FDA Clears Cymbalta to Treat Chronic Musculoskeletal Pain

The U.S. Food and Drug Administration approved Cymbalta (duloxetine hydrochloride) to treat chronic musculoskeletal pain, including discomfort from osteoarthritis and chronic lower back pain. Cymbalta was first used to treat major depressive disorder in 2004.

“Up to three quarters of the population experience chronic pain at some time in their lives,” said Janet Woodcock, M.D., director of FDA’s Center for Drug Evaluation and Research. “This approval means that many of those people now have another treatment option.”

Since its initial approval, about 30 million patients in the United States have used Cymbalta. It was approved for the treatment of diabetic peripheral neuropathy in 2004; generalized anxiety disorder and maintenance treatment of major depression in 2007; and fibromyalgia in 2008.

More than 29,000 patients have used Cymbalta in clinical trials, and more than 600 patients were studied in the clinical trials involving osteoarthritis and chronic low back pain. The safety evaluation for Cymbalta included review of data from the clinical trials as well as post-marketing data from the previously approved patient populations.

The safety evaluation for Cymbalta included review of data from the clinical trials as well as post-marketing data from the previously approved patient populations.

The FDA assessed the efficacy of Cymbalta in chronic low back pain and osteoarthritis in four double-blind, placebo-controlled, randomized clinical trials. At the end of the study period, patients taking Cymbalta had a significantly greater pain reduction compared with placebo.

The most common side effects reported with Cymbalta include nausea, dry mouth, insomnia, drowsiness, constipation, fatigue, and dizziness. Other serious side effects include liver damage, allergic reactions such as hives, rashes and/or swelling of the face, pneumonia, depressed mood, suicide, suicidal thoughts and behavior.

While these serious side effects have been associated with the use of Cymbalta, they have occurred in less than 1% of treated patients. There are a finite number of drugs available for the treatment of chronic musculoskeletal pain, all of which are associated with rare, serious side effects. There are patients in whom none of the available treatments are effective.

The recommended dose for Cymbalta is a 60 milligram capsule taken once daily without regard to meals. The capsule should be swallowed whole, and not chewed, crushed or opened; the contents should never be sprinkled on food or mixed with liquids.

Consumers and health care professionals are encouraged to report adverse events to the FDA’s MedWatch program at 800-FDA-1088 or online at www.fda.gov/medwatch/how.htm.

Cymbalta is manufactured by Indianapolis-based Eli Lilly and Co.

[FDA News Release November 4, 2010]

ASAP Elects New Officers and Board Members

On November 10, the Board of Directors elected new officers and directors.

Donald Williams was re-elected to the board and will serve as President. Judy Hunt will fill the office of Immediate Past President offering guidance and support to Don. Patrice Schaublin was elected as Vice President and Karen McFarland as Secretary.

Jo Prahl is returning as a Director after a two year absence and Barbara Banick was elected to her first term.
Save Your Canceled Postage Stamps

ASAP members began collecting canceled postage stamps as a fundraiser during the early 90s. They have enlisted the aid of local businesses, churches, social clubs, family and friends. The number of stamps donated has dramatically increased over the years.

This fundraising project is a favorite of many ASAP members. Although commemorative stamps such as the ‘State’ series bring in more money, the everyday ‘flag’ stamps are also of value. Over the years, ASAP has received thousands of dollars through this project. So the next time you start to toss that envelope, take a few minutes to help ASAP.

Cut stamp from envelope leaving a 1/4 inch border. It must be in good condition. Damaged stamps are not usable.

Please send stamps to:
Maynard Guss
9593 NW 26th Place
Sunrise FL 33322-2738

Spread Awareness with an ASAP Business Card

Don’t Just Tell People About CM/SM... Show Them!

Jerry Lindner, an ASAP member, designed the cards. He prints them on his home computer and makes them available to others for a small fee to cover the cost of stock and ink.

To place an order, include the information you would like on the front of the card; it may also be left blank. Enclose a self-addressed stamped (one stamp) envelope with $3.00 for 20 cards. Enclose a self-addressed stamped (two stamps) envelope with $6.00 for 40 cards.

Mail to: Jerry Lindner
5855 Muir St.
Simi Valley, CA 93063

If you have questions: call 805-581-1344, or Email jlindner99@sbcglobal.net

Awareness and Fundraising

Share your ideas and experiences with others. Submit a short story by email to Patricia_Maxwell@ASAP.org or mail typed or clearly written article to:

ASAP
PO Box 1586
Longview TX 75606-1586

Please Note: Articles in this newsletter are not intended as a substitute for medical advice and do not necessarily represent the viewpoints of the editor, Medical Advisory Board or Board of Directors. Please contact your doctor before engaging in any new therapy or medication.
Getting to Know the ASAP Board of Directors

ASAP Board members volunteer their time and skills to further the mission of the organization. They are elected for a term of three years by a majority vote of the current Board of Directors. The Directors are responsible for setting forth the policies of ASAP.

