BrightFocus® Chats

The Latest on New Treatments for Wet AMD
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Transcript of Teleconference with Dr. Alicia Menezes, a medical director in the U.S. Medical Affairs Department at Genentech.

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Please note: This Chat has been edited for clarity and brevity.

MICHAEL BUCKLEY: Hello, I'm Michael Buckley with the BrightFocus Foundation, and welcome to today's BrightFocus Chat, "The Latest on New Treatments for Wet AMD." Today we're going to spend probably 30, 35 minutes or so learning about some of the latest developments in the field of vision science. For context, for people who are new today, BrightFocus funds some of the top scientists in the world who are working to find better treatments—and, ultimately, cures—for macular degeneration, glaucoma, and Alzheimer's; and we do events like today's Chat to get the latest news from science as quickly as possible to families that are impacted by these diseases. We also have a lot of information on our website, www.BrightFocus.org. Today, we will hear from Dr. Alicia Menezes. She's a medical director in the U.S. Medical Affairs Department at Genentech, and Dr. Menezes will tell you today about some new developments that Genentech has in the field of new treatments. So, with that, Dr. Menezes, welcome to the BrightFocus Chats, and I wonder if

you could just tell us a little bit about yourself before we get into today's discussion.

DR. ALICIA MENEZES: Absolutely. Thank you so much for having me here today. It's really truly exciting to be here. So, my name is Alicia Menezes. I am an ophthalmologist, actually, and a glaucoma specialist, and I also am a medical director at Genentech, and I work in the U.S. Medical Affairs portion of the company, and am really excited to be here and to have a conversation with you today.

MICHAEL BUCKLEY: Well, great, Dr. Menezes. Let's start the meeting. How is AMD diagnosed?

DR. ALICIA MENEZES: That's a great question. AMD is typically diagnosed while visiting an eye care provider who performs a comprehensive eye exam, or also known as a dilated eye exam, and this type of exam allows a physician to look inside of the eye and, in particular, the back of eye to examine the retina, which may be affected by AMD.

MICHAEL BUCKLEY: Great. I like that you mentioned the term "comprehensive eye exam." I know that that's used a lot in health care settings, but people might not always know what exactly makes it comprehensive. Is there something that people should ask for when they are scheduling an appointment? Like, how does one know that they are getting what is known as comprehensive in an exam?

DR. ALICIA MENEZES: Yeah, so, typically a comprehensive eye exam is a full eye exam in which your vision is being checked, the front of the eye is being checked, as well as the back of the eye is being checked. And in order to check the back of the eye, the eye needs to be dilated. You know, we have that colored part of our eye, which is the iris, which becomes...a pupil becomes small when light is shined into the eye, and so it's difficult to look into the eye. And so, we often place drops in the eye to dilate that pupil so that we can then get a good look inside of the eye to examine all of the structures of the eye and assess a full comprehensive eye exam.

MICHAEL BUCKLEY: Great. Now, am I correct about this, the comprehensive exam might show some early risks or indicators for AMD?

DR. ALICIA MENEZES: Yes, that is exactly right. And, in addition to taking a complete medical history during your visit to identify potential medical or family history risk factors, the physician will also complete this full dilated eye exam to identify potential risk factors or disease indicators, such as drusen, which are small round yellow lesions in the retina, and these are characteristic findings of AMD. They are also looking for other potential findings, such as fluid or blood in the retina, which also may be a result of AMD.

MICHAEL BUCKLEY: Well, great. This might be too broad of a question, but for the comprehensive exam that looks at some of these risk factors, when should people start getting those in their life, and is there a—generally speaking—a frequency that is ... that's a best practice?

DR. ALICIA MENEZES: Yeah. You know, all adults, even without symptoms or eye complaints, should have a baseline eye examination. The frequency of exams following this baseline exam will depend on your age and risk factors that are identified. And so, for example, the AAO, or American Academy of Ophthalmology, recommends an eye exam every 1 to 2 years for anyone over the age of 65, even without symptoms. However, if an individual has new symptoms, new vision changes, or a recent injury, they should be seen and examined sooner, so it really depends.

MICHAEL BUCKLEY: I appreciate that. And, you know, on these BrightFocus Chats—and, particularly, today, we're going to talk about the wet form of AMD—I was wondering if you could tell us what is the wet form of AMD, and when does it start building up? Is this days, months, years? How does this come to be and get to the point where your eye exam might pick it up or a person might notice some problems?

