

Helping You Understand Treatment with ENSPRYNG

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[00:00:00] **Roberta Pesce:** Our next talk of the day is helping you understand treatment with ENSPRYNG. Please feel free to head over to a Genentech's booth over the course of the symposium we have today and tomorrow to learn more. And now I'm joined by Jason Kohari, marketing director, MS/NMO at Genentech. Jason, over to you.

[00:00:26] **Jason Kohari:** Thanks, Roberta. Hi, everyone. I appreciate your time today. Thanks for the opportunity to share information with you about ENSPRYNG or satralizumab, a treatment for neuromyelitis optica spectrum disorder, or NMOSD or NMO for short, in adults who are aquaporin 4 antibody positive, or AQP4 positive. I'm going to spend a few minutes sharing how it works, the clinical data, how to take it and our patient support programs. I'll review important the safety information throughout the presentation and of course you're welcome to review the full prescribing information, medication guide, and then the instructions for use at ENSPRYNG.com. That's ENSPRYNG, E-N-S-P-R-Y-N-G. Spring with a Y and then add on EN.

[00:01:08] It's not known if ENSPRYNG is safe and effective in children. It's currently proved for adults and, you shouldn't take it if you're allergic to any of the ingredients in ENSPRYNG, if you have an active Hep B infection, or if you have active or latent TB. As I mentioned, we'll review how ENSPRYNG works, how it was studied, how to take it and then the support options available to you to make sure that once prescribed, you're able to start and stay on ENSPRYNG. So, it's approved for adult patients who are AQP4 positive NMO.

[00:01:39] And ENSPRYNG is thought to affect a protein in our body's called interleukin-6, or IL-6, and it's the first treatment designed to block that protein, which is made by our immune cells in the body and that may play a key role in the inflammation that occurs in people with NMO. ENSPRYNG may cause serious infections, which can be life threatening, so talk to your health care provider if you're being treated for an infection and call them right away if you think if you have signs of an infection with or without a fever, chills, aches, tenderness, or belly pain. ENSPRYNG is designed to block the action of the IL-6 protein, which is believed to play a part in NMO. And with ENSPRYNG, the IL-6 protein is blocked from connecting to the surface of the cell which prevents the activation of that cell and then that may impact the resulting downstream inflammation and immune response in your body.

[00:02:35] So now let's review the clinical trial results of ENSPRYNG. So ENSPRYNG was studied in two clinical trials. ENSPRYNG alone versus placebo and the ENSPRYNG plus certain immunosuppressive therapies, or ISTs. And those were conducted to prove that ENSPRYNG along or ENSPRYNG plus IST can lower the risk of relapse in patients with NMO. And before starting ENSPRYNG, your HCP, or health care provider, will check if you have an infection and treat it if needed, including a test for Hepatitis or TB. ENSPRYNG was the only NMO studied and proven in two clinical trials, which represented a diverse group of people around the world from different countries, different ages, genders, AQP4 antibody status, and disease severity, and based on the clinical trials and the FDA approval, ENSPRYNG is appropriate for those adults with NMO who are AQP4 positive.

[00:03:33] All required vaccinations should be completed before you start ENSPRYNG and depending on that type of vaccination, it should be given at last 2 or 4 weeks before you start treatment and talk to your health care provider and refer to the med guide for the prescribing information for more details. So, study one of the two was ENSPRYNG alone versus placebo and included 95 total patients who were randomly chosen to take ENSPRYNG or placebo. Some took ENSPRYNG and some of those were AQP4 positive and some received placebo and some of those were AQP4 positive.

[00:04:07] Your HCP will order blood tests to check your liver enzymes before and while you're taking ENSPRYNG. And we'll tell you how often those tests need to be taken and if you need to wait to start ENSPRYNG depending upon those tests. In study one, ENSPRYNG versus placebo had met the main study goal by reducing the risk of relapse and resulted in more AQP4 positive adult patients who were relapse-free at 2 years. ENSPRYNG significantly reduced the risk of relapse by 74 percent versus placebo. And then at that 96-week or 2-year period, more patients were relapse-free with ENSPRYNG, 77 percent in fact, versus those on placebo, 41 percent of those patients.

[00:04:52] ENSPRYNG can cause a decrease in neutrophil counts in your blood, which are the white blood cells that help the body fight off infections, and your health care provider will order those tests to check while you're taking ENSPRYNG. Study two compared ENSPRYNG plus certain immunosuppressive therapies, or ISTs, such as azathioprine, mycophenolate, and oral steroids versus placebo and ISTs. Seventy-six patients were enrolled in this study randomly chosen to take ENSPRYNG and IST or placebo plus IST. And, again, some of those actually took the treatment versus placebo and some of those were AQP4 positive. Serious allergic reactions can be life-threatening and have happened with other medicines like ENSPRYNG, so talk to your health care provider if you've had a rash, hives, or flushing after your injection before or after taking the next dose.

