1
00:00:08,967 --> 00:00:09,551
REBLOZYL

2
00:00:09,551 --> 00:00:13,263
or luspatercept is indicated for the treatment of anemia

3
00:00:13,263 --> 00:00:17,475
without previous erythropoiesis stimulating agent use

4
00:00:17,559 --> 00:00:21,271
in adult patients with very low-to intermediate-risk

5
00:00:21,271 --> 00:00:26,818
myelodysplastic syndromes who may require regular red blood cell transfusions.

6
00:00:26,901 --> 00:00:31,364
REBLOZYL is not indicated for use as a substitute for RBC

7
00:00:31,364 --> 00:00:36,911
transfusions in patients who require immediate correction of anemia.

8
00:00:36,995 --> 00:00:42,459
This promotional educational activity is brought to you by Bristol Myers Squibb

9
00:00:42,542 --> 00:00:46,046
and is not certified for continuing medical education.

10
00:00:46,129 --> 00:00:50,592
I am a paid speaker for Bristol-Myers Squibb and must present information

11
00:00:50,592 --> 00:00:56,389
in compliance with FDA requirements applicable to Bristol Myers Squibb.

12
00:00:56,473 --> 00:00:57,932

Hi, I'm Jamie Koprivnikar;

13
00:00:57,932 --> 00:01:01,102
a Hematologist/Oncologist at the John Theurer

14
00:01:01,102 --> 00:01:05,023
Cancer Center at Hackensack University Medical Center.

15
00:01:05,106 --> 00:01:08,902
Erythropoiesis-stimulating agents, also known as ESAs,

16
00:01:09,152 --> 00:01:13,656
have been commonly used for the treatment of anemia in patients with non deletion (5q)

17
00:01:13,656 --> 00:01:17,285
lower-risk myelodysplastic syndromes.

18
00:01:17,368 --> 00:01:22,707
However, data from a real-world retrospective analysis study demonstrated

19
00:01:22,707 --> 00:01:26,836
that approximately 7 out of 10 patients fail to respond

20
00:01:26,836 --> 00:01:32,550
to ESAs, and 53% of patients in this analysis were RS negative.

21
00:01:32,634 --> 00:01:36,262
With the approval of REBLOZYL as a first-line option vs

22
00:01:36,262 --> 00:01:39,891
an active comparator, the treatment paradigm has shifted,

23
00:01:40,100 --> 00:01:45,438
making it possible to fulfill long-standing unmet needs in low-risk MDS.

24

00:01:45,522 --> 00:01:48,525
Having this treatment choice with a broad indication,

25
00:01:48,733 --> 00:01:49,943
where you don't need to think

26
00:01:49,943 --> 00:01:54,280
about specific subgroups, allows health care professionals like myself

27
00:01:54,364 --> 00:01:59,452
to confidently prescribe REBLOZYL for my eligible ESA-naïve patients,

28
00:01:59,536 --> 00:02:04,457
regardless of their ring sideroblasts status or serum erythropoietin levels.

29
00:02:04,541 --> 00:02:08,253
When I'm making treatment decisions, I'm always looking for appropriate,

30
00:02:08,461 --> 00:02:11,840
efficacious, and safe options for my patients.

31
00:02:11,923 --> 00:02:15,969
In the case of REBLOZYL, the safety and efficacy were demonstrated

32
00:02:15,969 --> 00:02:20,765
in COMMANDS-a Phase 3, open-label, randomized,

33
00:02:20,765 --> 00:02:25,937
active-controlled clinical trial of REBLOZYL vs epoetin alfa in

34
00:02:25,937 --> 00:02:30,441
ESA-naïve, adult patients with anemia due to lower-risk MDS.

35
00:02:30,525 --> 00:02:34,362
The clinical trial met the composite primary endpoint of red blood

36

00:02:34,362 --> 00:02:38,783
cell transfusion independence for 12 weeks and a mean hemoglobin

37
00:02:38,783 --> 00:02:43,788
increase of greater than or equal to 1.5 g/dL.

