

THE PRESCRIBE AWARDS FOR 2023

The annual Prescrire Awards are granted in total independence by the Prescrire Editorial Staff.

2023 Prescrire Drug Awards



Every month, Prescrire's Editorial Staff help health professionals decide which of the multitude of newly authorised products or indications are worth adding to their list of useful treatment options, and which are to be avoided. We do this by conducting systematic analyses of the relevant evaluation data available on new drugs, new indications, new pharmaceutical forms and new dose strengths authorised in Europe or in France. European authorisations account for the majority, and these are the focus of our English edition, *Prescrire International*. The 2023 Prescrire Drug Awards are based on the reviews published in the Marketing Authorisations section of our French edition in 2023.

Prescrire's multidisciplinary team has been conducting and publishing independent drug analyses for 43 years, free from the influence of any companies involved in the healthcare sector.

No Pilule d'Or, and only one Prescrire Drug Award

None of the drugs examined by Prescrire in 2023 represented a major therapeutic advance worthy of a Pilule d'Or (Golden Pill Award). Only one drug received an award, earning a place on the Honours List.

Honours List: blinatumomab (Blincyto®) in high-risk first-relapse acute lymphoblastic leukaemia in children.

Acute lymphoblastic leukaemia (ALL) relapses in about 15% to 20% of children following first-line treatment. The relapse is considered high-risk when it occurs within 18 months of diagnosis or within 6 months of completing first-line treatment. It is usually treated with several phases of chemotherapy, with no standard protocol.

The anti-CD19 and anti-CD3 bispecific monoclonal antibody *blinatumomab* was evaluated as consolidation therapy in children with Philadelphia chromosome-negative high-risk first-relapse ALL in a non-blinded randomised trial versus chemotherapy in 108 patients. When half of the patients had been followed up for at least 31 months, mortality in the *blinatumomab* group was about 17%, versus 43% in the chemotherapy group. Some longer-term data have been published since we last searched the literature for our initial article about this authorisation (1). According to these data, obtained when half of the patients had been followed up for at least 44 months, the estimated 4-year mortality was 23% in the *blinatumomab* group, versus 51% in the control group. These differences in mortality are statistically significant.

Another non-blinded randomised trial compared *blinatumomab* to chemotherapy, using a different dosage of *blinatumomab* from that recommended in the European summary of product characteristics (SmPC). The results also showed lower mortality in the *blinatumomab* group.

The main adverse effects of *blinatumomab* are: neurological disorders, pancreatitis, tumour lysis syndrome and haematological disorders. In these trials, *blinatumomab*'s serious adverse effects appeared to be less frequent than those of the chemotherapy received in the control groups. However, the quality of this evidence is weakened by the absence of blinding.

A notable reduction in mortality, demonstrated in two randomised comparative trials in children with high-risk first-relapse ALL, is a clear therapeutic advance that justifies *blinatumomab*'s place on this year's Honours List.

Blinatumomab illustrates how a drug's harm-benefit balance depends on the clinical situation. In the absence of evidence that *blinatumomab* improves clinical outcomes in adults with ALL who are in remission but have residual leukaemic cells, its harm-benefit balance in that situation is unfavourable (see *Prescrire Int* n° 223).

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1- Locatelli F et al. "Improved survival and MRD remission with blinatumomab vs. chemotherapy in children with first high-risk relapse B-ALL" *Leukemia* 2023; **37** (1): 222-225.

Pilule d'Or/Golden Pill

A Pilule d'Or (Golden Pill) is awarded to drugs that represent a major therapeutic advance in a particularly poorly served field.

Not awarded in 2023

2023 Honours List

Drugs included on the Honours List constitute a clear advance for some patients compared with existing therapeutic options, albeit with limitations.

Blincyto® (*blinatumomab*) Amgen

In high-risk first-relapse acute lymphoblastic leukaemia in children (*Prescrire Int* n° 248)

Noteworthy

Drugs deemed "Noteworthy" provide a modest improvement in patient care.

No Noteworthy drugs in 2023