[**Arzerra (Humax-CD20) Approved**](http://updates.clltopics.org/1611-arzerra-humax-cd20-approved)

Chaya Venkat

October 27th, 2009

**Arzerra (Humax-CD20) approved**

I am pleased to report that finally **Arzerra (Humax-CD20) has been approved by the FDA for treatment of refractory CLL**. Since this accelerated approval was based on a clinical trial cohort of patients who were fludarabine refractory and Campath refractory (or ineligible), the FDA approval is for treatment of that group of patients.

However, now that the drug will be available commercially in a few weeks (see below), it is up to you and your doctors to decide if this drug is right for your individual situation. All of us who have been around the block more than a few times are very aware of use of drugs outside of the narrow guidelines of the FDA approval. Rituxan (the previous generation anti-CD20 monoclonal antibody) has been used as a single agent in front line therapy of CLL patients for several years now – even though it has never received formal approval from the FDA for that purpose.

In other words, sit down and have an informed talk with your healthcare providers about what is the right therapy option for you. That is good advice in any case, whether or not Arzerra is in your future. This site and our flagship website [www.clltopics.org](http://www.clltopics.org) have many articles regarding Arzerra, all you have to do is search for them using the key phrase “Humax-CD20”

This is a bitter sweet moment for me. My husband PC and I fought for this approval for several years. He was fortunate to get compassionate use access to Humax-CD20 back in 2006 and we were impressed how well it worked for him. Back then we had to travel all the way to Bournemouth (UK) to get this drug administered. Now, in a few weeks, you can get it infused in the comfort of your local oncologist’s backroom. I am sorry PC is not here to celebrate this development, it is truly a victory for our patient community. He would have been proud.

**GSK AND GENMAB RECEIVE ACCELERATED APPROVAL FOR ARZERRA**

Philadelphia, PA and Copenhagen, Denmark; October 26, 2009 – Today, GlaxoSmithKline (GSK) and Genmab A/S (OMX: GEN) announced the accelerated approval of ArzerraTM (ofatumumab) from the US Food and Drug Administration for use in patients with chronic lymphocytic leukemia (CLL) that is refractory to fludarabine and alemtuzumab.

The approval is based on results from a pivotal study in which 42% of patients with CLL who were refractory to both fludarabine and alemtuzumab (two therapies used in treating CLL) responded to treatment with Arzerra. These patients had a median duration of response of 6.5 months. The most common adverse reactions (≥10%) seen were neutropenia, pneumonia, pyrexia, cough, diarrhea, anemia, fatigue, dyspnea, rash, nausea, bronchitis, and upper respiratory tract infections. The most common serious adverse reactions seen were infections (including pneumonia and sepsis), neutropenia, and pyrexia.

Arzerra is a monoclonal antibody that causes the body’s immune response to fight against normal and cancerous B-cells. Arzerra attaches to the small and large loop epitopes – on a molecule called CD20, which is found on the surface of B-cells, the type of cell which becomes cancerous in CLL.

The approval of Arzerra was supported by a positive recommendation by the FDA’s Oncologic Drugs Advisory Committee (ODAC) at ASCO on May 29, 2009, in which the panel voted, 10-3, that the Arzerra data were likely to predict clinical benefit for patients with CLL whose disease is refractory to fludarabine and alemtuzumab.

Arzerra is anticipated to be available for prescription use in the coming weeks.

GSK has added Arzerra to its expanding patient assistance program, Commitment to Access, and has expanded the program. This program assists eligible patients, with or without insurance, with paying for cancer medicines. For more information about the program, visit www.CommitmentToAccess.com or call 1-8ONCOLOGY1 (1-866-265-6491).



**29 comments on "Arzerra (Humax-CD20) Approved"**

drdave333

October 27th, 2009 at 8:24 am

Thanks again Chaya.
Just going through a second round of Rituxan only and the response is not as robust nor as
quick as the first time 20 months ago. Glad to know of these additional possibilities when
the old ones seem to be slipping a bit. Sorry too that PC isn’t here to share in this and to
be in your life. Regards.
Dave Mikol

ljeisenberg

October 27th, 2009 at 8:34 am

Wonderful news for our community, Chaya. Our thanks to PC for helping to blaze the Azerra trail and for your advocacy work in getting it approved.
All the best,
Leslie Eisenberg

United

October 27th, 2009 at 9:36 am

Thanks for keeping us informed of this excellent new development, great news.
My partner is a patient currently on a Humax(Arzerra)trial, and has also seen the benefit of this drug.

