Gamunex Approved to Treat CIDP

By Amanda M. Traxler

F or the approximate 25,000 Americans who suffer from chronic inflammatory demyelinating polyneuropathy (CIDP), Sept. 12 was an important day.

That Friday, the Food and Drug Administration (FDA) announced approval for Gamunex as a treatment for CIDP, a rare neurological disorder characterized by progressive weakness and impaired sensory function in the legs and, to a lesser extent, the arms.

The approval marks a couple of firsts for Gamunex. Currently the only therapy of any kind with an approved indication for the treatment of CIDP, Gamunex is also the only intravenous immune globulin (IVIG) therapy approved to treat a neurological disorder in the country.

And for patients, says Estelle Benson, executive and founding director of the GBS/CIDP Foundation International, that’s a positive development.

“We’re very proud of Talecris for taking the effort to do this,” Benson said in October. “Our patient population has been waiting for some type of breakthrough.”

According to Benson, U.S. patients with CIDP now have an FDA-approved medication to help limit CIDP’s peripheral nerve damage, which improves both neurological function and quality of life.

“I speak on behalf of the 26,000 members of the GBS/CIDP Foundation who are excited to learn that Talecris has established that Gamunex is a successful treatment for patients with CIDP. What good news!” Benson said in the Sept. 15 press release.

IG Living readers with CIDP have similar sentiments.

“When I received the letter that Gamunex is now an approved treatment for CIDP, I felt validated,” said Mary Klatt of Gresham, Ore.

“Validated in the fact that I have this disease, there is a real treatment for it, and maybe now there are doctors who are becoming more aware of it. I see the approval not only as a form of validation for the insurance company and reimbursement issues but also for physicians to see that IVIG is an approved standard of care in CIDP.”

Regarding doctor awareness, Talecris also announced that it is developing programs to educate neurologists on the new indication and the clinical trial that supported it.

That’s something Klatt appreciates.

“It is sad that I no longer see my neurologist because she was not comfortable prescribing IVIG for me any longer,” Klatt said. “She was more comfortable switching me from IVIG that worked for me to a more experimental treatment that had a possibility of causing cancer in the long run. This news was wonderful and lets me breathe easier knowing I can continue to receive my IVIG.”

J. Armstrong of Fairfax, Va., began using IVIG for CIDP about four and a half years ago. Always aware of long-term access issues, she followed the clinical trial intently.

“I was truly surprised in my initial research about FDA policies regarding IVIG use before starting the therapy, particularly as it has been an established and accepted practice, albeit an ‘off-label’ use, by a majority of medical insurance companies for well over 20 years,” Armstrong said. “Yet the FDA could not act to approve it until this one trial, [which] is I believe the first one specifically for CIDP. I was following it closely and eager for results.”

The study, published in the February 2008 issue of Lancet Neurology, is the first and only large-scale clinical trial documenting the long-term safety and efficacy of Gamunex to treat CIDP.

Even before the recent approval, Armstrong considered herself lucky.

“I am truly fortunate for having doctors who were knowledgeable and open to this treatment option, especially as prednisone for me was not considered due to other medical issues,” Armstrong said.

Just a week after the Gamunex approval, a subanalysis of the Lancet Neurology study was presented at the American Neurological Association’s annual meeting.

In the Sept. 22 presentation, study author Norman Latov, M.D., from Cornell University, reported that among patients who responded to IVIG therapy, 41 percent improved after the first treatment course, while 94 percent improved after the second treatment course.

According to study authors, some patients may require more than one treatment course to achieve clinical response. In conclusion, the authors recommended further studies in CIDP to “more clearly define the duration of treatment required to achieve and maintain maximal response to IVIG therapy.”

For patients like Armstrong—for whom IVIG has been so helpful—any future studies will surely be greatly appreciated.

“I will not forget my first round of the ‘loading dose’ series. After the second day, I was able to walk and move for over an hour after treatments!” Armstrong said. “Whereas before I was lucky to be able to walk, at most, 15 minutes followed by two days of additional pain and serious naps to recover from the fatigue. I now time things I want to do for after infusions whenever possible.”

In August, Talecris Biotherapeutics launched www.CIDPinfo.com, a peer-reviewed, clinical and scientific information center that offers healthcare providers a comprehensive resource focused exclusively on CIDP.

Resources
GBS/CIDP Foundation International
www.gbs-cidp.org
CIDP Information Center
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