Opdivo Qvantig™ (nivolumab/hyaluronidase-nvhy) – New formulation approval

- On December 27, 2024, the FDA announced the approval of Bristol Myers Squibb's Opdivo Qvantig (nivolumab/hyaluronidase-nvhy), a **subcutaneous (SC) formulation of** Opdivo® (nivolumab).

- **Opdivo Qvantig (SC) is approved across adult, solid tumor Opdivo intravenous (IV) indications** as monotherapy, monotherapy maintenance following completion of IV Opdivo plus Yervoy® (ipilimumab) combination therapy, or in combination with chemotherapy or cabozantinib.

    - Approved indications include renal cell carcinoma, melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, urothelial carcinoma, colorectal cancer, hepatocellular carcinoma, esophageal carcinoma, gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma.
    - Opdivo Qvantig is not indicated in combination with intravenous Yervoy.
    - Refer to Opdivo Qvantig drug label for a complete listing of its indications.

- Opdivo is a programmed death receptor-1 (PD-1)-blocking antibody.

- The approval of Opdivo Qvantig was based on CheckMate-67T, a randomized, open-label study in 495 patients with advanced or metastatic clear cell renal cell carcinoma. Patients were randomized to either SC Opdivo Qvantig or IV Opdivo. The primary objective was to assess the nivolumab exposure of SC administration of Opdivo Qvantig compared to IV Opdivo. The key secondary objective was to evaluate overall response rate (ORR).

    - The trial met the predefined acceptance margin for pharmacokinetic endpoints.
    - ORR was 24% (95% CI: 19, 30) in the SC Opdivo arm and 18% (95% CI: 14, 24) in the IV Opdivo arm.

- Warnings and precautions for Opdivo Qvantig include severe and fatal immune-mediated adverse reactions; complications of allogeneic hematopoietic stem cell transplantation; embryo-fetal toxicity; and increased mortality in patients with multiple myeloma when nivolumab is added to a thalidomide analogue and dexamethasone.

- The most common adverse reactions (≥ 10%) with Opdivo Qvantig use as monotherapy in patients with renal cell carcinoma were musculoskeletal pain, fatigue, pruritus, rash, hypothyroidism, diarrhea, cough, and abdominal pain.

- The safety of Opdivo Qvantig for its other indications is based on safety of intravenous Opdivo.

- Opdivo Qvantig is administered via SC injection over 3 to 5 minutes by a healthcare provider. The IV formulation requires 30 minutes for infusion.

    - Refer to the Opdivo Qvantig drug label for complete dosing and administration recommendations.

- Bristol Myers Squibb plans to launch Opdivo Qvantig in **early January 2025**. Opdivo Qvantig will be available as a single-dose vial containing 600 mg nivolumab and 10,000 units hyaluronidase per 5 mL (120 mg/2,000 units per mL). **The list price is expected to be at parity with Opdivo IV**.

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— Opdivo IV has a list price of $7,635 per infusion for two weeks for the lower dose and $15,269 per infusion for four weeks for the higher 480-milligram dose.