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Transcript of Video - What You Need to Know About Mavenclad

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WORLDWIDE COURT REPORTING & LITIGATION TECHNOLOGY

MERCK 2008
HOPEWELL v MERCK
IPR2023-00481

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RECORDED VIDEO - WHAT YOU NEED TO KNOW ABOUT

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MAVENCLAD

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10 <https://www.nationalmssociety.org/Treating-MS/Medications/Mavenclad>

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22 Transcribed by: Lauren Bishop

1 DR. AARON MILLER, MD: It's always exciting
2 to have a new medication for the treatment of
3 multiple sclerosis. In this case, we're going to be
4 talking about a new medicine called Mavenclad. The
5 scientific name for Mavenclad is Cladribine. And
6 Cladribine has been used has been approved to be used
7 in patients with relapsing, remitting multiple
8 sclerosis and secondary progressive MS with activity.
9 So nowadays, we classify multiple sclerosis into
10 several different types. One is relapsing remitting
11 MS. These are people who have clear cut relapses and
12 then a relapse resolves often completely. Sometimes
13 leaving some degree of neurological deficit behind
14 until another relapse comes.

15 At the very first episode of MS, a first
16 attack of something that looks like MS, we may refer
17 to that as a clinically isolated syndrome, meaning a
18 person doesn't meet the criteria for definite MS yet.
19 In some cases we may treat patients with CIS with
20 certain medicines, but specifically Mavenclad has not
21 been approved for the treatment of clinically
22 isolated syndrome. Other forms of MS are progressive

1 disease, and we have two types of progressive
2 disease. Secondary progressive disease and primary
3 progressive MS. Secondary progressive MS is diagnosed
4 in a person who once upon a time had at least one
5 relapse and then ultimately the disease course
6 changes so that the person is little by little
7 getting worse.

8 Primary progressive MS refers to a patient
9 who from the very beginning had a progressive course.
10 Relapses are sometimes superimposed later on but the
11 initial course was progressive.

12 Nowadays, however, we apply modifiers to
13 these Progressive courses depending on whether or not
14 an individual has what we refer to as activity.
15 Activity could either be clinical activity that is a
16 relapse or it could be new lesions on MRI. So the FDA
17 in approving Mavenclad for the very first time use
18 the term secondary progressive MS with activity so
19 that means a person who has been getting
20 progressively worse, but in the recent past has had
21 either new relapses or new lesions appearing on the
22 MRI scan. Interestingly, the FDA did not apply a time

1 frame for what they meant by activity. Usually
2 clinicians will be thinking about activity in the
3 relatively recent past. Let's say the past year or
4 two, but the FDA specifically did not mention that in
5 the prescribing information for Mavenclad.

6 Mavenclad is a drug which interferes with
7 the synthesis and repair of DNA in certain cells and
8 by interfering with these processes, it kills certain
9 cells. In particular, it's use in MS has come about
10 because the substrate for Mavenclad is particularly
11 concentrated in lymphocytes. And so the drug has a
12 particularly strong effect in destroying lymphocytes.
13 Lymphocytes are a form of immune cells that are
14 involved in the MS process and lymphocytes come in
15 two major varieties, T cells and B cells. And both of
16 these are affected by Mavenclad.

17 The treatment regimen for Mavenclad is
18 rather unique. So Mavenclad is a -- a tablet. It
19 comes as a 10-milligram tablet and the dose of
20 Mavenclad is dependent on an individual's weight.
21 This is the only MS medicine that we have that is not
22 given in a fixed dose but rather the dose is

1 determined by how much the individual weighs.
2 Mavenclad is given in -- in courses so that the first
3 course starts at the beginning and you get you get
4 two cycles approximately a month apart. So at the
5 very beginning, you take a number of tablets over 4
6 to 5 days, exactly how many tablets again depending
7 on the weight and then you wait between three and
8 four weeks to get the -- the second part of that
9 course, the second cycle in that treatment phase. And
10 after that second course, so now you're roughly one
11 month into treatment, then you have the rest of the
12 year off and you come back at the beginning of the
13 second year and you get another cycle. Again, another
14 course rather of two cycles about a month apart with
15 the same dose that you got at the beginning. After
16 that you don't get any more medicine. Mavenclad by
17 the FDA's recommendation is considered a second-line
18 therapy. Meaning that the recommendation is that a
19 person either have had breakthrough disease on a
20 previous therapy or has not tolerated previous
21 therapy before Mavenclad is used.

