New Pain Medication Receives FDA Approval
by Patricia Maxwell

Zorvolex, manufactured by Iroko Pharmaceuticals, received approval from the US Food and Drug Administration (FDA) in October 2013. FDA approval was supported by information from a Phase 3 multi-center, randomized study.

Used to treat mild to moderate acute pain in adults, approved dosage strengths are 20 percent lower than currently available diclofenac products. Diclofenac is
• a nonsteroidal anti-inflammatory drug (NSAID),
• taken or applied to reduce inflammation,
• as an analgesic reducing pain in certain conditions,
• and supplied as or contained in medications under a variety of trade names (Wikipedia).

Patients and physicians who need new options for effective pain relief may find Zorvolex a viable option. The risk of serious adverse symptoms associated with NSAIDs will be reduced due to the lower dose. Developed using SoluMatrix Fine Particle Technology™ Zorvolex contains diclofenac as submicron particles. Approximately twenty times smaller, the reduction in particle size provides an increased surface area, leading to faster dissolution.

Zorvolex may be a welcome therapeutic option for those concerned about the effectiveness of medication and adverse side effects. It is important that patients discuss all medications with their physician. Your doctor will know if this is the right option for you.

ASAP.org

In our continued efforts to bring you information that is easy to find, our website has received a makeover. Just click any of the three pictures to find a list of related landing sites. Or click on the menu at the top to go directly to the first page in that topic. Once you arrive at the new page, you will notice a submenu on the right for a list of additional pages. Click on any title to go directly to that page.

Not finding what you want? Use the search at the top. Type in a word or phrase for a list of possibilities.

Each of the icons under the pictures will take you to main pages for those topics. For example, interested in becoming a volunteer? Click on the volunteer icon and it will take you directly to the form which you can complete and submit in a few easy steps.

When you are ready to return to the home page, just click on the ASAP logo at the top.

Watch videos, read medical articles, see what is happening with awareness or request additional information. Our site was created for you and we are interested in knowing what you think. See page 6 for a variety of ways to contact us.

www.ASAP.org

25th Anniversary Drive

Thank you to everyone who responded to our recent 25th Anniversary Drive with a total donation of $8,075.

Thank you for your continued support!
Stamp Project

We are happy to announce we have a volunteer to coordinate the Stamp Project. Charles worked with Maynard Guss in the past and has graciously agreed to take over.

Please send postage stamps that are in good condition (attached to envelope and trimmed with a 1/4 to 1/2 inch border around undamaged stamp). Remember nonprofit and presort stamps are not accepted. But Charles told me they also have an outlet for postcards. So send those too!

Charles Petkevich
ASAP Stamp Project
6202 SW 2nd Court
Plantation FL 33317

Volunteering

by Patricia Maxwell

I sadly announce that ASAP volunteer, Monica Reents, has resigned as chair of the KIDS For A Cure Club. I am sure you enjoyed her additions to our newsletter as much as I did. We appreciate the months she dedicated to making the lives of all children affected by these disorders a little brighter.

With Monica’s departure, once again a void is created that needs to be filled. ASAP is dependent upon volunteers and we need your help, not only for the kids but for other committees as well.

If you are interested in donating a few hours a week or even once a month, contact the ASAP office or go online to ASAP.org and submit a volunteer form. Let us know your interests, your expertise and the time you feel you can dedicate to making a difference in the lives of others affected by syringomyelia and Chiari.

A few of the positions we would like to fill are volunteer coordinator, KIDS For A Cure Club chair, and development committee members. We look forward to hearing from you soon.

Membership Fundraiser

ASAP members set up personal fundraising pages through our eTapestry module to spread awareness and raise funds for programs and research. Jennifer is one of those members.

Jennifer Vasek

For my senior project at Mineola High School I decided to organize a fundraiser for ASAP, a nonprofit organization. ASAP is the leading organization in the fight against Chiari and syringomyelia.

The reason why I chose to do this fundraiser is because I was diagnosed with Chiari malformation and syringomyelia in May 2009. I suffered with many symptoms that I still have every day.