DR. ALICIA MENEZES: Right. So, wet AMD is often a progression from the dry form of AMD, and the wet form of AMD is when blood vessels begin to grow in the retina, and these are not very healthy blood vessels. They will often leak and cause fluid to accumulate in the retina, and this may affect,

ultimately, vision. And I would say it is difficult to predict when dry AMD may progress to wet AMD, but the good news is that only about 10–15 percent of people with dry AMD develop wet AMD. So, the overwhelming majority of people with dry AMD will never develop wet AMD. However, with our current technology, we really aren't able to definitively predict if and when wet AMD will develop, and this is why routine eye exams are so important to be able to pick up on any changes that may go unnoticed.

MICHAEL BUCKLEY: Yeah, that's certainly a great point. And kind of along those lines of maintaining and monitoring your vision health as best you can, how does either the patient or their doctor...how do you look for signs that maybe this wet AMD is developing or getting worse?

DR. ALICIA MENEZES: That's a great question, and I would say that some of the most important information we get is from the patient and what the patient communicates to us. So, is your vision getting worse? Is the quality of the vision different? Have you noticed any changes when looking at an Amsler grid? And an Amsler grid is a grid of lines on a piece of paper, and those lines should be straight. And when you look at that grid with one eye, you're looking for any changes in the grid. Are you seeing a grid of straight lines? Are any portions of the grid missing? Are any of the lines becoming wavy? These are all things that can be done to monitor, and I'm sure that there's additional information on BrightFocus, as well as how to obtain an Amsler grid and what to be looking for, but these are certain things that the patients can be doing at home to monitor themselves and then communicating any of that information to their physician. There are times when the patient tells us what is happening even before we begin to examine the patient. But in addition to the patient's history, we have additional tools to monitor for wet AMD, including assessing your vision with an eye chart, performing those dilated eye exams, looking for changes in the retina. We also have many different exam tools that take images and different kinds of pictures inside the eye that can help us identify if there are signs of wet AMD or worsening wet AMD.

MICHAEL BUCKLEY: Great. And also on that line of monitoring health, we hear a lot of different medical settings about AI—artificial intelligence—and I was wondering, is there...is that something that is showing some

promise in vision health, particularly AMD or glaucoma?

DR. ALICIA MENEZES: Yeah. So, AI, or artificial intelligence, is showing some great signs of potential, and it brings with it the promise of analyzing all of the images and photos that we take in the office and analyzing them in a way that our own human eyes cannot. It picks up on details that, potentially, we cannot, and so with all of this information, AI has the potential then to make conclusions from that data. And I would say that here at Genentech Roche, we have an entire group that is working on AI and big data, and this group has the audacious goal to predict and prevent vision loss using these tools, and our hope is that with these new tools, it will help us find the right treatment at the right time for each individual patient. And so, it's truly an exciting field right now, and it's bringing lots of important science and hope to the field.

MICHAEL BUCKLEY: That's great. That's a nice springboard, Dr. Menezes, to hear about, what is new at Genentech for families that are impacted by wet AMD?

DR. ALICIA MENEZES: So, it's a great question, and we have two new treatments, one called VABYSMO® and the other SUSVIMO™, and these are new treatments for wet AMD, and they both recently received FDA approval.

MICHAEL BUCKLEY: Great, congratulations.

DR. ALICIA MENEZES: Yeah, thank you. A very exciting time for the field and for vision.

MICHAEL BUCKLEY: Well, great. If you don't mind, let's turn with the first one, VABYSMO. Doctor, if could you just kind of start telling us about that new product, VABYSMO.

DR. ALICIA MENEZES: Sure. So, it is very exciting to be able to offer a new treatment option for patients with wet AMD, and VABYSMO is one that inhibits two pathways. It is a bispecific antibody, which means that it targets two different pathways. The first pathway is VEGF, which we

all know very well, but it also has a second arm on the antibody, which inhibits and blocks angiopoietin II, or also for short it's called Ang2. And this is exciting because, you now, we have known for some time that blocking VEGF is beneficial for the treatment of wet AMD, but in addition, there has been great interest in blocking Ang2 as well because early studies have shown that eyes with wet AMD have higher levels of not only VEGF but also Ang2 compared to normal eyes. And early studies also have suggested that Ang2 binds receptors on blood vessels and may play a role in destabilizing these blood vessels, leading to a breakdown and leakage of blood vessels, and this is a main driver of the disease wet AMD. And so, by inhibiting or blocking Ang2, VABYSMO is thought to work together and synergistically with blocking VEGF to promote the stability of blood vessels and, hopefully, to better treat wet AMD.

