What's new in drug therapy

کتابخانه بیمارستان کوثر

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DRUG OR INDICATION WITHDRAWALS

- **Sodium phenylbutyrate-taurursodiol withdrawn from market (April 2024)**

Sodium phenylbutyrate-taurursodiol (PB-TURSO) was approved by the US Food and Drug Administration for patients with amyotrophic lateral sclerosis (ALS) in September 2022 after an initial placebo-controlled trial of 137 participants showed a slowing in clinical deterioration at 24-week follow-up. However, the company has indicated that a confirmatory trial involving 664 participants with ALS failed to confirm the efficacy of PB-TURSO at 48 weeks (unpublished data) [9]. In response, in April 2024, the medication was withdrawn from the market by the manufacturer in Canada and the United States [10]. PB-TURSO may continue to be available for some patients already on therapy and trial participants. (See "Disease-modifying treatment of amyotrophic lateral sclerosis", section on 'Sodium phenylbutyrate-taurursodiol'.)

RECENT APPROVALS - HEMATOLOGIC AND ANTICOAGULANT

- **Zanubrutinib plus obinutuzumab in multiply relapsed follicular lymphoma (April 2024)**

Zanubrutinib, a Bruton tyrosine kinase inhibitor, has received regulatory approval by the US Food and Drug Administration for use with obinutuzumab in patients with multiply relapsed follicular lymphoma (FL) [28]. Approval was based on results from a randomized trial in which >200 patients who had received two or more prior systemic therapies for FL experienced improved overall response rates and progression-free survival with the addition of zanubrutinib to obinutuzumab. Toxicities with zanubrutinib were modest. Although we prefer other combinations, including lenalidomide with either rituximab or obinutuzumab, for multiply relapsed FL, we consider zanubrutinib plus obinutuzumab to be an acceptable alternative or later-line option. (See "Treatment of relapsed or refractory follicular lymphoma", section on 'Zanubrutinib plus obinutuzumab'.)

RECENT APPROVALS - HEMATOLOGIC AND ANTICOAGULANT

- **CAR-T cell therapy for multiply relapsed CLL (April 2024)**

The US Food and Drug Administration recently granted accelerated approval of the CD19-directed chimeric antigen receptor T (CAR-T) cell therapy lisocabtagene maraleucel for patients with relapsed or refractory chronic lymphocytic leukemia (CLL) after two or more lines of systemic therapy including a Bruton tyrosine kinase inhibitor and a BCL2 inhibitor [29]. Approval was based on accumulating evidence from single-arm prospective trials that show variable response rates and duration of response; remissions have lasted over a decade in some patients with persistent CAR-T cells. This population has few therapeutic alternatives, and we consider CAR-T cell therapy an option for fit patients who meet these criteria. However, given the toxicity, complexity, and cost, the decision is individualized and highly dependent on an estimation of complication risk and the needs and wishes of the patient. (See "Treatment of relapsed or refractory chronic lymphocytic leukemia", section on 'Chimeric antigen receptor T cells'.)

COVID-19 MANAGEMENT

Pemivibart for prevention of COVID-19 in selected immunocompromised patients (April 2024)

- Monoclonal antibodies have been used as adjunctive pre-exposure prophylaxis to reduce the risk of COVID-19 in individuals expected to have suboptimal response to vaccination, although emergence of variants that escape neutralization limit their utility. In March 2024 in the United States, the novel monoclonal antibody pemivibart received emergency use authorization (EUA) to prevent COVID-19 in individuals age 12 years or older (weighing at least 40 kg) who have moderate-to-severe immunocompromising conditions (table 2) [61]. Pemivibart is active against JN.1, the dominant SARS-CoV-2 variant. We suggest pemivibart in individuals at the highest risk for vaccine nonresponse (eg, those with hematologic malignancy or recent history of transplantation) as long as it remains active against the main circulating variants. (See "COVID-19: Epidemiology, virology, and prevention", section on 'Limited role for monoclonal antibodies in selected patients'.)