leaky, and the disease was active. I was treated with oral prednisone until, until I could be put on IV steroids.

[00:16:39] But while I was waiting for the approval to come through for the IV medication, the vomiting began, and I was nonstop vomiting for 24 hours and not sure why. I later learned that this

is one of the symptoms of NMOSD. I was treated with IV steroids, which slowed down the numbness, but the pain continued.

[00:17:03] My neurologist decided to do a spinal tap and a blood test, which showed the presence of aquaporin-4 antibodies. I was then finally diagnosed with NMOSD. I learned that NMOSD can manifest itself in many different ways, and because of this, it's often hard to diagnose. The numbness and shooting pain I was dealing with was due to the inflammation of my spinal cord.

[00:17:29] My neurologist explained to me that NMOSD can also cause inflammation of the optic nerve, causing vision pain and problems. Luckily, I never experienced any of those symptoms in my eyes. It took about three months from my initial symptoms to my diagnosis of NMOSD. I know firsthand that because of the variety of symptoms, the disease can be difficult to diagnose.

[00:17:52] There is often many initial misdiagnoses. Once I received the NMOSD diagnosis, my neurologist told me about the treatment options available for patients living with NMO. And there were none. So, no approved drugs at the time. So I was enrolled in a clinical study now known as UPLIZNA. My physician explained that UPLIZNA is designed for patients with NMOSD and is designed to deplete the B cells that are making the antibodies, which lead to the disease. After learning more about the drug, it felt like the right drug for me and that it would fit into my lifestyle. When I first started treatment, I was meeting with doctors about once a month for routine tests to see how I was responding.

[00:18:47] After using UPLIZNA for several years, I now get an infusion every six months. It fits well into my routine. Before beginning the UPLIZNA injection, I first received a steroid, an antihistamine, and a fever preventer to help with weight infusion reactions. The whole process takes about four hours and is followed by an hour of observation.

[00:19:11] My care team also gives me an examination to check in and ensure that I'm healthy before the infusion. Although everyone responds to treatment differently, after treatment, I have a full appetite, normal energy level, and I'm able to drive myself home. To date, I haven't experienced any side effects from the treatment.

[00:19:30] This is my experience only, and patients should always discuss what is right with their doctor, the right treatment option. Since using UPLIZNA, I haven't had any additional attacks. While I take certain precautions knowing I have a suppressed immune system, I've been able to continue to do things I enjoy. I can still teach second grade. I can travel, spend time with my family, and be active outside. Personally, I feel less anxious about traveling and being away from home and doing things I love because I no longer have been having attacks since using UPLIZNA. Because I have nerve damage in my hands, I still have some numbness and pain. But overall, my symptoms are under control and the fear of NMOSD attack no longer guides my decision making. Thanks for listening to my story.

Viola Bio: [00:20:31] Thank you so much for sharing your story with us, Sally. Finally, I would like to introduce Denise Butler, Director of Patient Support at Viela Bio. Denise, don't forget to unmute your microphone and share your video now.

Denise Butler: [00:20:46] Good afternoon, everyone. Thank you so much for joining this evening or afternoon. Again, my name is Denise Butler, Patient Support Services Director here at Viela Bio. We

certainly appreciate your time and engagement this evening. I wanted to take just a few moments to give you some information about the Viela VIPs program.

[00:21:06] So when you think of Viela VIP, VIP definitely sticks out. Most people think of very important player, very important person. Well, here at Viela Bio, we consider VIP a very important person and patient. So what we have tried to do and endeavor to do with our patient support program is create a program that is comprehensive, that will encompass all patients that have been prescribed UPLIZNA, their caregivers, as well as their healthcare professionals, because we understand that this journey to treatment and living with NMOSD, it does take an entire comprehensive effort from everyone involved to make sure that patients stay on journeys and stay on treatment.

[00:21:51] Personal care managers are available with the Viela VIP program. They are able to provide benefit investigation, assess for copay assistance, help patients, again, from the entire journey from start to finish. We realize that diagnosis journeys are very, very different, as Sally previously mentioned. Her journey was very brief to the appropriate diagnosis, but we understand that that's not necessarily the case for each patient.

[00:22:20] So when a patient is prescribed UPLIZNA and that enrollment comes into the Viela VIP program, the case manager will take an individualized approach to see where this patient is in their journey and make a treatment plan, and a cadence for follow-up that is applicable and perfect for that particular patient.

[00:22:43] Our case managers are also able to provide educational resources that will, again, help to educate, provide you all with options and resources that may be available, whether that be from an emotional support standpoint or as well as a financial support. With the Viela VIPs program, again, the initial step in enrolling is making sure that a conversation is had between the patient and the prescriber to make sure that UPLIZNA is the right fit for the patient.

[00:23:16] The physician would then complete the patient referral form and send that into the Viela VIPs program, and that will start each patient on their journey. We do have multiple ways in which to get additional information. If you're asking how you enroll, the great question would be to first start talking with your physician about getting that patient referral form completed.

[00:23:39] The referral form is an editable PDF version that can be found on our Viela VIPs website. It is www.VielaVIPs.com. If the physician or the patient have additional questions about the program, what service offerings we have regarding copay or free product assistance for patients that are uninsured, they can contact the Viela VIPs directly at (833) 842-8477.

[00:24:08] And that is 833-ViB-VIPs. Again, we are very excited about the launch of UPLIZNA and the launch of the Viela VIPs program. If any questions are needed, the number and the website I listed at the very bottom of the slide listed below. Thank you so very much for your time and attention and have a great evening.

Viela Bio: [00:25:01] That concludes today's webinar. On behalf of Viela Bio, we would like to thank you for your time today. A special thank you to SRNA for allowing us to share information about UPLIZNA with your members. If you have any questions about the information from today's webinar, please email vielaquestions@spectrumsience.com or contact your physician. Viela Bio is not able to

answer specific questions about your own condition, but we encourage you to reach out to your physician to learn more. Thank you and have a wonderful evening.