Tremfya® (guselkumab) – New indication

- On September 11, 2024, J&J announced the FDA approval of Tremfya (guselkumab), for the treatment of adult patients with moderately to severely active ulcerative colitis (UC).

- Tremfya is also approved for the treatment of adult patients with:

  — Moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy; and
  — Treatment of adult patients with active psoriatic arthritis.

- The approval of Tremfya for the new indication was based on an induction and maintenance therapy study. The induction therapy study (UC-1) was conducted in 701 patients with moderately to severely active UC. Patients were randomized to receive either Tremfya or placebo by intravenous (IV) infusion at week 0, week 4, and week 8. The primary endpoint was clinical remission at week 12 as defined by the modified Mayo score (mMS).

  — Clinical remission was achieved in 23% of patients with Tremfya vs. 8% with placebo (treatment difference 15%, 95% CI: 10, 20; $p < 0.001$).

- The maintenance therapy study (UC-2) was conducted in 568 patients who received Tremfya induction regimens in previous induction therapy studies and demonstrated clinical response per mMS after 12 weeks. Patients were re-randomized to receive a subcutaneous (SC) maintenance regimen of either Tremfya 100 mg every 8 weeks, Tremfya 200 mg every 4 weeks, or placebo for up to an additional 44 weeks. The primary endpoint was clinical remission at week 44 defined by mMS.

  — Clinical remission was achieved in 45% of patients with Tremfya 100 mg, 50% with Tremfya 200 mg, and 19% with placebo. Treatment difference vs. placebo was 25% (95% CI: 16, 34; $p < 0.001$) for Tremfya 100 mg and 30% (95% CI: 21, 38; $p < 0.001$) for Tremfya 200 mg.

- The most common adverse reaction (≥ 2%) with Tremfya induction therapy was respiratory tract infections. The most common adverse reactions (≥ 3%) with Tremfya maintenance therapy were injection site reactions, arthralgia, and upper respiratory tract infection.

- The recommended induction dosage of Tremfya is 200 mg administered by IV infusion over at least one hour at week 0, week 4, and week 8.

- The recommended maintenance dosage of Tremfya is 100 mg administered by SC injection at week 16, and every 8 weeks thereafter; or 200 mg administered by SC injection at week 12, and every 4 weeks thereafter. The lowest effective recommended dosage should be used to maintain therapeutic response.

  — Tremfya is intended for use under the guidance and supervision of a healthcare professional. Tremfya may be administered by a healthcare professional, or a patient/caregiver may inject after proper training on correct SC injection technique.

- Refer to the Tremfya drug label for dosing for its other indications.

- In June 2024, J&J also submitted a supplemental Biologics License Application (sBLA) to the FDA seeking approval of Tremfya for the treatment of adult patients with moderately to severely active Crohn's disease.

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— Assuming a standard review, an approval decision is expected in the first half of 2025.