

Besponsa[™] (inotuzumab ozogamicin) – New orphan drug approval

- On August 17, 2017, the <u>FDA announced</u> the approval of <u>Pfizer's Besponsa (inotuzumab ozogamicin)</u> for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).
- <u>ALL</u> is a type of cancer in which the bone marrow makes too many lymphocytes and leads to infection, anemia and bleeding. It can also spread to the central nervous system.
- The efficacy and safety of Besponsa were evaluated in an open-label clinical study of 326 patients with relapsed or refractory ALL. Patients were randomized to receive Besponsa or investigator's choice of chemotherapy.
 - Of the initial 218 randomized patients, 35.8% (95% CI: 26.8 45.5) of those who received Besponsa experienced complete remission (CR) for a median 8.0 (95% CI: 4.9 – 10.4) months and 89.7% (95% CI: 75.8 – 97.1) of those patients achieved minimal residual disease (MRD)-negativity.
 - Of the patients who received chemotherapy, 17.4% (95% CI: 10.8 25.9) experienced CR for a median 4.9 months (95% CI: 2.9 7.2) and 31.6% (95% CI: 12.6 56.6) of those patients achieved MRD-negativity.
- Besponsa carries a boxed warning for hepatotoxicity, including hepatic veno-occlusive disease, and increased risk of post-hematopoietic stem cell transplant non-relapse mortality.
- Other warnings and precautions of Besponsa include myelosuppression, infusion related reactions, QT interval prolongation, and embryo-fetal toxicity.
- The most common (≥ 20%) adverse reactions with Besponsa use were thrombocytopenia, neutropenia, infection, anemia, leukopenia, fatigue, hemorrhage, pyrexia, nausea, headache, febrile neutropenia, increased transaminases, abdominal pain, increased gamma-glutamyltransferase, and hyperbilirubinemia.
- For the first cycle, the recommended total dose of Besponsa for all patients is 1.8 mg/m² per cycle, infused as 3 divided doses on day 1 (0.8 mg/m²), day 8 (0.5 mg/m²), and day 15 (0.5 mg/m²). Cycle 1 is 3 weeks in duration, but may be extended to 4 weeks if the patient achieves a CR or CR with incomplete hematologic recovery, and/or to allow recovery from toxicity.
 - Refer to the Besponsa drug label for specific dosing instructions for subsequent cycles depending on treatment response.
 - Premedication with a corticosteroid, antipyretic, and antihistamine is recommended before each dose.
- Based on the typical duration of treatment, the total cost of the drug will be \$168,300.
- Pfizer plans to launch Besponsa next week. Besponsa will be available as a 0.9 mg lyophilized powder in a single-dose vial for reconstitution.



optumrx.com

OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.