22 So in order for a drug to be approved by

1 the FDA, it has to go through phase 3 testing, the
2 last stage of testing which is aimed at determining
3 that a drug is effective as well as continuing to
4 demonstrate a satisfactory safety profile that would
5 allow the FDA to approve the drug.

6 So the major phase three trial for -- for
7 Mavenclad was known as the CLARITY trial and it
8 involved over 1,300 patients. There were three arms
9 in that trial. So close to 500 patients in each of
10 the three arms. The primary endpoint of the trial was
11 looking to see whether there would be a reduction in
12 the annualized relapse rate. The number of relapses
13 that an average individual had per year.

14 So there was a roughly 58 percent
15 reduction in the annualized relapse rate for -- for
16 Mavenclad compared to Placebo. The investigations
17 also looked at what we refer to as confirmed
18 disability progression. That is a person who shows a
19 worsening of their neurological examination to a
20 certain degree specified by the protocol and then
21 maintains that degree of worsening at least three
22 months later. That's referred to as 3-month confirmed

1 disease progression. And this was reduced by about 33
2 percent in the patients taking Mavenclad. Also the
3 use of Mavenclad was associated with an extremely
4 robust reduction in MRI activity, both contrast
5 enhancing lesions, which reflect active lesions or
6 other types of lesions, which developed at some point
7 in the period between the prior MRI and the -- and
8 the new MRI.

9 So this drug is quite -- is quite
10 effective and certainly compares favorably with the
11 other oral drugs in terms of efficacy. Whenever we
12 prescribe a drug for MS, we have to balance the
13 potential benefits of the drug. In this case the
14 reduction in relapse rate, the far fewer MRI lesions,
15 the lower rate of disability progression against what
16 are the tolerability issues of the drug and the
17 potential -- potentially serious adverse events or
18 side effects. Mavenclad appears to be very well
19 tolerated. There is a slightly increased rate of
20 headache with the drug and there are some slight
21 increases in the risks of minor infections and to a
22 lesser extent, more severe infections. Other side

1 effects that we are concerned about, we need to watch
2 out for liver injury. We get baseline liver function
3 tests and monitor liver function in patients who are
4 on Mavenclad. And one of the infections that we're
5 concerned about is the possibility of shingles which
6 is caused by the varicella virus, which is the virus
7 that also causes chickenpox. So the incidence of
8 shingles is somewhat elevated in patients taking
9 Mavenclad.

10 So one of the things we do before putting
11 a person on this medication is check for their immune
12 status to varicella. If they're not immune to
13 varicella, we recommend the immunization with
14 varicella vaccine and then that because it's a live
15 virus vaccine should be given at least four to six
16 weeks before one initiates treatment with Mavenclad.
17 A rare thing that we need to consider is an entity
18 called graft-versus-host disease. Graft-versus-host
19 disease is a an unusual situation in which
20 transplanted tissue of one type starts to attack the
21 recipient's own tissue. The concern with regard to
22 Mavenclad is specifically relates to blood

1 transfusions. So if a person on Mavenclad needs to
2 get a blood transfusion, graft versus host disease
3 can prevent -- be prevented fairly simply and readily
4 by irradiating the blood that's going to be
5 transfused. But that is an important thing to
6 remember all be it a relatively unusual situation.

7 One of the major concerns that the FDA had
8 about the safety of Mavenclad regard -- regards a
9 potentially increased risk of cancer. So that's an
10 increased risk, but it's a very low increased risk.
11 It's also important to note that the cancers that
12 occurred with Mavenclad were all different types of
13 cancers. We -- the warning about cancer is in a boxed
14 warning in the prescribing information, but I think
15 it's important that patients understand that this
16 does appear to be a very low risk.

