## Tremfya™ (guselkumab) – New drug approval

- On July 13, 2017, Janssen Biotech announced the FDA approval of Tremfya (guselkumab), for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

- Psoriasis is an autoimmune disorder affecting the skin. The condition most often begins in people between 15 – 35 years of age.

    — The most common form of psoriasis is plaque psoriasis, in which people develop thick, red skin with flaky, silver-white scales.

- Tremfya is the first human monoclonal antibody therapy that selectively blocks interleukin (IL)-23, a cytokine that plays a key role in plaque psoriasis.

- The safety and efficacy of Tremfya were based on results from a clinical development program involving more than 2,000 adult patients in the VOYAGE 1, VOYAGE 2, and NAVIGATE studies.

    — In VOYAGE 1 and VOYAGE 2, at 16 weeks, 70% – 73% of Tremfya-treated patients achieved ≥ 90% clearer skin from baseline, and 84% – 85% demonstrated clear or almost clear skin.
    — In addition, at week 24, 71% – 80% of Tremfya-treated patients achieved ≥ 90% clearer skin from baseline vs. 44% – 51% of patients treated with Humira® (adalimumab).
    — In NAVIGATE, the effectiveness of Tremfya was demonstrated in patients who had an inadequate response to treatment with Stelara® (ustekinumab). At week 28, 31% of Tremfya-treated patients were considered clear or almost clear with a ≥ 2-grade improvement vs. 14% of Stelara-treated patients.

- Warnings and precautions of Tremfya include infections, pre-treatment evaluation for tuberculosis, and immunizations.

- The most common adverse reactions (≥ 1%) with Tremfya use were upper respiratory infections, headache, injection site reactions, arthralgia, diarrhea, gastroenteritis, tinea infections, and herpes simplex infections.

- The recommended subcutaneous (SC) dose of Tremfya is 100 mg at week 0, week 4, and every 8 weeks thereafter.

    — Tremfya is intended for use under the guidance and supervision of a physician. Tremfya may be administered by a healthcare professional, or a patient may self-inject after proper training in SC injection technique.

- Janssen plans to work closely with payers, providers and pharmacy benefit managers to ensure Tremfya is broadly accessible and affordable for patients and that the cost for payers is competitive with currently available biologic therapies for psoriasis.

    — Janssen offers a number of patient support programs, including a co-pay card for patients with commercial insurance that reduces their out-of-pocket cost for Tremfya to no more than $5 per dose.

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- Janssen Biotech's launch plans for Tremfya are pending. Tremfya will be available as a single-dose 100 mg/mL prefilled syringe.