I had my first brain surgery on June 1, 2009. I was told that if I didn’t have the surgery I was going to be paralyzed due to syringomyelia. Since there is no one correct way to do the surgery and no cure, the first surgery was unsuccessful except for the syringomyelia being corrected. My symptoms became worse and there were days where I couldn’t walk. I had my second brain surgery on April 28, 2010 with a neurosurgeon who specializes in Chiari. Some symptoms improved but many stayed the same. Unfortunately I suffer from this every day. I can’t participate in gym or play sports due to the risk of hitting my head and increasing my chances for another surgery. There are many things that I would love to do but I’m restricted from most of them due to my Chiari. Due to my constant headaches I miss out on a lot of things and have trouble doing every day activities.

If you would like to help Jennifer reach her goal, go to https://asap.myetap.org/ASAP/. On the upper left side of page click on ‘Find a Team/Participant’ then type in JEN VASEK (all caps) and hit ‘search’. If you click on Jen’s name, it will take you to her page. Select ‘Make a Donation’ follow the prompts to fill in your information. Be sure to only click ‘submit’ once. It may take a few seconds to complete the transaction.

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.
A Word From Our President

As another year comes to a close I would like to take this opportunity to wish each and all a safe, happy, loving and symptom-free holiday season. I know sometimes it is hard to count your blessings, but know that each one of you reading these words is part of a community that offers you comfort and support. It has been our goal to provide everyone the love and support that we all need when times get tough.

It has been a busy and exciting year for ASAP. We have continued our social media support outlets, maintaining our level of support through various Facebook pages and our bulletin board. We have continued our legacy of providing telephone support and expanded our base of support groups. Our website has been completely revamped, providing a place where people can feel comforted while investigating information relevant to their disorders in a logical, organized and factual manner. Four new research grants totaling over $100,000 were awarded. We recently held our annual conference which commemorated 25 years of service to our community including 25 annual conferences, 25 years of research, 25 years of raising awareness, 25 years of support, 25 years of new friends, and 25 years of fundraising to achieve our goals. We are honored to have served you during this time and look forward to many more years of service.

All of which leads me to what we are doing to continue our mission. Recently we increased our social media presence with a group page dedicated solely to persons affected by syringomyelia without Chiari. This page allows people to interact with others who share their experiences. Often times, symptoms of both syringomyelia and Chiari are lumped together causing confusion about the singular effects of syringomyelia. This page will provide a site to share stories, compare experiences, and offer a forum for support and encouragement.

We are pleased to announce the Sy-ringo-my-What?? Steps Across the States walk-a-thon. It is our hope that each state will be represented in this national event. This walk will be held April 26, 2014. We are currently in the planning stages and look forward to it being a success. This is an opportunity for all those affected by syringomyelia to raise funding, awareness, and education about the devastating effects of this disorder. If you are interested in hosting a Sy-ringo-my-What?? Steps Across the States event in your area please contact me. In order to allow adequate preparation, please contact me prior to December 31, 2013. As our way of thanking you for continuing our mission, monies raised through this walk will qualify for the L.E.A.R.N. Points Program thereby giving you the opportunity to attend our next annual conference.

Before I close, I would like to take this opportunity to ask each of you to consider a year-end show of support with a donation to ASAP. There is no amount that is too large or too small and I am pleased to say that 87% of any donation goes directly to our programs, including but not limited to research, support, conference, etc. It is through your generosity that we have come this far. Twenty five years ago, when this organization was founded by Barbara and Don White, very few people had ever heard of these disorders. Never have we or the medical community had the understanding of these disorders that we have today. Thank yourselves and your generosity for bringing us to the level of awareness and research that we currently enjoy. Unfortunately, even with everything that has been accomplished, our mission is ongoing. So please take a moment, go to the website, make a donation, and show your support.

Lastly, I wanted to take this moment and offer thanks to our community, their caretakers and loved ones, our staff, boards and doctors for seeing us through yet another year. I think of you all with thoughts of deep gratitude and fond appreciation for all you have done, still do, and will do in the future for all of those persons, who we are related to through this common bond.

