Annals of Medicine and Surgery 79 (2022) 104050

Contents lists available at ScienceDirect

Annals of Medicine and Surgery

journal homepage: www.elsevier.com/locate/amsu

Dostarlimab, a boon or a healthcare burden- too early to acertain!

Nabeela Fatima *, Nashra Tabbasum, Kiranmai Mandava

Department of Pharmacy Practice, St Pauls College of Pharmacy, Turkayamjal, Hyderabad, India

A ray of hope or a hasty decision..! If the drug shows such promising results on a large population, the drug would be an asset towards a cancer-free world, but how about its affordability..?

A small study conducted by Memorial Sloan Kettering (MSK) Cancer Center that included 12 patients with rectal cancer who were given dostarlimab every 3 weeks for 6 months. The patients enrolled had faced previous treatment problems due to chemotherapy, radiation & invasive surgeries. After 6 months, the cancer was undetectable by physical examination, PET scan or MRI. The study is going to be extended for up to 30 patients, but the question is this size is enough to decide if the drug is effective for all kinds of cancers and all populations. This study proves complete remission which is unheard of till date but a long term follow up is required to support and prove the efficacy of the drug.

Dostarlimab is available as Jemperli (dostarlimab-gxly injection) at a dose of 500mg/10 ml. The cost of each dose of the drug is $11,000 (Rs. 8,54,119/-) € 19355 (Rs 16,07,316/-) and Rs. 3.4 lakh/vial in India. Is this amount affordable by all members of our society? Is this something that the lower classes can afford?

Dostarlimab is a D-potent, selective, humanized IgG-4 monoclonal antibody derived from mouse hybridoma using SHM-XEL system. It is used for the treatment of endometrial cancer. It was approved in April 2021 in the US and European Union. It was a newer type of immunotherapy which is been effective in patients with recurrent primary cancers. GARNET trails (NCT02715284) was first inhuman study on safety, efficacy, tolerability, pharmacokinetic, pharmacodynamics and clinical activity across multiple solid tumor subtypes such as endometrial cancer, non-small-cell lung cancer, ovarian carcinomas, etc. The GARNET trials are still underway in US, that is being carried out on over 750+ patients [1,2].

On June 5, 2021, a study was published in NEJM which included 12 patients with mismatch-repair-deficient (dMMR) stage-2,3 rectal adenocarcinoma. The study included follow-up for 6 weeks, where the patients were detected cancer free. Following this, on August 17, 2021, USFDA granted accelerated approval for dostarlimab for patients with mismatch-repair-deficient (dMMR) that are recurrent or advanced solid tumors [3,4].

Table 1
Pharmacokinetics and side effects of dostarlimab.

MOA	Anti PD-1 receptor
Mean Elimination half-life	10–20 days Approximately
Dosing	500 mg IV every 3 weeks, followed by 1000 mg IV every 6 weeks
Side Effects	● Fatigue, asthenia, nausea, diarrhea, anemia, constipation, increased transaminases, increased lipase. ● Vomiting, joint pain, itching, rash, fever and hypothyroidism.
Series adverse events	Sepsis, AKI, UTI, abdominal pain and pyrexia.
Immune mediated adverse reactions	Pneumonitis, colitis, hepatitis, endocrinopathies and nephritis.

We await a large population study to prove its efficacy and hope for a cancer-free world. However, all considerations must be considered before making a decision, as the availability and affordability of the drug is also a concern once the drug is approved.

Ethical approval

Not required.

Sources of funding

None.

Author contribution

All authors contributed equally.

Abbreviations: PET, Positron emission tomography; MRI, Magnetic resonance imaging.

* Corresponding author.
E-mail address: nab.hameed25@gmail.com (N. Fatima).

https://doi.org/10.1016/j.amsu.2022.104050
Received 14 June 2022; Accepted 18 June 2022
Available online 24 June 2022

Consent

None.

Registration of research studies

Not applicable.

1. Name of the registry:
2. Unique Identifying number or registration ID:
3. Hyperlink to your specific registration (must be publicly accessible and will be checked):

Guarantor

Nabeela Fatima.

Declaration of competing interest

None.

References

[1] L. Kasherman, S. Ahrari, S. Lheureux, Dostarlimab in the treatment of recurrent or primary advanced endometrial cancer, Future Oncol. 17 (8) (2021) 877–892. Feb.
[2] A. Markham, Dostarlimab: first approval, Jul, Drugs 81 (10) (2021) 1213–1219, https://doi.org/10.1007/s40265-021-01539-5. PMID: 34106455.
[3] A. Cercek, M. Lumish, J. Sinopoli, J. Weiss, J. Shia, M. Lamendola-Essel, I.H. El Dika, N. Segal, M. Shcherba, R. Sugarman, Z. Stadler, PD-1 blockade in mismatch repair–deficient, locally advanced rectal cancer, N. Engl. J. Med. 5 (2022). Jun.
[4] A. Oaknin, L. Gilbert, A.V. Tinker, et al., Safety and antitumor activity of dostarlimab in patients with advanced or recurrent DNA mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) or proficient/stable (MMRp/MSS) endometrial cancer: interim results from GARNET-a phase I, single-arm study, J Immunother Cancer 10 (1) (2022), e003777, https://doi.org/10.1136/jitc-2021-003777.