November 2010, Don Williams was elected to serve as President of the ASAP Board of Directors.

Don has been involved in ASAP almost since its inception when he was a baffled parent trying to get information. He later served on the Board of Directors from 2002 to 2008.

After graduating from Yale College and Law School he practiced law and was involved in various business ventures, including founding Carnegie Bank in Princeton, NJ. At his retirement he was a principal in the Breen Capital Group, a financial investment firm.

His oldest daughter was initially diagnosed with scoliosis in 1978 and some years later, with the introduction of the MRI, with Chiari and syringomyelia. She has endured over a dozen surgeries, the most recent at Johns Hopkins in 2010. She is a psychotherapist in private practice in Washington, D.C. where she lives with her husband.

His younger daughter began her career in investment banking and now is the mother to Don’s two grandchildren. She lives with them and her husband in Manhattan.

His step-daughter, also a psychotherapist, recently moved back to Philadelphia after three years in Chicago.

Don has lived for the past ten years in New Hope, PA. He and his wife, Diana, live in a tenant cottage built in 1731, the upkeep of which takes virtually all of their spare time. Whatever time is left, after the grandchildren, is spent sailing on the Chesapeake or making offshore trips to the Caribbean.

A Word from Our President

As I begin my term as President of this passionate organization, it seems fitting to dedicate the year 2011 to the memory of Barbara and Don White, our founders, and to rededicate the organization to the goals that they so effectively championed for over twenty years.

When my daughter was first diagnosed with Chiari/SM in the mid 1980’s the Internet was something most of us knew nothing about and the MRI at Children’s Hospital of Philadelphia was just being installed. There was no place to find support and information about the condition. The White’s were the first to begin remedying that with the founding of ASAP. Their goal of providing support and information has made the lives of hundreds of thousands a little bit less stressful as they chart a course of treatment for these conditions. Our website, www.ASAP.org, remains the most visited site related to Chiari/SM in the world.

But as sophisticated technology has shown a dramatic increase in Chiari/SM diagnosis, we have also seen an increase in the number of organizations trying to help. The National Organization of Rare Diseases now shows over fifteen such groups worldwide. Working together we can move more quickly to finding a cure. As the leader in this effort ASAP must continue to fund patient information and support and the vital research which the esteemed members of our Medical Advisory Board pursue every day.

So, as I begin my term, I ask all of you who read this to think of some way to be involved. Whether through contributions of ideas, time or money, we need you to be part of the ASAP family as we continue to stand beside all those battling these debilitating conditions.

Very truly yours,
Don Williams

Sara Patterson

In October when Sara’s term on the Board of Directors expired, she decided not to run for reelection. Sara felt that her increased work responsibilities and her daughter’s continued health problems would not allow her to dedicate the time required to continue as a Director.

An energetic volunteer, Sara worked diligently to promote awareness, develop programs and raise funds. She worked on and/or chaired multiple committees, helped organized our national conferences and developed the ASAP website just to mention a few of her many accomplishments.

Sara will continue to work with ASAP as much as possible but her contribution to the Board will be greatly missed by her fellow Directors.

Thank you Sara for giving so much to help make a difference in the lives of many!
**Ask The Experts**  
**Questions and Answers**

**Question**: What would cause increased intracranial pressure after they've been decompressed? What are some of the symptoms?

**Dr Keating**: Was the intracranial pressure if you know that's a real issue, do you have a monitor and an LP and so forth, maybe that's what's driving the Chiari in the first place. The longer I do this, we see kids with pseudotumor that don’t have Chiari but they have small ventricles, terrible symptoms. They have optic nerve changes, papilloedema and so forth. I think there probably is a subset of patients that have some type of increased intracranial pressure for many different reasons: brain is stiff, there’s been infection, or there was a hemorrhage when the babies were young. There’s a million reasons to have high pressure in your head and that may be what's causing the Chiari and/or syrinx to some degree. You may address the Chiari but if that’s not the cause it may not solve your problem.

**Dr Albright**: Post-operatively you can easily have inflammation that will cause scarring down at the outlets of the fourth ventricle. But if you have a mild amount of bleeding, the blood clot can cause enough inflammation and scarring so that it impedes the outflow of spinal fluid and raises your pressure.

**Question**: Are pseudotumor patients a candidate for a third ventriculostomy or is shunting the best option for them?

**Dr Albright**: That would be a shunt because most of the time those people have intact spinal fluid pathways. So it's made in the right place, it goes through the right channel and gets absorbed. As best as I know, there’s not an obstruction that you can bypass with an ETV (shunt).

**Question**: If a child has developed a pseudotumor after a Chiari, or vice versa since it’s not known which one was first, would that child be a candidate for a third ventriculostomy?

