LymphomaHub

DLBCL

FDA grants selinexor Fast Track Designation for the treatment of patients with DLBCL

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On 7 November 2018, the US Food and Drug Administration (FDA) granted Fast Track Designation to selinexor for the treatment of patients with diffuse large B-cell lymphoma (DLBCL) who have received at least two prior therapies and are not eligible for high-dose chemotherapy with stem cell rescue or CAR-T therapy. Selinexor is a novel, selective inhibitor of nuclear export (SINE) compound, which inhibits exportin 1 (XPO1), a karyopherin protein, that facilitates the nuclear export of tumor suppressor proteins.[1]

The efficacy of single-agent selinexor is being examined in a phase IIb study (SADAL) in patients with relapsed or refractory (R/R) DLBCL after ≥ 2 prior regimens. In an interview with the Lymphoma Hub, John Kuruvilla from the Princess Margaret Cancer Centre, Toronto, CA, talks about the design of the phase IIb study. Briefly, patients were randomized to receive 60 mg or 100 mg of selinexor twice weekly (8 doses) per 28-day cycle. Additionally, patients were grouped by the subtype of their DLBCL (GCB or non-GCB). The primary and secondary endpoints were to determine the objective response rate (ORR), and duration of response respectively.

Data from this study presented at the 23rd Congress of the European Association of Hematology demonstrated that monotherapy with selinexor exhibits anti-cancer activity in R/R DLBCL patients including those with GCB subtype. In addition, dosing at 60 mg twice weekly was tolerated better than 100 mg twice weekly, with fewer interruptions to dosing due to toxicity. Moreover, durable objective responses were achieved with selinexor, which may be "associated with clinical benefit."[2]

According to the manufacturers, the Fast Track Designation granted to selinexor for patients with R/R DLBCL "underscores the great unmet medical need for this aggressive form of lymphoma."[1]

References

1. Karyopharm Therapeutics Inc.: Karyopharm's Selinexor Receives Fast Track Designation from FDA for the Treatment of Patients with Relapsed or Refractory Diffuse Large B-cell Lymphoma. 2018 Nov 7. https://globenewswire.com/news-release/2018/11/07/1646944/0/en/Karyopharm-s-Selinexor-Receives-Fast-Track-Designation-from-FDA-for-the-Treatment-of-Patients-with-Relapsed-or-Refractory-Diffuse-Large-B-cell-Lymphoma.html [Accessed 2018 Nov 7].

2. Maerevoet. M. *et al*. Single agent oral selinexor exhibits durable responses n relapsed/refractory diffuse large b-cell lymphoma (DLBCL) of both GCB and non-GCB subtypes: The phase 2b SADAL study. Abstract #S469. 23rd Congress of the European Association of Hematology. Stockholm, Sweden.

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