Kesimpta® (ofatumumab) – New drug approval

- On August 20, 2020, Genmab and Novartis announced the FDA approval of Kesimpta (ofatumumab), for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

- The precise mechanism by which Kesimpta exerts its therapeutic effects in MS is unknown, but is presumed to involve binding to CD20, a cell surface antigen present on pre-B and mature B lymphocytes. Following cell surface binding to B lymphocytes, Kesimpta results in antibody-dependent cellular cytolysis and complement-mediated lysis.

- Ofatumumab is also available as an intravenous formulation (Arzerra®) indicated for chronic lymphocytic leukemia. Kesimpta is a subcutaneous injection.

- The efficacy of Kesimpta was established in two double-blind, active comparator studies in 1,882 patients with relapsing forms of MS. Patients were randomized to Kesimpta or teriflunomide. The primary endpoint of both studies was the annualized relapse rate (ARR) over the treatment period.

    — In study 1, the ARR was 0.11 for the Kesimpta group vs. 0.22 for the teriflunomide group (Relative reduction: 51%; $p < 0.001$).
    — In study 2, the ARR was 0.10 for the Kesimpta group vs. 0.25 for the teriflunomide group (Relative reduction: 59%; $p < 0.001$).

- Kesimpta is contraindicated in patients with active hepatitis B virus infection.

- Warnings and precautions for Kesimpta include infections, injection-related reactions, reduction in immunoglobulins, and fetal risk.

- The most common adverse reactions (> 10%) with Kesimpta use were upper respiratory tract infection, headache, injection-related reactions, and local injection site reactions.

- The recommended dose of Kesimpta is initial dosing of 20 mg by subcutaneous (SC) injection at weeks 0, 1, and 2, followed by subsequent dosing of 20 mg by SC injection once monthly starting at week 4.

    — Kesimpta is intended for patient self-administration by SC injection.
    — Kesimpta should be administered in the abdomen, thigh, or outer upper arm SC. Kesimpta should not be injected into moles, scars, stretch marks or areas where the skin is tender, bruised, red, scaly or hard.
    — The first injection of Kesimpta should be performed under the guidance of a healthcare professional.

- Novartis plans to launch Kesimpta in early September 2020. Kesimpta will be available as 20 mg/0.4 mL in a single-dose prefilled Sensoready® pen or single-dose prefilled syringe.