Blenrep® (belantamab mafodotin-blmf) – New orphan drug approval

- On August 6, 2020, GlaxoSmithKline announced the FDA approval of Blenrep (belantamab mafodotin-blmf), for the treatment of adult patients with relapsed or refractory multiple myeloma (MM) who have received at least 4 prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.

    — This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

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- MM is the second most common blood cancer in the U.S. and is generally considered treatable, but not curable.

    — In the U.S., more than 32,000 people are estimated to be diagnosed with MM this year and nearly 13,000 people will die from the disease.

- Blenrep is an antibody-drug conjugate. The antibody component is directed against the B cell maturation antigen (BCMA), a protein expressed on normal B lymphocytes and MM cells. Blenrep is the first drug to target BCMA.

- The efficacy of Blenrep was demonstrated in DREAMM-2, an open-label study enrolling 97 patients with relapsed or refractory MM, who had previously received 3 or more prior therapies, including an anti-CD38 monoclonal antibody, and were refractory to an immunomodulatory agent and a proteasome inhibitor. Patients received Blenrep 2.5 mg/kg intravenously (IV) once every 3 weeks until disease progression or unacceptable toxicity. The major efficacy outcome measure was overall response rate (ORR).

    — The ORR was 31% (97.5% CI: 21%, 43%).
    — In addition, the median time to first response was 1.4 months (95% CI: 1.0, 1.6). Seventy-three percent of responders had a duration of response ≥6 months.

- Blenrep carries a boxed warning for ocular toxicity, including severe vision loss, corneal ulcer, blurred vision, and dry eyes. In a safety analysis, 77% of patients developed ocular adverse events. Blenrep will be available through a REMS program to ensure appropriate use monitoring for ocular toxicity.

- Warnings and precautions for Blenrep include thrombocytopenia, infusion-related reactions, and embryo-fetal toxicity.

- The most common adverse reactions (≥ 20%) with Blenrep use were keratopathy (corneal epithelium change on eye exam), decreased visual acuity, nausea, blurred vision, pyrexia, infusion-related reactions, and fatigue.

- The most common grade 3 or 4 laboratory abnormalities (≥ 5%) with Blenrep use are decreased platelets, decreased lymphocytes, decreased hemoglobin, decreased neutrophils, increased creatinine, and increased gamma-glutamyl transferase.

- The recommended dose of Blenrep is 2.5 mg/kg of actual body weight given as an IV infusion over approximately 30 minutes once every 3 weeks until disease progression or unacceptable toxicity.

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- Blenrep will be priced at $23,900 per month.

- GlaxoSmithKline's launch plans for Blenrep are pending. Blenrep will be available as a 100 mg of lyophilized powder in a single-dose vial for reconstitution and further dilution.

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