38
00:02:43,872 --> 00:02:47,375
As the data show, nearly twice as many patients achieved

39
00:02:47,375 --> 00:02:50,378
RBC transfusion independence with REBLOZYL

40
00:02:50,461 --> 00:02:55,258
and a mean hemoglobin increase, demonstrating superiority vs epoetin alfa.

41
00:02:55,258 --> 00:02:58,970
Patients who responded well to treatment with REBLOZYL

42
00:02:58,970 --> 00:03:04,893
also had lasting transfusion independence, with a median duration of 2.5 years

43
00:03:04,976 --> 00:03:09,564
compared with 1.5 years for patients on epoetin alfa.

44
00:03:09,647 --> 00:03:12,442
That additional year of transfusion independence has proved

45
00:03:12,442 --> 00:03:16,112
quite meaningful to my patients with low-risk MDS.

46
00:03:16,196 --> 00:03:18,990
REBLOZYL also demonstrated higher response

47
00:03:18,990 --> 00:03:21,993
rates across all secondary efficacy endpoints.

48

00:03:22,076 --> 00:03:26,372
When you review the data from the subgroup analysis of the COMMANDS trial,

49
00:03:26,456 --> 00:03:30,793
you'll notice that the clinical trial included 99 patients who were ring

50
00:03:30,793 --> 00:03:35,256
sideroblasts negative. Notably, this is the most of any Phase

51
00:03:35,256 --> 00:03:39,052
3 study conducted in patients with lower-risk MDS.

52
00:03:39,135 --> 00:03:42,013
The durable responses observed with REBLOZYL

53
00:03:42,013 --> 00:03:45,558
and the intention-to-treat population are also reflected

54
00:03:45,558 --> 00:03:49,187
in the subgroup data for RS-negative patients.

55
00:03:49,270 --> 00:03:53,358
As you can see, the response rate among patients in the RS-negative

56
00:03:53,358 --> 00:03:59,447
subgroup was 46.9% with REBLOZYL and 50% with epoetin alfa.

57
00:03:59,530 --> 00:04:04,202
However, it's important that you know that the subgroup analysis was not powered

58
00:04:04,202 --> 00:04:07,038
to detect statistically significant differences

59
00:04:07,038 --> 00:04:10,291
in the response rates or to draw conclusions.

60
00:04:10,375 --> 00:04:13,378
Although the response rates were numerically similar,

61
00:04:13,378 --> 00:04:18,466
as shown, more than 50% of patients on REBLOZYL remain transfusion

62
00:04:18,466 --> 00:04:22,220
independent, and the median duration was not reached.

63
00:04:22,303 --> 00:04:26,933
Whereas in the epoetin alpha group, more than 50% of RS-negative
patients

64
00:04:26,975 --> 00:04:30,603
lost transfusion independence, with the median duration

65
00:04:30,603 --> 00:04:33,606
being 95.1 weeks.

66
00:04:33,606 --> 00:04:37,402
Also, as you formulate a treatment plan, it may be helpful to know

67
00:04:37,402 --> 00:04:43,074
that the 2023 NCCN Guidelines in Oncology recommend luspatercept-aamt

68
00:04:43,324 --> 00:04:47,495
as a Category 2A therapy for the first-line treatment of

69
00:04:47,495 --> 00:04:52,500
RS-negative patients with symptomatic anemia due to lower-risk MDS.

70
00:04:52,583 --> 00:04:55,003
Now, let's have a look at the safety data

71
00:04:55,003 --> 00:04:58,006
from the full analysis of the COMMANDS trial.

72

00:04:58,006 --> 00:05:02,176
As you may have noticed, adverse events in the clinical trial were
Grade 1 or 2,

73
00:05:02,176 --> 00:05:06,723
mild or moderate. The most common all-grade

74
00:05:06,723 --> 00:05:10,601
adverse events occurring in more than 10% of patients included

75
00:05:10,601 --> 00:05:14,522
fatigue, diarrhea, peripheral edema, nausea,

76
00:05:14,605 --> 00:05:18,693
dyspnea, asthenia, dizziness, headache, back pain,

77
00:05:18,693 --> 00:05:22,488
COVID-19 and anemia.

