

Notice to 340B Covered Entities Regarding BALVERSA™ Limited Distribution Plan

April 25, 2019

This notice provides information to 340B covered entities on how BALVERSA™ (erdafitinib) will be distributed and how all providers and patients -- 340B and non-340B alike -- can obtain the product. Janssen manufacturers the following package configurations for BALVERSA:

3mg tablets: NDC 59676-030-56 (bottle of 56), NDC 59676-030-84 (bottle of 84)

4mg tablets: NDC 59676-040-28 (bottle of 28), NDC 59676-040-56 (bottle of 56)

5mg tablets: NDC 59676-050-28 (bottle of 28)

BALVERSA was granted Breakthrough Therapy Designation by the US Food and Drug Administration and was recently approved for the treatment of urothelial cancer. BALVERSA is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma with susceptible FGFR3 or FGFR2 genetic alterations after progression following platinum-containing chemotherapy including progression within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. Patients are selected for therapy based on an FDA-approved companion diagnostic for BALVERSA.

BALVERSA will be distributed to all patients through a single Specialty Pharmacy Provider (SPP), US Bioservices. The extent of clinical challenges in terms of early dose personalization, dose reductions, and dose interruptions based on phase 2 registration study supports distribution through a single source SPP and provides a unique approach to support patients. First, the FDA-approved label requires that serum phosphate levels be determined between 14 and 21 days after starting BALVERSA. If the level is below 5.5 mg/dL and there are no ocular disorders or Grade 2 or greater adverse reactions, the dose is up-titrated from 8 mg to 9 mg once daily. Second, the median duration of treatment is 5.3 months. Dosage interruptions and dose reductions occur in 68% and 53% of patients, respectively. Therefore, a single SPP can provide more consistent support for dose management, patient experience, and outcomes.

In addition, we anticipate a very small initial patient population (approximately 500) in the first year. Accordingly, Janssen is planning to manufacture a limited supply of product. Concentrating this limited volume of multiple product strengths in a single SPP should reduce the risk of product shortages which may otherwise interfere with patient therapy. In addition, Janssen can better manage downstream inventory, minimize wastage from partial fills, and reduce the likelihood of returns.

All providers, regardless of 340B status with patients who are prescribed BALVERSA must submit prescriptions to US Bioservices for fulfillment. All providers and patients are equally subject to this limited distribution plan.

Prescription Information and Patient Support for BALVERSA™

BALVERSA™ is dispensed by US Bioservices specialty pharmacy. To request BALVERSA™ for your patient, please call 877-757-0667 or complete and fax a BALVERSA™ Referral Form available at https://www.usbioservices.com/-/media/assets/usbioservices/rx-forms/1901_rf_jnj_balversa_enrollment-form_f08-fillable.pdf

<https://www.balversahcp.com/>