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Elrexfio™ (elranatamab-bcmm) – New orphan drug approval

- On August 14, 2023, Pfizer announced the FDA approval of Elrexfio (elranatamab-bcmm), for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

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

- Multiple myeloma affects plasma cells made in the bone marrow. Multiple myeloma is the second most common type of blood cancer, with over 35,000 new cases of multiple myeloma diagnosed annually in the U.S.

- Elrexfio is a B-cell maturation antigen (BCMA)-CD3-directed bispecific antibody immunotherapy that binds to BCMA on myeloma cells and CD3 on T-cells, bringing them together and activating the T-cells to kill myeloma cells.

- The efficacy of Elrexfio was established in MagnetisMM-3, an open-label, single arm study in patients with relapsed or refractory multiple myeloma who were refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one anti-CD38 monoclonal antibody. The trial included 123 patients naïve to prior BCMA-directed therapy (pivotal Cohort A) and 64 patients with prior BCMA-directed antibody drug conjugate or chimeric antigen receptor (CAR) T-cell therapy (supportive Cohort B). Efficacy was based on response rate and duration of response (DOR).

  — In BCMA-directed therapy naïve patients, the ORR was 57.7% (95% CI: 47.3, 67.7). The median DOR was not reached.
  — In patients with prior BCMA-directed therapy, the ORR was 33.3% (95% CI: 22.0, 46.3). The median DOR was not reached.

- Elrexfio carries a boxed warning for cytokine release syndrome (CRS) and neurologic toxicity including immune effector cell-associated neurotoxicity syndrome (ICANS).

  — Elrexfio is available only through a restricted program called the Elrexfio Risk Evaluation and Mitigation Strategy (REMS).

- Additional warnings and precautions for Elrexfio include infections, neutropenia, hepatotoxicity, and embryo-fetal toxicity.

- The most common adverse reactions (≥ 20%) with Elrexfio use were CRS, fatigue, injection site reaction, diarrhea, upper respiratory tract infection, musculoskeletal pain, pneumonia, decreased appetite, rash, cough, nausea, and pyrexia. The most common Grade 3 to 4 laboratory abnormalities (≥ 30%) were decreased lymphocytes, decreased neutrophils, decreased hemoglobin, decreased white blood cells, and decreased platelets.

- The recommended dosages of Elrexfio subcutaneous injection are: step-up dose 1 of 12 mg on day 1, step-up dose 2 of 32 mg on day 4, followed by the first treatment dose of 76 mg on day 8, and then 76 mg weekly thereafter through week 24.

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  - For patients who have received at least 24 weeks of treatment with Elrexfio and have achieved a response and maintained this response for at least 2 months, the dose interval should transition to an every two-week schedule.
  - Treatment should continue until disease progression or unacceptable toxicity.

- Pfizer plans to launch Elrexfio in the coming weeks. Elrexfio will be available as 76 mg/1.9 mL and 44 mg/1.1 mL single-dose vials.

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