Gentle Hugs always,
Patrice
Patrice_Schaublin@ASAP.org

New Support Groups Formed

CT Chiari/Chronic Pain Support Group
Leader: Jenny Mucciacciaro
email: lpmucci27@yahoo.com

Group meets the second Wednesday of each month from 7:00 PM - 8:00 PM at Waterbury Hospital, Waterbury, Connecticut, in the Bizzozero Dining Room on the 4th floor. Free parking and refreshments are provided.

U.P. of Michigan Support Group
Leader: Stephanie Carlson-Ballone
email: stephca@rocketmail.com

Hampton Rds VA Support Group
Leader: Wendy Ford
email: wendylinkford@cox.net
FDA approves extended-release, single-entity hydrocodone product. First to have updated labeling now required for all ER/LA opioid analgesics.

The U.S. Food and Drug Administration approved Zohydro ER (hydrocodone bitartrate extended-release capsules) for the management of pain severe enough to require daily, around-the-clock, long-term treatment and for which alternative treatment options are inadequate.

Zohydro ER, a Schedule II controlled substance under the Controlled Substances Act, is the first FDA-approved single-entity (not combined with an analgesic such as acetaminophen) and extended-release hydrocodone product.

Zohydro ER will offer prescribers an additional therapeutic option to treat pain, which is important because individual patients may respond differently to different opioids.

Zohydro ER is in the class of extended-release/long-acting (ER/LA) opioid analgesics. Due to the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with ER/LA opioid formulations, Zohydro ER should be reserved for use in patients for whom alternative treatment options are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. Zohydro ER is not approved for as-needed pain relief.

The approved labeling for Zohydro ER conforms to updated labeling requirements for all ER/LA opioid analgesics announced by the FDA on Sept. 10, 2013.

The new class labeling and stronger warnings will more clearly describe the risks and safety concerns associated with ER/LA opioid analgesics, along with the appropriate use of these medications. These warnings are expected to improve the safety of all such medicines by encouraging more appropriate prescribing, patient monitoring, and patient counseling practices. Zohydro ER is the first opioid to be labeled in this manner.

Schedule II drugs can only be dispensed through a physician’s written prescription and no refills are allowed. There are also stringent recordkeeping, reporting, and physical security requirements for Schedule II controlled substances.
Traveling for Treatment Assistance

by Amber Barnes

Lodging:

For Children: Ronald McDonald House 630-623-7048  www.rmhc.org This is a great organization that has lodging for families that are traveling for medical care. There is usually one near every major hospital, look on their site to find a specific one. I hear most of them run the same way.

When we were in NY, we had a bedroom with 2 queen beds, a closet, and a bathroom with tub/shower. There was also a desk, dresser, rocker and TV in the room. Most of them provide dinner at night to the guest; a company or another organization usually donates dinner to the house.

The fee for staying at RMH in NY was $25 a night; I know that is the same in Chicago, IL, and in OKC. I think that is a general rate around the US. If there is a problem with that fee, talk to the house manager about your situation. They also provide washers & dryers, and usually have any toiletries you need. This is a really great organization; I highly recommend it to ones traveling with children.

For Adults: In NY, there was a place called the Variety House, kind of like RMH, except for adults. If you ask the hospital where you are having treatment, there is usually a place like this, you just need to ask. I know there is a place in Iowa for the University of Iowa Hospital.


**Also ask your surgeon/doctor/hospital if they have special rates with any of the hotels that are nearby. Most usually do and give a special rate for medical treatment. This includes consults, rechecks, any reason needing to see your physician.

Air Flight Services:

- Miracle Flights  www.miracleflights.org  800-359-1711
- Air Care Alliance  www.aircareall.org  888-260-9707
- Patient Air Lift Services  www.palservices.org  888-818-1231
- Life Star  www.lifestarinc.com  716-713-2599
- Angel Flights  www.angelflight.com  918-749-8992
- Children’s Flight of Hope  www.childrensflightofhope.org  919-466-8593
- National Patient Travel Center  www.patienttravel.org  800-296-1217
- Hope Flight Foundation (flights in Nevada, California and Oregon only)  www.hopeflightfoundation.org  510-427-3956

Also check with American Airlines, & Southwest Airlines. Some of the big name carriers have special rates, or complimentary flights for medical reasons.

