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Editorial

Greetings from Drug Information Bulletin!

It is my proud privilege to write the editorial of the first issue of the 18th year of the Drug Information Bulletin (DIB). This bulletin started its journey seventeen years back on April 2007 under the Drug Information Centre (DIC), IPA Bengal Branch. Initially it started as a weekly bulletin and continued for eight years; thereafter this bulletin is being published on a bi-weekly basis. At the beginning it was sent to the members of IPA Bengal Branch, but on request it expanded its horizon including IPA members of the entire country and now is available globally to anyone interested to receiving it. During the last seven years it has been a joint publication of Drug Information Centre (DIC), IPA Bengal & Regulatory Affairs Division of IPA. It has earned several accolades to its credit from some international agencies like -Health Information for All, UK and Commonwealth Pharmaceutical Association (CPA). On completion of each year we conduct a survey among the readers through a structured questionnaire regarding their opinion on its content regularity, its quality. We are happy we have always received encouraging results and inputs. The inputs we received have been implemented as far as possible. The most satisfying fact is that a good number of electronic bulletins have been published during last few years by the individuals who were the readers of this bulletin. It has also been reported that a number of Group of Hospitals both in India and abroad are forwarding this bulletin amongst their doctors, pharmacists and nurses. Some of the pharmacy & medical colleges are keeping the printed copy of this bulletin in their library for reading and archiving. Our reader base is growing day by day on request from health personnel and even lay persons from India and abroad. We expect your inputs to serve you better.

Greetings to you all.

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DCGI revoked the order of authorizing State Licensing Authority to issue NOC for manufacturing of unapproved, approved new drugs and banned drugs for export only

New Drug: Faricimab for neovascular age-related macular degeneration and diabetic macular oedema
Approved indications: neovascular (wet) age-related macular degeneration, diabetic macular oedema
Vabysmo (Roche)
Each Vials containing 28.8 mg faricimab in 0.24 mL solution for intravitreal injection
Faricimab is the first bispecific monoclonal antibody for intraocular use, approved for treatment of neovascular (wet) age-related macular degeneration and diabetic macular oedema. Neovascular age-related macular degeneration (nAMD) is a form of advanced AMD characterised by abnormal proliferation of new blood vessels beneath the retina and macula (choroidal neovascularisation). These blood vessels leak fluid, lipids and blood into the outer retina, causing severe, irreversible loss of central vision if untreated. Approximately 21,000 new cases of nAMD are diagnosed in Australia each year. Diabetic macular oedema is a complication of diabetic retinopathy associated with fluid leakage from damaged blood vessels and swelling of the macula, resulting in loss of central vision.
Faricimab inhibits pathological angiogenesis and restores vascular stability in the eye. It acts by binding to vascular endothelial growth factor A (VEGF-A) and angiopoietin-2 (Ang-2), reducing vascular permeability and inflammation via 2 distinct pathways. Other VEGF inhibitors available in Australia are aflibercept, brolucizumab and ranibizumab. These drugs have substantially improved visual outcomes in patients with nAMD and diabetic macular oedema; however, long-term treatment is required, with frequent clinic visits for monitoring and intraocular injections.

The efficacy of faricimab versus aflibercept for nAMD was assessed in 2 identical randomised, double-blind phase 3 noninferiority trials: TENAYA and LUCERNE (pooled n=1329 participants aged 50 years or older). Participants were randomised to receive intravitreal faricimab 6 mg up to every 16 weeks (interval modified according to disease activity), or aflibercept 2 mg every 8 weeks. The primary endpoint was mean change in best corrected visual acuity (BCVA) at week 48, measured using the Early Treatment Diabetic Retinopathy Study (ETDRS) tool.* Faricimab was found to be noninferior to aflibercept in these trials, with participants in both the faricimab and aflibercept groups gaining approximately 6 ETDRS letters in reading improvement in both trials. At week 48, approximately 80% of faricimab-treated patients were on 12-week or 16-week dosing intervals.² Study treatment was administered up to week 108, but longer-term outcomes have not yet been reported.

