Click here for the BESPONSA SmPC

*Results from phase 3 INO-VATE study comparing BESPONSA and SC in adult patients with R/R B-cell ALL (n=218).[1]

†Results from pooled data from INO-VATE and the earlier phase 1/2 Study 1010 of patients who received HSCT after treatment (n=101 for BESPONSA, n=31 for SC).[3]

AE=adverse event; ALL=acute lymphoblastic leukemia; CR=complete response; CRi=complete response without complete blood count recovery; HSCT=hematopoietic stem cell transplantation; MRD=minimal residual disease; OS=overall survival; R/R=relapsed or refractory; SC=standard chemotherapy.

Before prescribing Besponsa, please refer to the full Summary of Product Characteristics (SmPC). Please refer to your local authorities concerning reimbursement status. Medicinal products subject to medical prescription. For healthcare professionals only. https://www.ema.europa.eu/en/documents/product-information/besponsa-epar-product-information_en.pdf

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BESPONSA® inotuzumab ozogamicin SOLUTION FOR INFUSION

IN RELAPSED OR REFRACTORY B-CELL ALL

MAKE YOUR FIRST SHOT COUNT **AND AIM TO INCREASE LONG-TERM SURVIVAL[1,2]**

BESPONSA achieved:

80.7%
CR/CRi rate[1]* (88/109)

78%
MRD-negativity rate in patients who achieved CR/CRi[1]* (69/88)

UP TO 51%
Post-transplant OS at 2 years[3]

Indication: BESPONSA is indicated as monotherapy for the treatment of adults with relapsed or refractory CD22-positive B cell precursor acute lymphoblastic leukaemia (ALL). Adult patients with Philadelphia chromosome-positive (Ph+) relapsed or refractory B cell precursor ALL should have failed treatment with at least 1 tyrosine kinase inhibitor (TKI).

Aim to Increase Long-term Survival Rates

BESPONSA more than doubled the rate of CR/CRi and achieved higher rates of MRD-negativity among responders vs SC[1]*

- Of patients receiving BESPONSA, 80.7% (95% CI, 72.1-87.7) achieved CR/CRi, vs 29.4% (95% CI, 21.0-38.8) with SC, a difference of 51.3 percentage points ($P<0.001$)[1]
  - BESPONSA was associated with higher remission rates when used for first salvage: 87.7% CR/CRi (95% CI, 77.9-94.2) vs 28.8% for SC (95% CI, 18.8-40.6)[1]
- Of responding patients, 78.4% (95% CI, 68.4-86.5) achieved MRD-negativity with BESPONSA vs 28.1%
  (95% CI, 13.7-46.7) with SC[1]

BESPONSA demonstrated a median OS benefit of 7.7 months (95% CI, 6.0-9.2) vs 6.2 months (95% CI, 4.7-8.3) with SC (HR 0.75 [97.5% CI, 0.57-0.99] $P=0.0105$)[2*†]

- The primary endpoint of OS was not met in the INO-VATE ALL study[1,2]
- BESPONSA improved 2-year OS vs SC (22.8% [95% CI, 16.7-29.6] vs 10.0% [95% CI, 5.7-15.5)[2]

*Results from phase 3 INO-VATE study comparing BESPONSA and SC in adult patients with R/R B-cell ALL (n=218).[1]
†One-sided *P*-value using log-rank test. Surviving patients followed for a minimum of 2 years. The median follow-up duration for patients who completed the study or were censored for OS was 29.6 months (range 1.7-49.7 months).[2]
ALL=acute lymphoblastic leukemia; CI=confidence interval; CR=complete response; CRi=complete response without complete blood count recovery; HR=hazard ratio; MRD=minimal residual disease; OS=overall survival; SC=standard chemotherapy.

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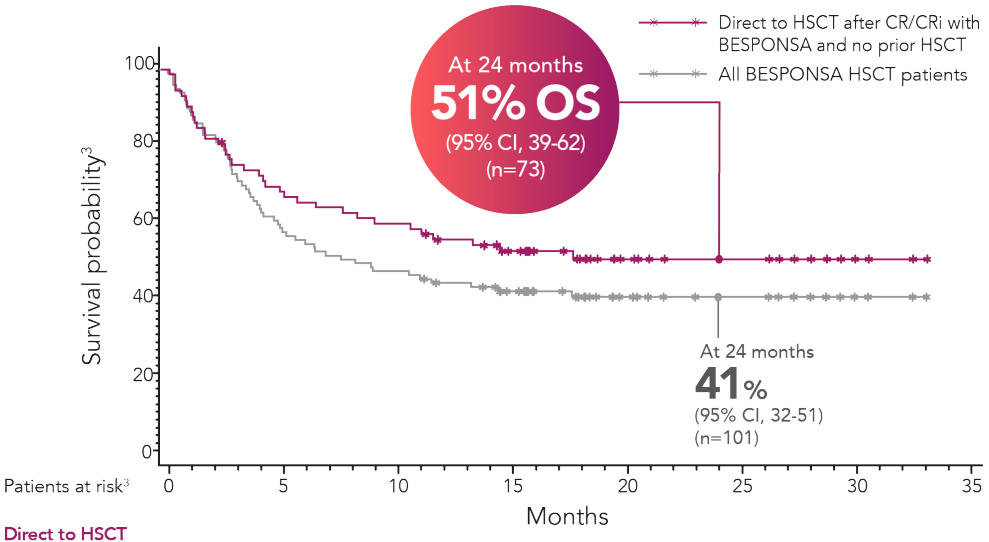
Higher Post-transplant OS Results Were Achieved After CR/CRi with BESPONSA Led Directly to a First HSCT[3]*

