

## Siliq™ (brodalumab) – New Drug Approval

- On February 15, 2017, the [FDA announced](#) the approval of [Valeant's Siliq \(brodalumab\)](#), for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.
- 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.
- Siliq contains brodalumab, a human monoclonal IgG2 antibody that selectively targets the interleukin-17 (IL-17) receptor. Blocking the IL-17 receptor inhibits certain inflammatory responses that play a role in the development of plaque psoriasis.
- The safety and efficacy of Siliq were based on three placebo-controlled trials involving 4,373 adult patients with moderate-to-severe plaque psoriasis.
  - In all three trials, more patients treated with Siliq had skin that was clear or almost clear compared to patients in the placebo group.
  - In addition, a greater proportion of patients treated with Siliq achieved 100% improvement in their symptoms compared to [Stelara® \(ustekinumab\)](#).
- Siliq carries a boxed warning regarding the risk of suicidal ideation and behavior.
- Siliq is contraindicated in patients with Crohn's disease because Siliq may cause worsening of disease.
- Other warnings and precautions of Siliq include Siliq REMS program, infections, risk for latent tuberculosis reactivation, and immunizations.
- The most common adverse events ( $\geq 1\%$ ) with Siliq use were arthralgia, headache, fatigue, diarrhea, oropharyngeal pain, nausea, myalgia, injection site reactions, influenza, neutropenia, and tinea infections.
- The recommended dose of Siliq is 210 mg administered by subcutaneous injection at weeks 0, 1, and 2, followed by 210 mg every 2 weeks.
  - If an adequate response has not been achieved after 12 – 16 weeks of treatment with Siliq, consider discontinuing therapy. Continued treatment beyond 16 weeks in patients who have not achieved an adequate response is not likely to result in greater success.

- Valeant plans to launch Siliq in the second half of 2017. Siliq will be available as a 210 mg/1.5 mL solution in a single-dose prefilled syringe.



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