Balversa™ (erdafitinib) – New drug approval

- On April 12, 2019, the FDA announced the approval of Janssen's Balversa (erdafitinib), for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (mUC), that has susceptible fibroblast growth factor receptor (FGFR)3 or FGFR2 genetic alterations, and progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

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  - Select patients for therapy based on a FDA-approved companion diagnostic for Balversa. Qiagen launched its *therascreen*® FGFR RGQ RT-PCR Kit as a companion diagnostic.
  - This indication is approved under accelerated approval based on tumor response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

- UC represents > 90% of bladder cancers. About one in five patients with mUC have a FGFR genetic alteration. In the U.S., it is estimated that up to 3,000 people with UC will test FGFR positive on an annual basis.

- Balversa is the first FGFR kinase inhibitor approved by the FDA. Balversa demonstrated antitumor activity in FGFR-expressing cell lines and xenograft models derived from tumor types, including bladder cancer.

- The efficacy and safety of Balversa were demonstrated in an open-label, single-arm study of 87 patients with locally advanced or mUC. Patients received Balversa until disease progression or unacceptable toxicity. The major efficacy outcome measures were objective response rate (ORR) and duration of response (DoR).

  - The ORR was 32.2% (95% CI: 22.4, 42.0).
  - The median DoR was 5.4 months (95% CI: 4.2, 6.9).

- Warnings and precautions of Balversa include ocular disorders, hyperphosphatemia, and embryo-fetal toxicity.

- The most common adverse reactions (≥ 20%) with Balversa use were increased phosphate, stomatitis, fatigue, increased creatinine, diarrhea, dry mouth, onycholysis, increased alanine aminotransferase, increased alkaline phosphatase, decreased sodium, decreased appetite, decreased albumin, dysgeusia, decreased hemoglobin, dry skin, increased aspartate aminotransferase, decreased magnesium, dry eye, alopecia, palmarplantar erythrodysesthesia syndrome, constipation, decreased phosphate, abdominal pain, increased calcium, nausea, and musculoskeletal pain.

- The recommended dose of Balversa is 8 mg (two 4 mg tablets) orally once daily, with a dose increase to 9 mg (three 3 mg tablets) once daily based on serum phosphate levels and tolerability at 14 to 21 days. Treatment should continue until disease progression or unacceptable toxicity occurs.

- Janssen's launch plans for Balversa are pending. Balversa will be available as 3 mg, 4 mg, and 5 mg tablets. Balversa will be available through the specialty pharmacy provider, US Bioservices.