Novel Therapies Bring Hope to Patients With Demyelinating Disorders

Although 2020 was a year most say they'd rather forget, for physician-scientists specializing in two demyelinating disorders — neuromyelitis optica spectrum disorder (NMOSD) and multiple sclerosis (MS) — the year offered cause for celebration. The approval of four new drug treatments, coming on the heels of three in 2019, means more options than ever for physicians to deliver the most targeted, individualized patient care possible.

"The rapidly evolving landscape of unique neurotherapeutics for MS and NMOSD allows a variety of choices for our patients and truly sets the stage for personalized decision making," says Carrie Hersh, DO, MSc, FAAN, Program Director of the Multiple Sclerosis Health and Wellness Initiative.

FDA approval of new treatments comes only after positive results from clinical research *(see page 9)*. Cleveland Clinic Lou Ruvo Center for Brain Health was involved in studying the two recently approved MS treatments, both of which are now being prescribed at our center and across the country.

"Our entire MS team is excited by this array of new, diverse treatments for demyelinating disorders, which hold the promise of making a significant impact on our patients' lives," says Dr. Hersh. "We are proud of our center's role in making these advances available to individuals who can benefit from them."

If you're interested in hearing more about the newest approved treatments being prescribed — or those still being studied in pursuit of FDA approval — contact us at 702.483.6000.

FOR PEOPLE WITH MS

Ozanimod (Zeposia®)
FDA approval date: March 2020

Ozanimod is a once-daily pill for the treatment of active (still inflammatory) forms of MS. Considered a disease-modifying therapy, ozanimod is another oral treatment option to address the disease's hallmark relapses and brain lesions. Pivotal clinical trials showed significantly less brain shrinkage and clinically meaningful improvements in cognitive processing speed compared with pre-existing treatments, thus "modifying" the disease.

Under the direction of Le Hua, MD, FAAN, in 2015, the Lou Ruvo Center for Brain Health was part of a Phase 3 clinical trial, SUNBEAM that led to FDA approval of ozanimod.

Ofatumumab (Kesimpta®)
FDA approval date: August 2020

Ofatumumab is the first self-injected (subcutaneous) B-cell depleting therapy for the treatment of relapsing (still inflammatory) forms of MS. This new drug therapy, which is considered a highly effective disease-modifying therapy, represents a novel treatment option for individuals who are interested in starting a B-cell depleting therapy, but who find administering the medication in the comfort of their own home more convenient than going to an infusion facility twice a year.

Under the leadership of Dr. Hersh, from 2016 to 2019, the Lou Ruvo Center for Brain Health was a site for the Phase 3 clinical trial ASCLEPIOS that led to FDA approval of ofatumumab. The center is currently conducting ALITHIOS, a clinical trial for the open label extension phase, in which participants are knowingly taking ofatumumab versus the Phase 3 trial, which randomized some participants to another approved therapy, teriflunomide (Aubagio®).

FOR PEOPLE WITH NMOSD

"The advent of three different FDA-approved therapies for seropositive NMOSD, with various mechanisms of action and administration, is a revolutionary opportunity to effectively treat this rare, yet complicated, condition," says Dr. Hersh. "We did not have an approved therapy before eculizumab was approved in 2019."

Eculizumab (SOLIRIS®)
FDA approval date: June 2019

The first immunotherapy for seropositive (AQP4 positive in serum/blood test) adults with NMOSD, eculizumab represented a breakthrough treatment for this devastating neurological disease, which affects principally the nerves of the eye and the spinal cord. While infusions every other week can present a logistical challenge for some, eculizumab remains a welcome option for patients.

Inebilizumab (UPLIZNA®)
FDA approval date: June 2020

The second disease-modifying therapy to be approved for seropositive adults, the immunotherapy inebilizumab is administered via infusion every six months. Individuals may like this option if they want a therapeutic strategy that is infrequent, with administration overseen by a medical team.

Satralizumab (ENSPRYNG®):
FDA approval date: August 2020

The third disease-modifying therapy to be approved for seropositive NMOSD, this immunotherapy is administered via subcutaneous injection once a month. Patients may prefer this option if they want a therapeutic strategy that they can self-administer at home or if there are safety issues with other treatments.