**Dr Albright**: If you developed hydrocephalus after a Chiari decompression and you had evidence of raised pressure I probably would do a third ventriculostomy. If the ventricles are small then you have to make sure that the pressure really is high. Because as you know, a lot of people have headaches before the Chiari decompression and they have headaches after the Chiari decompression and they’re not pressure related.

**Question**: Do you see a lot of children with cerebral palsy who develop Chiari? Can you tell me what the percentage is for children that have cerebral palsy? Is it a big concern for a child with that sort of disorder?

**Dr Keating**: I see a lot of patients with CP. More often than not most of these patients have had some type of radiographic study over the course of time. I’d have to admit it is an unusual scenario where I will see a Chiari related to that. Probably if I did I would anticipate that they may have hydrocephalus. It may be an acquired Chiari, the ventricles are pushing the tonsils down. I agree with Leland if the problems up here, pushing the tonsils down, then take care of the problem up here. I would defer to Dr. Albright as one of the giants in the world of spasticity and seeing lots of CP.

**Dr Albright**: You almost never see it. I mean in CP, they have many brain abnormalities but you almost never see a type I Chiari malformation.

**Question**: After you decompress a child and they're healed and feeling better, do you put any restrictions on the way they live their daily lives; as far as like sports or activities, water parks, roller coasters, trampolines, anything like that?

**Dr Keating**: You said the dreaded 'T' word to a neurosurgeon. Trampolines are another story. I don’t know about anybody else in this room. My feeling is kids need to be normal. They need to be out there riding their bikes into trees and God knows what else they're going to do. I mean that's part of being a kid. If you've adequately done what you set out to do and you feel that there are no areas of constriction or impingement upon the cranial cervical junction I don’t see any reason why they can’t play any sport. I think a lot of these kids will probably shy away from a contact sport where the goal is to kill the other guy, you know football, rugby. But I think in general if they’re doing well and they’re looking good and you’ve got a nice picture they need to be out there doing what everybody else is doing.

**Dr Albright**: I do the same thing. I don’t restrict them. I respect some neurosurgeons who say ‘No football’ but that’s about the only limitation.

**About the Experts:**

Robert Keating, MD - Chair of Neurosurgery, Children’s National Medical Center, Washington, DC

Leland Albright, MD - Pediatric Neurosurgery, University of Wisconsin, Madison, WI
Proposed National Center for Advancing Translational Sciences

On Dec. 7, 2010, the Scientific Management Review Board (SMRB) recommended that the National Institutes of Health (NIH) realign its resources to establish a new Center devoted to advancing translational sciences. The action came in response to NIH Director Francis Collins’s charge to the SMRB to formulate and recommend a plan for achieving optimal organization for therapeutic development within NIH.

As currently envisioned, the central role of the proposed National Center for Advancing Translational Sciences (NCATS) would be to establish a focused, integrated, and systematic approach for building new bridges to link basic discovery research with therapeutics development and clinical care. The Center would be formed initially by integrating selected translational research programs now located within the National Human Genome Research Institute (NHGRI), the National Center for Research Resources (NCRR), and the NIH Director’s Common Fund. Another component could be the new Cures Acceleration Network (CAN), which was authorized by the Affordable Care Act but has not yet received an appropriation.

NIH’s goal is to be as open and straightforward as possible throughout this process. At the SMRB’s Dec. 7, 2010 meeting, time was set aside for public comments on this vision for realignment and leveraging of translational resources. There will be continued opportunities for public input, including meetings and teleconferences hosted by NIH leadership, as we move forward.

The NIH Director plans to present a detailed plan for the new Center to Health and Human Services Secretary Kathleen Sebelius early next year. If all goes as planned, the reorganization will take effect on October 1, 2011.

Throughout this time of transition, all translational science programs at NIH will continue at full force. This Center is not intended to replace the current translational research efforts of the other Institutes and Centers, but will complement them.

Also at this time NIH will actively seek input and insights from NIH staff, extramural scientists, and the broader stakeholder community. One part of this effort is the launch of this website, Feedback NIH. This site will provide the most up-to-date information as we move through the planning and development phase. In addition, this is the place for us to hear from individuals across NIH and the public. Please use the comment link to provide direct, constructive feedback, and the question link to ask your questions. We will be periodically updating this site to answer your questions. We look forward to hearing from and working with you as we embark on this exciting future for translational sciences.

Geron Initiates Clinical Trial of Human Embryonic Stem Cell-Based Therapy

First Patient Treated at Shepherd Center in Atlanta

Menlo Park, Calif., October 11, 2010 - Geron Corporation (Nasdaq: GERN) announced the enrollment of the first patient in the company’s clinical trial of human embryonic stem cell (hESC)-derived oligodendrocyte progenitor cells, GRNOPC1. The primary objective of this Phase I study is to assess the safety and tolerability of GRNOPC1 in patients with complete American Spinal Injury Association (ASIA) Impairment Scale grade A thoracic spinal cord injuries. Participants in the study must be newly injured and receive GRNOPC1 within 14 days of the injury.

