

NEW INDICATION

Rituxan Approved for New Indication

The FDA has approved Genentech's and Biogen Idec's *Rituxan* (rituximab) for use in the first-line treatment of patients with diffuse large B-cell, CD20-positive, non-Hodgkin lymphoma, in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone) or other anthracycline-based chemotherapy regimens. *Rituxan* has previously been approved as a single agent for use in relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin lymphoma. (http://www.gene.com/gene/products/information/oncology/rituxan/rituxan_pi.pdf)

FDA STATUS

New-Onset Type 1 Diabetes Treatment Granted Orphan Drug Status

The FDA has granted orphan drug status to TolerRx's TRX4 for the treatment of new-onset type 1 diabetes mellitus. TRX4, a monoclonal antibody, has been shown to preserve the function of insulin-producing beta cells in the pancreas and reduce the amount of required exogenous insulin for at least 18 months.

Black Box Warning Added for Nimodipine

Bayer Healthcare is notifying health care professionals of changes to the prescribing information for nimodipine (*Nimotop*), indicated for oral administration to improve neurological outcome after subarachnoid hemorrhage. These changes include a Black Box Warning alerting prescribers about medication administration errors. The administration of nimodipine parenterally can lead to serious adverse events, including cardiac arrest, cardiovascular collapse, hypotension, bradycardia, and even death. The notification emphasizes that nimodipine must not be administered intravenously or by any other parenteral route.

Gaucher Disease Treatment Granted Orphan Drug Status

The FDA has granted orphan drug status to Amicus Therapeutics' AT2101, an experimental oral therapy for the treatment of Gaucher disease. The condition is a lysosomal storage disorder resulting from an enzyme deficiency that can cause damage to the liver, spleen, bone marrow, and, in some cases, the central nervous system. The therapy is expected to enter clinical studies in the first half of this year.