78
00:05:22,572 --> 00:05:26,617
The most common Grade 3 or higher adverse events

79
00:05:26,617 --> 00:05:30,830
occurring in more than 2% of patients included hypertension,

80
00:05:30,913 --> 00:05:35,543
dyspnea, COVID-19, pneumonia, thrombocytopenia,

81
00:05:35,626 --> 00:05:40,673
neutropenia, and anemia. Selected laboratory abnormalities

82
00:05:40,673 --> 00:05:44,886
that changed from Grade 0 to 2 at baseline to greater than Grade 2

83
00:05:44,886 --> 00:05:49,223
at any time during the studies and at least 10% of patients

84
00:05:49,307 --> 00:05:53,936

were glomerular filtration rate and total bilirubin increased.

85
00:05:54,020 --> 00:05:59,275
Other clinically relevant adverse events reported in fewer than 5% of patients

86
00:05:59,525 --> 00:06:04,405
were injection-site reactions, including erythema, pruritus, and rash.

87
00:06:04,489 --> 00:06:08,326
Taking this information together with my clinical experience,

88
00:06:08,326 --> 00:06:12,872
I feel that REBLOZYL can be administered and managed safely.

89
00:06:12,955 --> 00:06:17,043
For healthcare professionals evaluating first-line treatment options,

90
00:06:17,126 --> 00:06:21,255
the superior efficacy and lasting duration of transfusion

91
00:06:21,255 --> 00:06:25,468
independence with REBLOZYL in the intention-to-treat population,

92
00:06:25,551 --> 00:06:30,223
combined with a demonstrated safety profile and real-world evidence, help

93
00:06:30,223 --> 00:06:34,435
make it an appropriate treatment choice for patients with symptomatic anemia due

94
00:06:34,435 --> 00:06:40,525
to lower-risk MDS, irrespective of ring sideroblasts status or erythropoietin level.

95
00:06:40,525 --> 00:06:41,776
REBLOZYL is

96
00:06:41,776 --> 00:06:44,445
indicated for the treatment of anemia without previous erythropoietin

97
00:06:44,445 --> 00:06:47,323
stimulating agent use in adult patients with very low- to
intermediate-risk

98
00:06:47,323 --> 00:06:48,324
myelodysplastic syndromes

99
00:06:48,324 --> 00:06:50,993
who may require regular red blood cell transfusions.

100
00:06:50,993 --> 00:06:53,454
REBLOZYL is not indicated for use as a substitute for red blood

101
00:06:53,454 --> 00:06:56,457
cell transfusions in patients who require immediate correction of
anemia.

102
00:06:56,499 --> 00:06:58,042
In adult patients with beta thalassemia,

103
00:06:58,042 --> 00:07:01,421
thromboembolic events were reported in 3.6% of REBLOZYL-treated
patients.

104
00:07:01,421 --> 00:07:02,755
Thromboembolic events included deep

105
00:07:02,755 --> 00:07:05,800
vein thrombosis, pulmonary embolus, portal vein thrombosis and
ischemic stroke.

106
00:07:05,800 --> 00:07:07,885
Patients with known risk factors

107
00:07:07,885 --> 00:07:10,888

for thromboembolism may be at further increased risk of thromboembolic conditions.

108
00:07:10,930 --> 00:07:12,890
Consider thromboprophylaxis in patients at increased

109
00:07:12,890 --> 00:07:14,308
risk of thromboembolic events.

110
00:07:14,308 --> 00:07:15,309
Monitor patients for signs

111
00:07:15,309 --> 00:07:18,312
and symptoms of thromboembolic events and institute treatment promptly.

