Spevigo® (spesolimab-sbzo) – New orphan drug approval

- On September 1, 2022, Boehringer Ingelheim announced the FDA approval of Spevigo (spesolimab-sbzo), for the treatment of generalized pustular psoriasis (GPP) flares in adults.

- GPP is a rare, heterogenous and potentially life-threatening neutrophilic skin disease, which is clinically distinct from plaque psoriasis. GPP is caused by neutrophils accumulating in the skin, resulting in painful, sterile pustules all over the body. The clinical course varies, with some patients having a relapsing disease with recurrent flares, and others having a persistent disease with intermittent flares.

    — In the U.S., it is estimated that 1 out of every 10,000 people has GPP.

- Spevigo is a monoclonal antibody that inhibits interleukin-36 (IL-36) signaling by specifically binding to the IL36R. Binding of Spevigo to IL36R prevents the subsequent activation of IL36R and downstream activation of pro-inflammatory and pro-fibrotic pathways.

- The efficacy of Spevigo was established in a randomized, double-blind, placebo-controlled study (Effisayil-1) in 53 adult patients with flares of GPP. Patients were required to discontinue systemic and topical therapy for GPP prior to receiving study drug. Patients received a single dose of Spevigo or placebo during the double-blind portion of the study. The primary endpoint of the study was the proportion of patients with a Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) pustulation sub score of 0 (indicating no visible pustules) at week 1 after treatment.

    — The primary endpoint was met in 54% of patients with Spevigo vs. 6% with placebo (risk difference 49%, 95% CI: 21, 67).

- In Effisayil-1, patients in either treatment group who continued to experience flare symptoms at week 1 were eligible to receive a single open-label dose of Spevigo (second dose and first dose for patients in the Spevigo and placebo groups, respectively). At week 1, 12 (34%) patients and 15 patients (83%) in the Spevigo and placebo groups, respectively, received open-label Spevigo.

    — In patients who were randomized to Spevigo and received an open-label dose of Spevigo at week 1, 5 (42%) patients had a GPPPGA pustulation sub score of 0 at week 2 (one week after their second dose of Spevigo).

- Warnings and precautions for Spevigo include infections, risk of tuberculosis, hypersensitivity and infusion-related reactions, and vaccinations.

- The most common adverse reactions (≥ 5%) with Spevigo use were asthenia and fatigue, nausea and vomiting, headache, pruritus and prurigo, infusion site hematoma and bruising, and urinary tract infection.

- The recommended dose of Spevigo is a single 900 mg dose by intravenous (IV) infusion over 90 minutes.

    — If GPP flare symptoms persist, an additional IV 900 mg dose may be administered one week after the initial dose.

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- Boehringer Ingelheim's launch plans for Spevigo are pending. Spevigo will be available as a 450 mg/7.5 mL (60 mg/mL) solution in a single-dose vial.