17 Another concern about Mavenclad is that it
18 would have potential risks to a fetus if a woman were
19 taking Mavenclad during pregnancy, so we strongly
20 advise women not to get pregnant while they're taking
21 Mavenclad. They should use effective contraceptive
22 means and especially during their active cycles of

1 Mavenclad, they should use not only a hormonal
2 contraceptive but also barrier methods. When the man
3 is taking Mavenclad he should avoid impregnating a
4 woman until six months after the dose and women
5 should not attempt to get pregnant until six months
6 after a course of Mavenclad.

7 So the testing that we do before a patient
8 goes on Mavenclad relate to some of these adverse
9 events that we've been talking about. Mavenclad would
10 have the risk of activating latent infections. So one
11 of the infections that could be reactivated is
12 tuberculosis. So we screen patients for tuberculosis.
13 Another is hepatitis. So we recommend screening for
14 Hepatitis B and Hepatitis C. Mavenclad should not be
15 used in patients who are HIV positive. So we should
16 screen for HIV prior to the use of Mavenclad. We also
17 do routine blood counts and liver function testing.
18 Again, we want to make sure that the lymphocyte count
19 is at least a thousand prior to the first dose and at
20 least 800 prior to the second dose of Mavenclad. And
21 that I think pretty much encompasses the baseline
22 testing that we want to do in a patient going on

1 Mavenclad. Of course for a woman we want to make sure
2 that she's not pregnant.

3 One of our concerns with a number of drugs
4 that we use in MS is the risk of a brain infection
5 called PML which stands for Progressive Multifocal
6 Leukoencephalopathy. That's a mouthful so we will
7 stick with PML. PML is caused by a virus that many of
8 us live with comfortably. It doesn't do any harm to
9 people who are whose immune systems are not
10 compromised. PML has not been reported with
11 cladribine, with oral cladribine, but it is at least
12 a theoretical risk because of the effect on the
13 immune system that Mavenclad has. So patients before
14 going on Mavenclad should have an MRI test not only
15 to assess the status of their MS, but to look for any
16 evidence that might exist for PML.

17 Many people with MS start on a medication
18 and then need to change medication at some point for
19 one reason or another. Sometimes we need to do some
20 advance planning or at least thinking about the
21 timing in making a switch. And it depends not only on
22 the drug to which you are switching, but also the

1 drug that the patient has been on in the first place.
2 Now in the case of Mavenclad that the main
3 circumstance here would be that we need to have the
4 lymphocyte count be up to 1,000. And some of the
5 drugs that we -- that the person might have been on
6 before Mavenclad may have suppressed the lymphocyte
7 count. And so we may need to wait to get that
8 lymphocyte count back into the safe range for
9 Mavenclad. Mavenclad is generally not recommended as
10 an initial therapy because of the safety concerns
11 that it have been raised. It is on the market and
12 available -- available for prescriptions.
13 Unfortunately, like all of the other MS medications,
14 it has an enormously high price tag.

15 As providers, we only have access to
16 average wholesale prices and what was listed for
17 Mavenclad as I believe \$99,000 so as with most other
18 medications, we certainly don't expect that people
19 with MS are going to be paying these kinds of prices
20 for the drugs. Hopefully their insurer is going to
21 cover the drug and the patient hopefully would have a
22 relatively small copay. Even with that EMD Serono,

1 the manufacturer of Mavenclad has a patient
2 assistance program is available -- available. They
3 offer co-pay assistance to many patients who are
4 commercially insured.

5 Decisions about what disease-modifying
6 therapy to use are getting increasingly complex.
7 That's actually good news because the reason they're
8 complex is because we have so many good therapies and
9 any therapy -- any choice of therapy entails and
10 assessment of benefit versus risk. The benefits, of
11 course in reducing MS activity and the risks variable
12 depending on the particular medication.

13 I think the best thing that a patient
14 should do in is have a frank discussion with the
15 healthcare provider. They should have an open
16 discussion about what we know about the benefits of
17 the drug and go over not only the serious risks, but
18 any tolerability issues.

19 (The recording was concluded.)
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CERTIFICATE OF TRANSCRIBER

I, Lauren Bishop, do hereby certify that the transcript was prepared from the audio recording; that said transcript is a true and accurate transcription of the audio to the best of my knowledge, skills, and ability; and that I am neither counsel for, related to, nor employed by any of the parties to this case and have no interest, financial or otherwise, in its outcome.



LAUREN BISHOP

Planet Depos,

November 14, 2023

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