OS based on timing of HSCT (pooled analysis of 2 trials)



Patients at risk[3]								
Direct to HSCT after CR/CRi with BESPONSA and no prior HSCT	73	51	44	34	14	10	4	0
All BESPONSA HSCT patients	101	61	48	37	16	11	4	0

- **Higher frequency of early death post HSCT:** There was a higher frequency of early death post HSCT (at Day 100) in the BESPONSA arm; however, there was evidence of a late survival benefit for BESPONSA
- Monitor closely for toxicities post HSCT, including signs and symptoms of infection and VOD[4]

*Results from pooled data from INO-VATE and the earlier phase 1/2 Study 1010 of patients who received HSCT after treatment (n=101 for BESPONSA, n=31 for SC).[3]

CI=confidence interval; CR=complete response; CRi=complete response without complete blood count recovery; HSCT=hematopoietic stem cell transplantation; OS=overall survival; VOD=veno-occlusive disease.

BESPONSA® inotuzumab ozogamicin

BESPONSA Safety Profile

Incidence and Management of VOD Risks

- Of 79 BESPONSA-treated patients who underwent HSCT, 18 (22.8%) developed VOD/SOS[2]*
- Patient selection and therapy management should be a key focus to avoid VOD[2]
- Several risk factors were associated with increased risk for post-HSCT VOD[2]
  - Dual-alkylator conditioning regimens
  - Bilirubin ≥ULN before conditioning therapy
  - Bilirubin ≥ULN before follow-up HSCT
  - Prior HSCT
  - Age ≥55 years†
  - Number of treatment cycles received†

Other Adverse Events

- The most frequent grade ≥3 AEs in the BESPONSA arm were neutropenia (47%), thrombocytopenia (41%), leukopenia (27%), and febrile neutropenia (27%)[2]

For more information on AEs, see the BESPONSA SmPC

*Results from phase 3 INO-VATE study comparing BESPONSA and SC in adult patients with R/R B-cell ALL (n=218).[1]
†Additional VOD/SOS risk factors that were significant in a univariate analysis but not in multivariate analysis.
AE=adverse event; HSCT=hematopoietic stem cell transplantation; SOS=sinusoidal obstruction syndrome; ULN=upper limit of normal; VOD=veno-occlusive disease.

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References

1. Kantarjian HM, DeAngelo DJ, Stelljes M, et al. Inotuzumab ozogamicin versus standard care for acute lymphoblastic leukemia. *N Engl J Med.* 2016;375(8):740-753.
2. Kantarjian HM, DeAngelo DJ, Stelljes M, et al. Inotuzumab ozogamicin versus standard of care in relapsed or refractory acute lymphoblastic leukemia: final report and long-term survival follow-up from the randomized, phase 3 INO-VATE study. *Cancer*. 2019;125(14):2474-2487.
3. Marks DI, Kebriaei P, Stelljes M, et al. Outcomes of allogeneic stem cell transplantation after inotuzumab ozogamicin treatment for relapsed or refractory acute lymphoblastic leukemia. *Biol Blood Marrow Transplant.* 2019;25(9):1720-1729.
4. Besponsa summary of product characteristics, February 2022.

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BESPONSA® inotuzumab ozogamicin SOLUTION FOR INFUSION

Fachkurzinformation

BESPONSA 1 mg Pulver für ein Konzentrat zur Herstellung einer Infusionslösung

Qualitative und quantitative Zusammensetzung: Jede Durchstechflasche enthält 1mg Inotuzumab Ozogamicin. Nach der Rekonstitution enthält 1 ml Lösung 0,25 mg Inotuzumab Ozogamicin.

Liste der sonstigen Bestandteile: Sucrose, Polysorbat 80, Natriumchlorid, Tromethamin.

Anwendungsgebiete: BESPONSA ist indiziert als Monotherapie für die Behandlung von Erwachsenen mit rezidivierter oder refraktärer CD22-positiver B-Vorläufer-ALL (akuter lymphatischer Leukämie). Erwachsene Patienten mit Philadelphia-Chromosom-positiver (Ph+) rezidivierter oder refraktärer B-Vorläufer-ALL sollten eine vorhergehende erfolglose Behandlung mit mindestens 1 Tyrosinkinase-Inhibitor (TKI) aufweisen.

Gegenanzeigen: Überempfindlichkeit gegen den Wirkstoff oder einen der in Abschnitt 6.1 der Fachinformation genannten sonstigen Bestandteile. Patienten mit vorhergehender bestätigter schwerer oder bestehender venookklusiver Lebererkrankung/ sinusoidalem Obstruktionssyndrom (VOD/ SOS). Patienten mit schwerer bestehender Lebererkrankung (z. B. Leberzirrhose, nodulär regenerative Hyperplasie der Leber, aktive Hepatitis).

Pharmakotherapeutische Gruppe: Antineoplastische Mittel, andere antineoplastische Mittel, monoklonale Antikörper. ATC-Code: L01XC26.

Inhaber der Zulassung: Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Brüssel, Belgien.

Stand der Information: Februar 2022.

Rezeptpflicht/Apothekenpflicht: Rezept- und apothekenpflichtig, wiederholte Abgabe verboten. **Angaben zu besonderen Warnhinweisen und Vorsichtsmaßnahmen für die Anwendung, Wechselwirkungen mit anderen Arzneimitteln und sonstigen Wechselwirkungen, Fertilität, Schwangerschaft und Stillzeit und Nebenwirkungen entnehmen Sie bitte der veröffentlichten Fachinformation.**

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