Ocrelizumab (Ocrevus®)

Ocrevus is a disease modifying therapy administered as an IV infusion initially given twice in two weeks, then given once every 6 months. Ocrelizumab is a recombinant humanized monoclonal antibody (targeting CD-20 B-cells) that reduces the number and function of certain B-cells. This helps to calm the overactive immune system and improve the disease course of MS. Some practitioners may order immunophenotyping to help guide Ocrelizumab dosing. Ocrelizumab may be similar to Rituximab (Rituxan), which is an older chimeric monoclonal antibody also targeting CD-20. Rituximab has been used successfully to treat autoimmune conditions such as rheumatoid arthritis (approved use), SLE (off label), MS (off label) and NMOSD (off label)

RELAPSING REMITTING MS DATA: Ocrelizumab efficacy and safety was evaluated in 1600+ patients in 2 identical RRMS clinical trials (Opera 1 and Opera 2). Relapses: Ocrevus reduced annualized relapse rate vs. Rebif by 47%. Disability: Ocrevus reduced the risk of confirmed disability progression vs. Rebif by 40% at both 3 months and 6 months. MRI: Ocrevus reduced the mean number of new T1 Gd+ lesions per scan vs. Rebif by 94% and 95%. Ocrevus reduced the mean number of new and/or enlarging T2 lesions per scan vs. Rebif by 77% and 83% and reduced T1 black holes by 57% and 64% over the 96-week time frame. NEDA (No evidence of disease activity: no new relapses, no sustained 3-month disability, no new/enlarged T2 MRI lesions or new Gd+ lesions) was seen in 48% of Ocrevus patients compared with Rebif (25%-29%) in the 96-week trials. CDI (confirmed disability Improvements): Ocrevus increased likelihood of CDI (maintained for 6 months) 36% vs Rebif. (Ocrevus 16% vs Rebif 12%). Brain Volume: Ocrevus reduced rates of brain atrophy (shrinkage) over 96 weeks 24% vs Rebif.

PRIMARY PROGRESSIVE MS DATA: Ocrelizumab is currently the only approved product by the FDA for treatment of Primary Progressive MS. Its efficacy and safety were evaluated in 732 patients with Primary Progressive MS over 120 weeks compared to placebo. *Disability*: Ocrevus reduced the risk of disability progression on EDSS vs. placebo in PPMS by 24% and 25% confirmed at 12 and 24 weeks. *Walking Time*: Ocrevus reduced risk of progression in rate of walking time 29% over placebo (Ocrevus 39% worsened, Placebo 55% worsened). *NEP (No Evidence of Progression):* Over a period of 12 weeks, no progression noted on EDSS exam, no 20% change in 9-hole peg test, no 20% change in timed 25-foot walk test. Ocrevus increased likelihood of NEP by 47% vs placebo (Ocrevus 43% vs Placebo 29%). *MRI (T2 bright lesions):* Over the 96-week trial, Ocrevus group had a reduction in T2 lesion volume by 3.4% whereas placebo group increased T2 lesion volume by 7.4%. *MRI (Brain Volume*): Ocrevus reduced rates of brain atrophy (shrinkage) over 96 weeks 17% vs placebo.