**When looking into these companies, it’s best to call them to get all the required info. Some only travel certain areas of the US, so that is something else that needs to be checked.

---

Financial Resources

by Amber Barnes

Patient Advocate Foundation  www.patientadvocate.org  800-532-5274 - 421 Butler Farm Rd, Hampton VA  23666

If you go under “Resources”, then “National Financial Resources Directory”, select age range, patient’s residential state, medical diagnosis (for CM & SM, I selected rare disease). In the “Assistance Needed” area you can select from house & lodging, utilities, transportation, prescription copay, medication, etc.

NORD  www.rarediseases.org - 800-999-6673 (voicemail only)  203-744-0100 – 55 Kenosia Ave, Danbury CT  06810

Chiari, Syringomyelia, TC, Syringobulbia are all listed conditions as rare diseases. If you go under “Rare Disease Information”, then under “Other Resources and Tools”, there is a lot of information and links for financial & medication assistance, resources, health insurance, medicare & medicaid Information, education resources, genetics information.

Chronic Disease Fund  www.cdfund.org – 877-968-7233 6900 N Dallas Parkway Ste 200, Plano TX  75024

When I checked into this program CM & SM are not listed. But if you need assistance call and speak to them. Not just the person that answers the phone but a director or write them, telling them your story. You never know when someone’s case is picked up. They may need to know more about these conditions and have never come in contact with someone with them. This foundation helps with patient assistance with prescriptions, co-pay assistance, and travel assistance (which includes: transportation, lodging, travel expenses).

If you are in college or plan on attending, contact the Disability Resource Center at your college. Every school has one. This would be a great resource for finding out if there are any scholarships available for the disabled and/or persons living with chronic illness. This is also a great resource if you need help while attending school or any other special circumstances.
Remember ASAP...
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.

In Honor of Person
Donor
All SM’ers without CM
Cheryl Foster
Doug Kindlon & family
Timothy Kindlon
Harriet Meier
anonymous
Jack Nanbergs’ Bar Mitzvah
Stephen and Arlene Sharkey
Jackie Massman
Henry Massman
Jacqueline Babitts
Steven & Rosa Babitts
Kelly Homann Whitehead
Diane Homann
Robert Elliott
John Elliott
Sean McCarthy
Melinda McCarthy
Casper Chiarl
Suzanne McKenna, PhD
Jen Vasek
Suzanne Fassberg
Francisco Vidal
Tony Viviani
Margaret Scarola
Anne McAree
Maria Cizmarik
Mary Critchlow
Kathryn Sakotos
Otto Lohse
Mark Meisels
Manhasset Lakeville Fire Dept Co 2
Kaylie Lemmson
Clevie Luckadoo
Owoc Family
Matt & Leah Blanton
Brandy M Gardner
Betsy J Beam
Elizabeth A Ellis
The Britts & McMahans
Emily B Bellamy
Justin Witherspoon
Dave Lemmon
Aaron Elizabeth and Abigail Lemmon
Christina L Brewton
Marty Thomas

In Memory of
Donor
Ross Reisner
Stephen and Arlene Sharkey
Gordon DeMars
Guy and Marlene Petersen

Honor a loved one with a gift to ASAP on special occasions or just to let them know you care. For donation of $5 or more, ASAP will send an acknowledgement card to the individual.

Remember family and friends with a memorial gift to ASAP. Acknowledgement cards will be sent to family when an address is provided.

ASAP History
During the summer and fall of 1993, a few persistent ASAP members roamed the halls of the Congress on behalf of ASAP. Under the guidance of Ann Charnley, an ASAP board member and experienced lobbyist, a provision in the 1994 federal appropriation bill was included to call for a National Institutes of Health (NIH) conference to set a research agenda for syringomyelia. Representative Steny Hoyer of Maryland spearheaded the effort with help from Senators Robert Byrd, West Virgina, Tom Harkin, Iowa, and Alphonse D’Amato, New York.

The NIH conference was held June 20-21, 1994. The meeting, chaired by Ulrich Batzdorf, MD, UCLA School of Medicine, was attended by 19 neurosurgeons, neurologists, radiologists and researchers. Dr Patricia Grady and Dr Judy Small of NINDS hosted the conference.

