Regranex® (becaplermin) – Removal of warning

- On November 28, 2018, the FDA approved the removal of the *Boxed Warning* and the warning in the *Warnings and Precautions* section of the Regranex (becaplemin) drug label regarding increased rate of mortality secondary to malignancy.

- Regranex is indicated for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply, when used as an adjunct to, and not a substitute for, good ulcer care practices including initial sharp debridement, pressure relief and infection control.

    - The efficacy of Regranex has not been established for the treatment of pressure ulcers and venous stasis ulcers and has not been evaluated for the treatment of diabetic neuropathic ulcers that do not extend through the dermis into subcutaneous tissue (Stage I or II, International Association of Enterostomal Therapy staging classification) or ischemic diabetic ulcers.
    - The effects of Regranex on exposed joints, tendons, ligaments, and bone have not been established in humans.
    - Regranex is a non-sterile, low bioburden preserved product. Therefore, it should not be used in wounds that close by primary intention.

- Regranex is contraindicated in patients with known neoplasm(s) at the site(s) of application.