The efficacy of faricimab for diabetic macular oedema was also assessed in 2 identical randomised, double-blind phase 3 noninferiority trials: YOSEMITE and RHINE (pooled n=1891 participants with an average age of 62 years). Participants were randomised to receive intravitreal faricimab 6 mg every 8 weeks, faricimab 6 mg per personalised treatment interval (ranging from every 4 weeks up to every 16 weeks, modified according to disease activity), or aflibercept 2 mg every 8 weeks. The primary endpoint was mean change in BCVA at week 52. Faricimab was found to be noninferior to aflibercept in both trials, with participants who received faricimab every 8 weeks or at a variable dosage interval, or aflibercept, gaining approximately 11 ETDRS letters in reading improvement. At week 52, more than 70% of patients who received faricimab at variable intervals were on 12-week or 16-week dosing intervals.³ Improvements in visual acuity were maintained at 2 years.⁴

Safety of faricimab was assessed in 1926 patients across the 4 above-mentioned phase 3 trials for nAMD and diabetic macular oedema. Rates of ocular adverse events were similar for faricimab and aflibercept, ranging from 31 to 47% in different arms of the studies. Most of these events were mild or moderate in severity. In the pooled data for faricimab, the most frequently reported ocular adverse effects were cataract (10.7%), conjunctival haemorrhage (7.3%), increased intraocular pressure (3.6%), vitreous floaters (3.6%), eye pain (2.5%) and retinal pigment epithelial tear (nAMD only) (2.9%). Serious adverse effects included cataract (0.9%), uveitis (0.5%), endophthalmitis (0.3%), vitritis (0.3%), retinal tear (0.2%) and rhegmatogenous retinal detachment (less than 0.1%).⁵ Common non-ocular adverse events were generally similar for faricimab and aflibercept.⁵

Rare cases of retinal vasculitis and/or retinal occlusive vasculitis have been reported in patients treated with faricimab in the postmarketing setting. This is discussed in a recent Medicines Safety Update published by the Therapeutic Goods Administration.

The recommended dosage of faricimab for both nAMD and diabetic macular oedema is 6 mg by intravitreal injection every 4 weeks for the first 4 doses, followed by individualised dosing based on anatomic or visual outcomes (every 8 to 16 weeks for nAMD, and every 4 weeks but may be extended in 4-week increments up to every 16 weeks for diabetic macular oedema). Continued monitoring of disease activity and individualisation of dosing is recommended.⁵

In conclusion, faricimab provides clinical benefits for patients with nAMD and diabetic macular oedema, and has the potential to extend treatment intervals, thus reducing visits and treatment burden for the patient.

References
1. Macular Disease Foundation Australia. [cited 2024 Jan 30]


Ref. Australian Prescriber

**Status in India:** As per the report GSK has launched Faricimab 6mg/0.05mL solution for Intravitreal Injection in India on 5th March 2024 after receiving Import licence issued by the CDSCO. As per the industry source the treatment regime can cost upto Rs. 4 lakhs in the first year and it can reduce to around Rs. 2 lakhs in the subsequent year.

**Litigation on Safety of Ranitidine**

In a recent litigation filed at a Chicago court by one 89 years old person Angela Valadgela from Illinois, USA against GSK claiming that Zantac causes cancer. She allege that she developed colorectal cancer as a result of taking over-the-counter Zantac and generic versions of it from 1995 to 2014. She also stated that its active ingredient, ranitidine, as it ages turns into a cancer-causing substance called n-nitrosodimethylamine (NDMA). This news raised concern round the globe.

It may be noted that USFSA has requested that removing all Ranitidine product from the market through a press release on April 01, 2020 CDSCO in India also advised all state Drugs Controller for advising all manufacturer of Ranitidine to include the ADR-Cardiac arrest in the Product Information Labels (PIL). Thereafter there were several reports were not confirmed this ADR, but all concerned require to be alert about it.

Ref. Reuters

**AstraZeneca admits in court that its Covid vaccine can cause rare side-effect of Thrombosis with Thrombocytopenia Syndrome (TTS)**

Pharmaceutical giant AstraZeneca has accepted for the first time that its Covid vaccine “can, in very rare cases, cause TTS”.

Pharmaceutical giant AstraZeneca has accepted for the first time that its Covid vaccine “can, in very rare cases, cause TTS”. The admission was made in a legal document submitted to the High Court in February.

The company stated in the document that TTS can happen even if there is no vaccination, adding that expert testimony will be required to determine causation in every individual case.

AstraZeneca has been fighting a class action lawsuit that alleges its Covid vaccine, which was developed with the help of University of Oxford, has led to several deaths and serious injury.

According to the attorneys, some households faced a "devastating effect" of the vaccination.

Last year, Jamie Scott, the father of two, filed a first complaint against the British-Swedish multinational pharmaceutical and Biotechnology Company.

In his complaint, Scott mentioned that he developed a “blood clot and a bleed on his brain”, leaving him with a severe brain impairment. He blamed his situation on AstraZeneca Covid vaccine, which he received in April 2021. The hospital even informed his wife that Scott would not be able to survive. AstraZeneca is fighting these claims in the court.

Ref. Hindusthan Times

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