The patient was enrolled at Shepherd Center, a 132-bed spinal cord and brain injury rehabilitation hospital and clinical research center in Atlanta, GA. Shepherd Center is one of seven potential sites in the United States that may enroll patients in the clinical trial.

"Initiating the GRNOPC1 clinical trial is a milestone for the field of human embryonic stem cell-based therapies," said Thomas B. Okarma, Ph.D., M.D., Geron’s president and CEO. "When we started working with hESCs in 1999, many predicted that it would be a number of decades before a cell therapy would be approved for human clinical trials. This accomplishment results from extensive research and development and a succession of inventive steps to enable production of cGMP master cell banks, scalable manufacture of differentiated cell product, and preclinical studies in vitro and in animal models of spinal cord injury, leading to concurrence by the FDA to initiate the clinical trial."

“We are pleased to have our patients participating in this exciting research,” said Donald Peck Leslie, M.D., medical director, Shepherd Center. “Our medical staff will evaluate the patients’ progress as part of this study. We look forward to participating in clinical trials that may help people with spinal cord injury.”

David Apple, M.D., Shepherd Center’s medical director emeritus and principal investigator of the trial at Shepherd Center, said, "This clinical trial represents another step forward in Shepherd Center’s involvement in an attempt to find a cure for paralysis in people with spinal cord injury. Shepherd Center is an ideal place to conduct this study because of our clinical expertise and the volume of patients referred here for rehabilitation care."

In addition to Shepherd Center, Northwestern Medicine in Chicago, IL is also open for patient enrollment. As additional trial sites come online and are ready to enroll patients, they will be listed on the Patient Information pages of Geron’s website and on the NIH registry, ClinicalTrials.gov.

Further information on the criteria for patient eligibility for the study is also available on ClinicalTrials.gov.
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**When It’s Time to Remember Loved Ones**

Our appreciation to everyone who made a recent donation to ASAP on behalf of their friends / loved ones.

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Donations should be mailed to: ASAP, Inc. PO Box 1586, Longview TX  75606-1586

1-2011

Awareness and Fundraising

ASAP Spring Gala

The ASAP Spring Gala will be held April 8, 2011 in Westbury, New York on Long Island. After fine dining at the luxurious Westbury Manor, a traditional Victorian mansion with formal English gardens and classically elegant banquet rooms, attendees will enjoy an awards presentation, silent auction and raffles. Doctors Roger W Kula and Harold Rekate will be honored for their achievements and dedication to the Chiari and syringomyelia community.

Invitation

If you would like to receive an invitation to the event:
• Email info@ASAP.org with Spring Gala as the subject line and include your name and snail mailing address in the text, or
• Register online (go to ASAP.org, click ‘Get Involved’ and ‘ASAP Spring Gala’), or
• Call the ASAP office (903)-236-7079.

Program Advertisement

Advertise in the Gala Program to promote your business, wish us luck, or honor a friend. But hurry, the deadline for a submission is February 1. The Gala Program Advertisement Submission Form is available online or by contacting the ASAP office.

Get Involved

• Donate to the auction and raffles. Contact the ASAP office or print the Gala Reply Form (available on our website) to donate an item(s) to the auction, raffle or gift bags.
• Join the event committee. Contact Chair, Shananne Hutter, to let her know how you would like to help (Shananne27@msn.com).

Tickets, Sponsorships and Contributions

Individual tickets are available at $125 each. Sponsorship information is available on our website or by contacting the ASAP office. To make a contribution toward the event, please send your check to ASAP Spring Gala, PO Box 1586, Longview TX  75606 or donate online.

Thank You!

ASAP depends on volunteers to raise awareness and contributions. In addition to the awareness you raise, your fundraisers help support research, the website, ASAP Connections, free information packages and much more. Together We Can…
The American Syringomyelia & Chiari Alliance Project (ASAP) is a tax-exempt 501(c)(3) organization. Our goals include providing a clearinghouse for information on syringomyelia (SM), Chiari malformation (CM), and related conditions. We offer a supportive network of programs and services and fund research to find better therapies and cures. ASAP is supported by tax deductible donations.

ASAP Connections is published bimonthly for ASAP members. Your articles, letters to the editor, etc. are encouraged. The deadlines for these submissions are the 1st of February, April, June, August, October and December. The editor reserves the right to edit any article in order to accommodate space. Please send newsletter suggestions to: Patricia.Maxwell@ASAP.org or ASAP, PO Box 1586, Longview TX  75606

Patricia Maxwell  Editor, ASAP Connections

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