I wonder how long it will be before we see it approved by NICE over here in the UK ?

Best wishes,
JR

mickey1214

October 27th, 2009 at 9:37 am

The news, in and of itself, is a silent tribute to both of you. Many thanks.
Tom DeTemple

Chaya Venkat

October 27th, 2009 at 9:40 am

United:

One of the points I made during my presentation to the FDA advisory panel is that it is a good idea to have TWO candidate drugs available and competing for our healthcare dollar (or Pound). A little bit of competition is a good way to bring down prices, improve R&D and consumer service. Until now Rituxan was the only anti-CD20 monoclonal. Now that Arzerra is approved as well, let the games begin.

If NICE wants to be smart about pricing leverage, they too should be quick about approving Arzerra.

bethcat

October 27th, 2009 at 9:54 am

Again, congratulations Chaya, and PC, and to all who have particpated in getting one more bullet in our arsenal. This is good news for all CLLers even if it doesn’t fit each one of us. It brings with it more awareness of CLL, and that’s always good news. Chaya, as always, a valiant fight. A hearty thanks, beth

mikkimus

October 27th, 2009 at 10:09 am

Chaya-this is a major breakthrough! Thanks again for your unfailing tireless work!

rwitz18

October 27th, 2009 at 10:55 am

Chaya,

Thanks again for your hard work and determination.

Many Blessings,

Rita

aamster

October 27th, 2009 at 11:03 am

Congratulations on this finally getting approved. It is due to your hard work & efforts that we now have some options!

Thank you for all of your help

Susie

October 27th, 2009 at 11:24 am

Chaya,

Words alone do not seem enough to express the gratitude we feel for the efforts and achievements you and PC have made for the CLL community. My husband is about to begin Arzerra (was to be part of a clinical trial combined with Revlimid) so the approval will now ease the restraints of private insurance and having to fight for that. Thank you for all that you do.

Jaqui

October 27th, 2009 at 11:28 am

Re the UK: for United/JR. NICE will be considering this drug probably in the Spring of 2010, the appraisal meeting to discuss the drug is in the NICE programme. The CLL support association will be submitting comments and should be there at the meeting. We are still hoping to get Rituximab approved for second line use; we should know in the next few weeks.

molly fletcher

October 27th, 2009 at 12:47 pm

Great news Chaya and a fitting legacy for PC.
Good to know we might be getting the benefits in the UK next Spring.
In terms of the nausea side effect from this drug, has anyone else tried sea(travel)sickness bands? They are wrist bands from the chemist which press on the acupuncture point for all nausea. They certainly worked for me with chemo, pregnancy sickness and sea sickness. Nobody knows how they work but they are standard issue to sailors in the navy, so they must be effective.

Molly

elcaringo

October 27th, 2009 at 12:59 pm

Chaya,

I’m sure that your FDR presentation in Orlando had a major impact on it’s approval.

Thanks for all,

Cary

Monique

October 27th, 2009 at 1:10 pm

Great news Chaya.
Thanks for keeping us informed.

Monique

lynncollins

October 27th, 2009 at 1:50 pm

congratulations to us all and kudos especially to Chaya and PC for all they did to make this happen for all of us.

best,

lynn

EBW

October 27th, 2009 at 1:51 pm

Thanks Chaya for all of your work concerning this approval. PC would be so proud, and all of us owe the two of you so much, this is just the latest. Beth in Oregon

Brian

October 27th, 2009 at 5:51 pm

This is great news. The real story of ofatumumab will be written in how well it works in what combinations or in special circumstances: i.e. does it work better with certain patients or with certain conditions such as AIHA or ITP or bulky nodes.

These will be discovered both in clinical trials and in the experience of patients and doctors over the next several years.

