Vabysmo™ (faricimab-svoa) – New drug approval

- On January 28, 2022, Genentech announced the FDA approval of Vabysmo (faricimab-svoa), for the treatment of patients with neovascular (wet) age-related macular degeneration (nAMD) and diabetic macular edema (DME).

- Vabysmo is a bispecific antibody that works by neutralizing angiopoietin-2 (Ang-2) and vascular endothelial growth factor-A (VEGF-A). Ang-2 and VEGF-A contribute to vision loss by destabilizing blood vessels, causing new leaky blood vessels to form and increasing inflammation.

- The efficacy of Vabysmo was established in two randomized, double-masked, active comparator-controlled studies (TENAYA and LUCERNE) in 1,329 patients with nAMD. Patients received Vabysmo or another VEGF inhibitor, Eylea® (aflibercept). The primary endpoint was the mean change from baseline in Best Corrected Visual Acuity (BCVA) when averaged over the week 40, 44, and 48 visits and measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) letter chart.

    - Both studies demonstrated non-inferiority for Vabysmo to Eylea for the primary endpoint.

- In addition, the efficacy of Vabysmo was established in two randomized, double-masked, active comparator-controlled studies (YOSEMITE and RHINE) in 1,891 patients with DME. Patients were randomized to one of three treatment regimens: 1) Eylea administered every 8 weeks (Q8W) after the first five monthly doses; 2) Vabysmo administered every 8 weeks after the first six monthly doses (Vabysmo Q8W); and 3) Vabysmo administered every 4 weeks for at least 4 doses, then the interval of dosing was modified by up to 4-week interval extensions or reductions in up to 8-week interval increments based on clinical assessment (Vabysmo Variable). The primary endpoint was the mean change from baseline in BCVA at year 1 (average of the week 48, 52, and 56 visits), measured by the ETDRS letter score.

    - In both studies, Vabysmo Q8W and Vabysmo Variable treated patients had a mean change from baseline in BCVA that was non-inferior to the patients treated with Eylea.

- Vabysmo is contraindicated in patients with:

    - Ocular or periocular infections
    - Active intraocular inflammation
    - Known hypersensitivity to faricimab or any of the excipients in Vabysmo.

- Warnings and precautions for Vabysmo include endophthalmitis and retinal detachments, increase in intraocular pressure, and thromboembolic events.

- The most common adverse reaction (≥ 5%) with Vabysmo use was conjunctival hemorrhage.

- For nAMD, the recommended dose for Vabysmo is 6 mg administered by intravitreal injection every 4 weeks for the first 4 doses, followed by optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to inform whether to give a 6 mg dose via intravitreal injection on one of the following three regimens: 1) weeks 28 and 44; 2) weeks 24, 36 and 48; or 3) weeks 20, 28, 36 and 44.

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    - Although additional efficacy was not demonstrated in most patients when Vabysmo was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4-week (monthly) dosing after the first 4 doses. Patients should be assessed regularly.

- For DME, Vabysmo is recommended to be dosed by following one of these two regimens:

    - 6 mg administered by intravitreal injection every 4 weeks for at least 4 doses. If after at least 4 doses, resolution of edema based on the central subfield thickness (CST) of the macula as measured by optical coherence tomography is achieved, then the interval of dosing may be modified by extensions of up to 4-week interval increments or reductions of up to 8-week interval increments based on CST and visual acuity evaluations through week 52.
    - 6 mg dose of Vabysmo can be administered every 4 weeks for the first 6 doses, followed by 6 mg dose via intravitreal injection at intervals of every 8 weeks (2 months) over the next 28 weeks.
    - Although additional efficacy was not demonstrated in most patients when Vabysmo was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4-week (monthly) dosing after the first 4 doses. Patients should be assessed regularly.

- Vabysmo must be administered by a qualified physician and each vial of Vabysmo should only be used for the treatment of a single eye.

- Genentech plans to launch Vabysmo in the coming weeks. Vabysmo will be available as a 120 mg/mL solution in a single-dose vial.