112
00:07:18,521 --> 00:07:21,858
Hypertension was reported in 11.4% of REBLOZYL-treated patients.

113
00:07:21,941 --> 00:07:22,900
Across clinical studies,

114
00:07:22,900 --> 00:07:26,863
the incidence of Grade 3 to 4 hypertension ranged from 2% to 9.6%.

115
00:07:26,946 --> 00:07:30,450
In ESA-naïve adult patients with MDS with normal baseline blood pressure,

116
00:07:30,575 --> 00:07:34,996
36% of patients developed a systolic blood pressure of 140 millimeters of mercury

117
00:07:34,996 --> 00:07:38,082
or higher, and 6% of patients developed diastolic blood pressure

118
00:07:38,207 --> 00:07:40,334
of 80 millimeters of mercury or higher.

119
00:07:40,334 --> 00:07:42,462
Monitor blood pressure prior to each administration.

120
00:07:42,462 --> 00:07:43,838
Manage new or exacerbations

121
00:07:43,838 --> 00:07:46,841
of preexisting hypertension using anti-hypertensive agents.

122
00:07:46,841 --> 00:07:49,844
REBLOZYL may cause fetal harm when administered to a pregnant woman.

123
00:07:49,927 --> 00:07:52,680
REBLOZYL caused increased post implantation loss, decreased

124
00:07:52,680 --> 00:07:55,683
litter size, and increased incidence of skeletal variations in
pregnant

125
00:07:55,725 --> 00:07:56,767
rat and rabbit studies.

126
00:07:56,767 --> 00:07:58,269
Advise pregnant women of the potential risk

127
00:07:58,269 --> 00:08:00,646
to a fetus. Advise females of reproductive potential

128
00:08:00,646 --> 00:08:02,440
to use effective contraception during treatment

129
00:08:02,440 --> 00:08:04,650
and for at least 3 months after the final dose.

130
00:08:04,650 --> 00:08:07,653
Grade 3 or higher adverse reactions included hypertension and dyspnea.

131

00:08:07,904 --> 00:08:10,364
These were observed in 2% or more of patients.

132
00:08:10,364 --> 00:08:13,034
The most common all-grade adverse reactions included diarrhea,

133
00:08:13,034 --> 00:08:15,286
fatigue, hypertension, peripheral edema, nausea and dyspnea.

134
00:08:15,286 --> 00:08:18,247
These were observed in 10% or more of patients.

135
00:08:18,247 --> 00:08:20,082
It is not known whether REBLOZYL is excreted

136
00:08:20,082 --> 00:08:23,711
into human milk or absorbed systemically after ingestion by a nursing infant.

137
00:08:23,711 --> 00:08:25,630
REBLOZYL was detected in milk of lactating rats.

138
00:08:25,630 --> 00:08:28,382
When a drug is present in animal milk, it is likely that the drug will be present

139
00:08:28,382 --> 00:08:29,050
in human milk.

140
00:08:29,050 --> 00:08:30,885
Because many drugs are excreted in human milk,

141
00:08:30,885 --> 00:08:33,804
and because of the unknown effects of REBLOZYL in infants, a decision

142
00:08:33,804 --> 00:08:36,807
should be made whether to discontinue nursing or to discontinue treatment.

143
00:08:37,016 --> 00:08:39,936
Because of the potential for serious adverse reactions in the
breastfed child,

144
00:08:39,936 --> 00:08:41,562
breastfeeding is not recommended during treatment

145
00:08:41,562 --> 00:08:43,439
and for 3 months after the last dose.

146
00:08:43,439 --> 00:08:46,734
Abuse of REBLOZYL may be seen in athletes for the effects
erythropoiesis.

147
00:08:46,776 --> 00:08:48,819
Misuse of drugs that increase erythropoiesis,

148
00:08:48,819 --> 00:08:51,697
such as REBLOZYL, by healthy persons may lead to polycythemia,

149
00:08:51,697 --> 00:08:54,367
which may be associated with life-threatening cardiovascular
complications.