Thank you for your role in this important new option,

Linda Lee

October 27th, 2009 at 6:27 pm

Many thanks to you, Chaya and for PC. It is a legacy for him.

We read how you kept us informed and even went to bat for this approval including traveling to the Orlanda to present during your personal trials. That was sacrifice.

I’m excited to see how much this drug will mean for the CLL community. Just having a human based drug will avoid much suffering over those derived from mice.
Stay well in India!

LynnS

October 27th, 2009 at 7:35 pm

Chaya,

Thank you so very much for all you and PC have done to get this drug moved down the road.

Are there studies in place looking at this as a first treatment, either alone or with F and/or C? Is anyone enrolled in this site participating?

Chaya Venkat

October 27th, 2009 at 7:51 pm

HOUSEKEEPING NOTE

I will be away for 4 days on a short trip – no internet connectivity. See you guys when I get back!

frank

October 27th, 2009 at 8:35 pm

Chaya,
Thank you for all you have done and continue to do. My husband lost a 6 year battle against CLL just 2 weeks ago. He would have been a perfect candidate for Humax CD20. But it does give me much consolation that others will now have what we were not able to get. We tried other clinical trials, including Treanda, Revlamid, and even started a NCI experimental protocal for a T-cell genetic modification. The heart and mind was willing but the body was not. I will continue to read your site every time an alert is sent out, and I will pray for all the others and their caregivers that battle this “lucky” disease.
Nurse Glatts

midgetb@aol.com

October 27th, 2009 at 10:09 pm

Chaya,
OK. Great news! Your efforts and PC’s are greatly appreciated as everone has noted here.

This gives me another question to ask with my MDA oncologist when I meet with him. Unfortunately, I will be an experiement of N = 1 since neither oncologist (SCCA or MDA) believes what is proposed has ever been done before…monoclonal four infusions over four weeks with undetermined steroid (please, not Solu-Medrol again) and then a dose of same once every three months to keep my lungs free of CLL.

Now for the serious business: will insurance providers pay for ofatumumab?

Barry

mairst

October 28th, 2009 at 1:32 am

Chaya- Congratulations! Your hard work has paid off.

As you know I’ve been waiting for this drug for a LONG time. I’m hoping this is a relatively benign but more effective alternative than Rituxan.

I recently completed my 60th Rituxan infusion, so I’ll be able to get ofatumumab when I need it. My Kaiser Oncologist has already confirmed he’ll use it when approved.

Kindest regards,
Malcolm Airst

Lupner9

October 28th, 2009 at 7:44 am

Chaya,
You had a big part in getting this approved with your testimony before the FDA. I cannot thank you enough. PC would have been proud of you. You are a great asset in the arsenal of CLL weapons thru your advocacy and the CLL Topics etc. Can’t thank you enough
Chris

Waynewells

October 28th, 2009 at 6:21 pm

A celebratory cyber toast to you and PC in your efforts to get another option for us. I want to include Diane McKinnon and others who are there on the front lines who voted for this to become a reality.

Though I recently had a great response to Rituxan and Fludarabine (RF) I ended up with a renal failure event now thought to be a very rare reaction to Fludara. Though my bloodwork looks nearly normal after only 2 cycles the cancer is still present in the nodes though greatly diminished. Bone marrow was 91% impacted prior to TX so there is undoubtedly cancer there too.

The approval of Arzerra (Ofatumumab) may signal a change in my treatment protocol. I will be having a strategy meeting with my Kidney doc and Onc in a couple of weeks.

Encouraging news came from the LRF Conference in Brooklyn this past weekend regarding the outcome of a syk inhibitor in CLL/SLL for a small trial of eleven patients.

Keep the good news coming!

WWW

warmac9999

October 29th, 2009 at 6:44 am

Was just at the Ohio State CLL center and was told about the the CD-20 situation. However, was also told that another clinical trial using CD-20 was planned for about 6 months from now. Am somewhat confused as to what type of clinical trial would involve a now approved treatment. I am also interested in the difference between non-profit consortiums and for profit companies. It seems there are two different approaches to treatment – one involving this collection on non-profits and another involving dealing with individual companies. I would be interested in comments on this.