Spesolimab in Generalized Pustular Psoriasis Flares

ICD-10-PCS Presentation

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What is Spesolimab?

- Spesolimab is a humanized antagonistic monoclonal immunoglobulin G1 antibody blocking human IL-36 Receptor signalling

- The efficacy and safety of a single intravenous dose of Spesolimab for GPP flares was evaluated in Effisayil-1™, a multi-center, double-blind, randomized, placebo-controlled, Phase II study

- As of January 2022, an indication of Spesolimab for the treatment of GPP flares is under FDA review

What Does Spesolimab Do?

- The immunopathological component of GPP flares has been linked to the IL-36 pathway, with dysregulated signaling stimulating excessive proinflammatory cytokine and chemokine production, leading to neutrophilic and mononuclear inflammatory infiltrates in the epidermis, and the development of sterile, macroscopic pustules.

- Spesolimab is a humanized antagonistic monoclonal immunoglobulin G1 antibody blocking human IL36Receptor signaling.

- Blockade of the IL-36 pathway with Spesolimab has a rapid biological effect, normalizing cytokine signaling, immune cell activation and neutrophil recruitment, and inhibiting hyperkeratosis to restore epithelial barrier function in the skin.

How is Spesolimab Used?

- The efficacy and safety of a single intravenous dose of Spesolimab for GPP flares was evaluated in Effisayil-1™, a multi-center, double-blind, randomized, placebo-controlled, Phase II study
  - Spesolimab treatment of GPP flares was associated with rapid pustular and skin clearance within 1 week compared with placebo, with complete clearance of pustules observed as early as 24 hours in some patients
  - Pustular and skin clearance was sustained during the 12 weeks trial duration
  - These improvements were accompanied by clinically significant improvements in patient-reported quality of life and symptoms, such as pain, cutaneous symptoms and fatigue
  - Adverse events were reported in 66% of patients treated with Spesolimab and 56% of those receiving placebo after the first week. Infections were reported by 17% and 6% of patients in the Spesolimab and placebo groups, respectively.

Procedural Steps to Administering Spesolimab[1]

Spesolimab must be diluted before use

Preparation

- Use aseptic technique to prepare the solution for infusion.
- Draw and discard 15 mL from a 100 mL container of sterile 0.9% sodium chloride solution.
- Slowly replace with 15 mL of Spesolimab (complete content from two vials of 450 mg/7.5 mL).
- Mix gently before use.
- The diluted Spesolimab solution for infusion should be used immediately.

[1]These preparation and administration steps were implemented in the Phase II trial Effisayil-1™

Procedural Steps to Administering Spesolimab[1]

Administration

- Do not mix Spesolimab with other medicinal products.
- Administer Spesolimab as a continuous intravenous infusion through an intravenous line containing a sterile, non-pyrogenic, low protein binding in-line filter (pore size of 0.2 micron) over 90 minutes.
- If the infusion is slowed or temporarily stopped, the total infusion time (including stop time) should not exceed 180 minutes.
- A pre-existing intravenous line may be used for administration of Spesolimab. The line must be flushed with sterile 0.9% sodium chloride solution prior to and at the end of infusion. No other infusion should be administered in parallel via the same intravenous access.

[1]These preparation and administration steps were implemented in the Phase II trial Effisayil-1™

Spesolimab Utilization by Setting

- Pending the ongoing FDA review of the submitted Spesolimab BLA and an FDA approval upon action, Spesolimab will be administered to the appropriate patients in both the hospital inpatient and outpatient settings

- Setting for utilization will be determined by the clinical presentation

Diagnostic Codes to Report the Indication for the Use of Spesolimab

- The ICD-10-CM code to report the indication for the use of Spesolimab is L40.1 for Generalized Pustular Psoriasis

- There are no other ICD-10-CM coding options that apply to Generalized Pustular Psoriasis

Where is the Use of Spesolimab Reported in a Medical Record?

- The administration of Spesolimab would be reported in the body of the procedure report with details on dose and route of administration

- The use of Spesolimab will also be recorded in the Medication Administration Record (drug chart)

- Medical coders will determine the appropriate ICD-10-PCS code from the name of the drug administered, based on the descriptor assigned the new code, if granted

What are the Different Naming Conventions for Spesolimab?

- The generic name for this drug is Spesolimab
- As of January 2022, Spesolimab has not yet received FDA approval and no trade name has been approved

What is the Route of Administration for Spesolimab?

- Spesolimab is administered by intravenous infusion as a single 900 mg (2 x 450 mg/7.5 mL vials) over 90 minutes

Possible Complications for Spesolimab

- As of January 2022, Spesolimab has not yet received an FDA approved label
  - Potential risks of Spesolimab include hypersensitivity, infection and malignancy, common to biologic/antibody therapeutics
  - Adverse Drug Reactions include urinary tract infection, upper respiratory tract infection, pruritis, injection site reactions, and fatigue

Summary of Adverse Events through 12 Weeks in Spesolimab Effisayil-1 Clinical Trial

Patients with AE, n (percentage)	Week 1		Week 12
	Spesolimab (n 35)	Placebo (n 18)	Spesolimab (n 51)
Any AE	23 (66)	10 (56)	42 (82)
Severe AE (RCTC grade 3 or 4)	2 (6)	1 (6)	5 (10)
Investigator-defined drug-related AE	10 (29)	5 (28)	28 (55)
Serious AE	2 (6)	0	6 (12)
Death	0	0	0
Common AEs			
Pyrexia (PT)	2 (6)	4 (22)	5 (10)
Dizziness (PT)	0	2 (11)	0

Common AEs were defined as those experienced by ≥10% of patients in any treatment group.

Thank You