MICHAEL BUCKLEY: Well, that's fantastic. That's great. Before we turn to the second product, SUSVIMO, is there anything else you'd like to add at this moment about VABYSMO?

DR. ALICIA MENEZES: Yeah, sure. So, you know, I think the great promise that VABYSMO potentially brings is that, you know, the current standard of care for treating people with wet AMD involves eye injections with anti-VEGF medications that are given as often as once a month to prevent vision loss and maintain sight. And the approval of VABYSMO is significant for people living with, for example wet AMD because it offers them a new class of medicine that inhibits two disease pathways, as I mentioned, and has been proven to improve patients' vision just as well as the current standard of care but with potentially fewer injections over time. And so, this has the potential then to greatly impact patients' lives for the better.

MICHAEL BUCKLEY: Well, great. That's wonderful. Turning to the second of two new treatments that we want to talk about today, SUSVIMO, tell us about it.

DR. ALICIA MENEZES: Yeah, sure. So, SUSVIMO is a completely different and new approach to the delivery of anti-VEGF medication to the eye. It is refillable eye implant, which delivers an anti-VEGF medicine called ranibizumab continuously into the eye. And so, this is a small

implant, which has a reservoir, and is filled with a special formulation of ranibizumab, and then surgically implanted into the eye in an operating room. And this is, typically, a one-time procedure in an outpatient setting, so the patient goes home the same day. And once the implant is inserted into the eye, the implant slowly releases the drug over an extended period of time, and the implant has been designed then to be accessed and refilled when the time comes, about every 6 months, during an in-office refill exchange procedure.

MICHAEL BUCKLEY: Wow. So, is it currently...am I correct in the way you describe it? It's currently being used in doctors' offices right now?

DR. ALICIA MENEZES: Yes, that is correct. SUSVIMO was approved by the FDA in October 2021, and it has been approved for the treatment of wet AMD for patients that have responded to intravitreal injections of anti-VEGF.

MICHAEL BUCKLEY: And so, what type of feedback are you getting? How's the real life experience been for patients and their physicians that are using SUSVIMO?

DR. ALICIA MENEZES: Yeah, that is a great question, and we are greatly inspired by the feedback from the clinical trials and, ultimately, by the FDA approval of SUSVIMO. And we are so thankful to all the patients and their physicians who put in so much effort into the clinical trials. In the Phase III Archway trial, we did a patient preference questionnaire that was administered to patients, and in the Archway trial, patients who participated in this questionnaire, more than 90 percent of patients preferred the port delivery system, or SUSVIMO™, to intravitreal injections. And so, this was a great reminder and reassurance that this is a great option—a potential option—for patients.

MICHAEL BUCKLEY: Yeah, that's great. I think that's really interesting. I think there's these parallel tracks of the scientific process, the drug development, and then there's people's daily lives, so it seems like this has been off to a good start to bridge those two worlds.

DR. ALICIA MENEZES: Absolutely.

MICHAEL BUCKLEY: Yeah, so the two new products we talked about today, the VABYSMO and SUSVIMO with FDA approval, any other things on the horizon for you and Genentech?

DR. ALICIA MENEZES: Well, I would say that Genentech is deeply committed to developing treatments that address the unique needs of people living with any vision-threatening condition, and we strongly believe in the importance of providing additional treatment options. And so, now with VABYSMO and with SUSVIMO, we hope to broaden the treatment landscape and offer a meaningful alternative to people living with wet AMD. In addition, Genentech is still researching and developing new treatments for people living with a range of eye diseases that can cause visual impairment and blindness, and this includes additional research and development in wet AMD, as well as diseases like diabetic macular edema, or DME; diabetic retinopathy; as well as geographic atrophy; and a whole host of other retinal diseases. So, as you can see, we have a deep commitment to ophthalmology.

MICHAEL BUCKLEY: Well, that's great, and it really seems like it's a tremendously exciting time for vision science, and as you know, BrightFocus supports a number of researchers all around the nation and the world on AMD and glaucoma, and we hear the same thing from them. They're very, very optimistic about the power of science to save sight, and they really feel like this is a great time for that. And I think that underneath everything we've talked about today are clinical trials and how this makes these things possible. I've always found that clinical trials, it's a term that everybody's heard of but maybe don't completely understand, so I was wondering if you could just tell us briefly: How does someone participate in a trial? What's their patient experience like when they volunteer in a clinical trial?