ASAP members were active participants in the workshop expressing the patient’s point of view and concerns. Not only was a research agenda developed, but important connections were established between the doctors, the government institutes and ASAP.

In August 1995, the Neurological Center for Inherited and Genetic Disorders at Duke University agreed to undertake a pilot study to determine if sufficient evidence was available to warrant a large scale effort to search for genes predisposing SM or Chiari malformation in individuals. In February 1998 ASAP approved a $100,000 grant to the genetics group at Duke to continue the study. They later received a grant from the National Institutes of Health to continue the research project which is still active today.

ASAP Financial Information
The ASAP Annual Report 2011 is available by request or online at www.ASAP.org under About Us.

You can view past copies of the audited financial reports, IRS 990 and organization information at GuideStar or contact the office for copies.

Contact Information
American Syringomyelia & Chiari Alliance Project

Mailing Address: PO Box 1586
Longview TX 75606-1586

Physical Address: 300 North Green Street, Suite 412
Longview, Texas 75601

Phone: 903-236-7079
Fax: 903-757-7456
Toll-free: 800-ASAP-282 (800-272-7282)
Staff: Patricia Maxwell & Jamie Mayhan
Email: info@ASAP.org
Patricia_Maxwell@ASAP.org
Jamie_Mayhan@ASAP.org
FDA Issues Final Guidance on Mobile Medical Apps

Tailored approach supports innovation while protecting consumer safety

The US Food and Drug Administration issued final guidance for developers of mobile medical applications, or apps, which are software programs that run on mobile communication devices and perform the same functions as traditional medical devices. The guidance outlines the FDA’s tailored approach to mobile apps.

The agency intends to exercise enforcement discretion (meaning it will not enforce requirements under the Federal Drug & Cosmetic Act) for the majority of mobile apps as they pose minimal risk to consumers. The FDA intends to focus its regulatory oversight on a subset of mobile medical apps that present a greater risk to patients if they do not work as intended.

Mobile apps have the potential to transform health care by allowing doctors to diagnose patients with potentially life-threatening conditions outside of traditional health care settings, help consumers manage their own health and wellness, and also gain access to useful information whenever and wherever they need it.

Mobile medical apps currently on the market can, for example, diagnose abnormal heart rhythms, transform smartphones into a mobile ultrasound device, or function as the “central command” for a glucose meter used by a person with insulin-dependent diabetes.

“Some mobile apps carry minimal risks to consumer or patients, but others can carry significant risks if they do not operate correctly. The FDA’s tailored policy protects patients while encouraging innovation,” said Jeffrey Shuren, MD, JD, director of the FDA’s Center for Devices and Radiological Health.

The agency does not regulate the sale or general consumer use of smartphones or tablets nor does it regulate mobile app distributors such as the “iTunes App store” or the “Google Play store.”

The FDA received more than 130 comments on the draft guidance issued in July 2011. Respondents overwhelmingly supported the FDA’s tailored, risk-based approach.

“We have worked hard to strike the right balance, reviewing only the mobile apps that have the potential to harm consumers if they do not function properly,” said Shuren. “Our mobile medical app policy provides app developers with the clarity needed to support the continued development of these important products.”

The agency has cleared about 100 mobile medical applications over the past decade; about 40 of those were cleared in the past two years.

For more information (www.fda.gov/MedicalDevices/default.htm):

- Mobile Medical Applications Final Guidance
- Consumer Update: Keeping Up with Progress in Mobile Medical App
- Mobile Medical Applications Web Page

FDA NEWS RELEASE: Sept. 23, 2013

Media Inquiries: Synim Rivers, 301-796-8729, synim.rivers@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA
ASAP Connections

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 quarterly for ASAP members. Your contributions of articles, letters, and photos are encouraged. The editor reserves the right to edit any article in order to accommodate space.

Email: Patricia_Maxwell@ASAP.org

Mail: ASAP Connections
PO Box 1586
Longview TX 75606

ASAP Connections Editor: Patricia Maxwell