[00:05:43] And again, in study two, ENSPRYNG met the main study goal by reducing the risk of relapse and resulted in more AQP4 adult patients who were relapse-free at 2 years. And for those adult patients on ENSPRYNG plus IST, ENSPRYNG significantly reduced the risk of relapse by 78 percent versus placebo. And then more patients were relapse-free at 2 years with ENSPRYNG plus IST, 91 percent of them in fact, versus placebo and IST, and that's 51 percent. And seek medical attention right away if you have any symptoms of a serious allergic reaction like those listed here on the slide.

[00:06:24] Okay. Now that I've given you a very quick overview of our clinical trial data, let's discuss how to actually take ENSPRYNG. ENSPRYNG can be self-administered either at home or elsewhere with proper training and provided your health care provider says it's okay. You or your caregiver or somebody in your home can administer ENSPRYNG. It's supplied in a single use prefilled syringe showed on the screen there. It's typically sent directly to you at home or your specialty pharmacy, and there's more information about injecting, including a training video at our website [ENSPRYNG.com](https://www.enspryng.com). And before you take ENSPRYNG, make

sure your health care provider knows about all of your medical conditions, including infections, liver problems, Hep B, if you've been exposed to somebody with TB or if you've recently received your vaccine or are planning on receiving one.

[00:07:12] So once you've been prescribed ENSPRYNG, during the first 4 weeks you'll have three starting doses 2 weeks apart and then after those three starting doses in the first 4 weeks, your ongoing dose will be once every 4 weeks. Each dose is just one injection or one pre-filled syringe. So, after your starting doses, you'll self-inject ENSPRYNG once a month. And as I mentioned in the last slide, before you take ENSPRYNG, make sure your health care provider knows about all of your medical conditions, including some of those listed here. So, you'll keep ENSPRYNG in the fridge in the original box that it arrives in to protect it from light. Don't freeze or shake it, and ENSPRYNG can be given in the comfort of your own home or if you're traveling. If it's unopened, it can actually be removed from the refrigerator for a total time of up to 8 days as long as the temperature doesn't get above 86 degrees.

[00:08:03] Before you take ENSPRYNG, make sure your health care provider knows if you're pregnant, think that you're pregnant, or might plan on becoming pregnant and it's not known if ENSPRYNG will affect your unborn baby. Okay so we viewed ENSPRYNG trial results, the fact that it is a self-administered once a monthly treatment you can take on the go. And it is just as important that once prescribed you're able to actually start and stay on ENSPRYNG. So, let's discuss the support options available to you and those who are on ENSPRYNG. So, our access solutions team is able to provide answers and support to you once you and your health care provider have determined that ENSPRYNG is right for you. While we can't guarantee what your health care plan will cover, we'll work with you and your health care provider to make sure that the correct paperwork is completed and submitted.

[00:08:50] We offer a number of services, including a dedicated patient navigator who can answer your questions and will be your personal guide and single point of contact thorough your entire ENSPRYNG treatment journey. We offer extra or supplemental injection training and financial assistance to help you pay for ENSPRYNG. And if you're breastfeeding or plan to breastfeed, talk to your health care provider. It's not known if ENSPRYNG passes into your breast milk. So, you can call list 844-ENSPRYNG, or 844-677-7964 to be connected directly with a patient navigator. They'll work with you and your health care provider's office, your health insurance, your specialty pharmacy, to make sure you get your medicine, explain how your insurance can cover ENSPRYNG, help you find financial assistance options, including the co-pay program if you're eligible, answer your questions, and connect you to a clinical education manager if you'd like to meet with someone one-to-one, in person or online for some extra injection training.

[00:09:48] The most common side effects of ENSPRYNG include sore throat, runny nose, upper respiratory tract infection, rash, nausea, fatigue, and the others listed here. So, at Genentech, we're committed to helping you get and pay for ENSPRYNG. Your patient navigator can help you find those assistance options depending upon the type of insurance that you have, including the co-pay program, independent co-pay assistance foundations, or the Genentech patient foundation. Each of these options depends on the type of health insurance that you have and other requirements and details. Your patient navigator will explain them to you, work with you and your health care provider to determine the best options available to you based on your situation.

[00:10:31] I didn't list all the possible side effects of ENSPRYNG but talk to your health care provider and you can also report side effects to the FDA. So, if you'd like extra injection training support after it has been explained to you by your health care provider or you just need a reminder or a refresher or someone to explain it to you, we do have clinical education managers available to set up a free one-to-one training session with

you as many times as you need it. While they won't inject you and can't provide medical advice, they will walk you through the injection training process and answer any questions you may have about injecting the product or a little bit more about NMO.

[00:11:08] And you can call, again, 844-ENSPRYNG, our phone number, to learn more. And of course, you can report any side effects or issues to Genentech, and you can also go online to our website at ENSPRYNG.com, or, again, call 844-677-7964. And I reviewed the key important safety information throughout this presentation. Again, you can find that information at ENSPRYNG.com, and I appreciate the opportunity to provide a quick overview of ENSPRYNG, a treatment for NMO for patients who are positive for AQP4. Thank you very much. And again, for more information go to ENSPRYNG.com or call 844-ENSPRYNG. Thank you.

[00:11:56] **Roberta Pesce:** Wonderful. Thank you so much, Jason, for your time. We appreciate it.