DR. ALICIA MENEZES: Yeah, that's a great question. I would say that we try to make the patients' experience in a clinical trial as easy as possible and as close to real life as possible. And I would say that, first, a patient needs to have a good understanding of the clinical trial that they would

like to become involved in and give their consent and agree to participate. It all begins with the patient, and so, if a patient fits the criteria for the study and, ultimately, gives their consent to participate, then the patient is enrolled in the study. And depending on the study, the patients may be randomized to the investigational treatment or they may be randomized to a control treatment, which would be the current standard of care. In some cases, there is no standard treatment for a disease, in which case the control arm is a placebo, which is a treatment that is known to have no benefits, and patients are then ... once enrolled in the study, they are then followed very closely with doctor visits and tests ultimately until the end of the study. And that is a brief overview of what participating in a clinical trial may be like.

MICHAEL BUCKLEY: Great. Well, thank you for that overview. You know, sometimes we hear about patients who have a concern that they might be in that placebo arm or placebo track—that their vision might get worse or they might not be getting the treatment that they need. I was wondering: How do you address that concern that some patients might have about ending up in a placebo arm?

DR. ALICIA MENEZES: Well, this, I would say, is a very legitimate question and thought, and a placebo arm exists only if there are no other possible treatments available for the disease. It would be unethical to withhold a treatment that has been clinically proven to be beneficial, and what is reassuring is that there are processes and monitoring systems in place to identify if there is a clear benefit of the investigational treatment, even before the study is completed. So, there have been times in which an investigational treatment shows a clear and significant benefit over the control or placebo arm, and the study may be stopped early, and the beneficial treatment then is offered to the placebo or control group so they may begin to receive the benefits of the investigational treatment as soon as possible.

MICHAEL BUCKLEY: Well, that's good. No, that's good to know, and I think that it's just important for everybody to know the new treatments you talked about today and others in the past or in the future are made possible by people who do volunteer for clinical research. Dr. Menezes, is

there anything else that you'd want to add about clinical trials? Any other common questions that people may have about the trial process?

DR. ALICIA MENEZES: Yeah. You know, I think what I would want patients to know is that they are truly at the center and the most important part of clinical trials, and that if they are interested or curious about clinical trials, then I would encourage them to keep exploring and keep asking questions. I think, BrightFocus, you've done a fantastic job of being able to provide additional information, so certainly use BrightFocus as a resource. Ask your physician questions, speak with your friends, have discussions with your family, and try to become as informed as possible so that when the time comes you can make a decision that is right for you. So, keep asking questions, and keep staying curious.

MICHAEL BUCKLEY: Yeah, that's great. That is great advice for clinical trials and probably life—probably life, in general. A couple of final notes before we conclude. Next month, May 25, we have a fantastic discussion coming up about the role of diet, a healthy diet or a less-healthy diet, and how that impacts your vision health. It's going to be with Dr. Sheldon Rowan of Tufts University in Massachusetts. He's one of the top researchers in the world on the intersection of your diet and your eyes. So, that will be on May 25. That Chat will also have a new host. Today is my last BrightFocus Chat because I've moved on to a different position in the health care sector, so starting next month, my friend and colleague, Diana Campbell, will be your host for upcoming Chats. To close out today, Dr. Menezes, I think this has been a really great conversation. I think you've given our audience some clear information about two new products, and, hopefully, they feel a little more confident about where treatments for wet AMD are going and have some things they can mention to their eye doctor on the next. So, before we conclude, are there any final remarks you'd like to share with the audience?

DR. ALICIA MENEZES: Well, I would just like to thank you for having me here today, and to all of the people on the line, as I mentioned, you know, keep being curious, keep learning, and keep using those resources that are out there for you to learn more about wet AMD or any other condition. It was really a pleasure to be here today. Thank you so much for having me.

MICHAEL BUCKLEY: Great. Well, thank you for your time, Dr. Menezes. On behalf of BrightFocus Foundation and the audience, we want to say thank you very much for educating us today about two new treatments for wet AMD, and this concludes today's BrightFocus Chat, and we will return on May 25. Thank you.

Useful Resources and Key Terms

BrightFocus Foundation: (800) 437-2423 or visit us at www.BrightFocus.org. Available resources include—

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