Q&A GENMAB

8. AUGUST 2011

MED CEO Jan van de Winkel

Transcript Live Q and A Genmab CEO Jan van de Winkel, 8th of Aug. 2011

akademikeren	First of all, I would like to say welcome to Jan Van de Winkel, its an honour to have you here. Are you online Jan?
Jan Van de Winkel	Yes, both David and I are sitting here, ready for questions!
akademikeren	Thats great. We have a lot of questions lined up for you guys. The theme of today talks are your Q2 report, but there will Certainly be some question about the DLBCL data from friday also. But first of all can you walk us through the highlights of This quarter?
Jan Van de Winkel	Thanks, we had a successful R&D day at the start of the year and we have made excellent progress with partnered Programmes.... Arzerra sales went up 48% over H1...and the drug is now available in 21 countries. GSK presented v good sc ofatumumab data in RA at Eular in May and ... we finalised recruitment in important front line CLL Phase III study almost 6 months ahead of schedule....and Roche started second large phase II study with RG1512 in Q", and we expanded the Seattle Genetics collaboration and Added a new product to pipeline HuMax-CD74-ADC. Lastly... we have continued our strong focus on cost control. New question?
akademikeren	I will open the session up now. Because we have a lot now already
Bauerz	Q regarding the DLBCL data in comparison to the CORAL study; you reach 61% vs. 51% but (1) can we expect the pts to be comparable to this subgroup (refractory vs. relapsed >12month) and (2) do you now feel more confident with the ORCHARRD study outcome ? Thanks
Solsen	Hello Mr Winkel Did the new data in DLBCL give you a better confidence to the outcome of the phase 3 (OCHARRD). I wonder if 380 patients will give a significant result with the CORAL study in mind, where 51% ORR was recorded in the subgroup with “prior exposure to rituximab” patients ? And second what could the market peak (revenue) be in DLBCL ?
Jan Van de Winkel	We are very pleased with the Phase II data, as it reconfirms the activity of ofatumumab with chemo in difficult to treat cancer Patients. It also strongly confirms that our ORCHARRD phase III head to head study is the right path forward.
akademikeren	I just included a question on the sames lines above
Jan Van de Winkel	Yes, the new data strongly supports the Phase III design and powering. DLBCL is about a third of all NHL so it is a very Sizeable market.
akademikeren	and should we calculate 1)about 20% as refrac 2)4000 mg dosis treatment?

Jan Van de Winkel	We would probably estimate around 40% as refractory or relapsed. The effective dose is 1000mg per infusion.
troldmanden	Are you pursuing larger and broader R&D deals where a partner get access to your technology? Something like what Neurosearch have done successful with the partner paying 30-40 FTE and where Neurosearch can get 300+ mill euro in milestones per molecule + double-digit royalties. Deals like that often also gives a niche amount upfront. Or do you prefer to make smaller and more narrow R&D deals?
Jan Van de Winkel	We aspire to do both smaller and larger deals. We have a deal with Lundbeck for example, where we create antibodies against three CNS targets..and…
	we will in the future do deals for both technologies and products. For example, our novel DuoBody technology platform is an Area of active partnering activities for us right now.
troldmanden	When do you see the next possible approval for Arzerra and in which indication?
Solsen	Dear Mr Winkel When can we expect ofatumumab in sc version on the market in MS/RA ? And do you fear competition from rituximab generics in 2015 ?
Jan Van de Winkel	We most excited about CLL frontline, where we finished recruitment in the Phase III study almost 6 months ahead of Schedule. We still anticipate data to become available in early 2013 which could form the basis for an sBLA in that year.
Jan Van de Winkel	Re the sc question: GSK intends to start recruiting patients in a Phase IIb MS study in the second half of this year. Depending on the data this could roll into Phase III studies. The timing would be impacted by the size and extent of the Studies. Re rituximab generics. We hope our head to head studies will show we have a superior product and our ofatumumab Patents extend beyond 2023.
Solsen	Could Genmab be interested in making a license deal with Daratumumab when phase I/II are made public - I would expect it could secure the cash position until arzerra sales can bring Genmab byond alone
Jan Van de Winkel	Daratumumab is a very potent therapeutic candidate and a potential first in class for a very sizeable market. The antibody therefore ticks all the boxes for big pharma to be interested - we would be pleased to discuss a potential Partnership based on data generated in early clinical studies.
troldmanden	You cannot tell us the amount. But would it be possible to tell which Arzerra event could trigger the next potential milestones?
Jan Van de Winkel	There may be a small milestone to filing in Japan but the larger milestones will be related to filing and approval in FL.
RTH	are you still looking for a partner for zalutumumab? eg. in conjunction with a sale of your fabric facility in the USA?
HSK	as the (deduction) incentive for someone else to purchase such a production facility time seems to be running out....

Jan Van de Winkel	We are open to finding a partner for zalutumumab if the opportunity arises. We would be open to a combination deal with the Manufacturing facility if it came up.
	We are happy to stay answering questions for another 10 minutes
akademikeren	These questions is in regards to the minnesota facility
Jan Van de Winkel	We are still firmly focused on selling the MN facility.
Bauerz	Q regarding zalutumumab: Are you still in talks with potential partners ? and secondly, do you think the readout from eg the dahanca study could add interest from partners, or is it more a question of market potential vs the investment needed? Thanks
Jan Van de Winkel	We are still open to partner zalutumumab if it is the right thing for us to do. The DAHANCA study could create interest when the data becomes available - but a partner would still need to invest a sizeable amount in further development in order to create a sizeable market for this product.
Bauerz	Finance question: David, could put some flavor on your development spending for 2012 – should we expect this to be in line With 2011 outlook minus the DKK80m from zalu? Thanks
Jan Van de Winkel	We would expect our cash spend to be similar in 2012 compared to 2011. We will save on Zalutumumab but this will be Offset by new Daratumumab trials.
akademikeren	We need to round up here, unfortunately with a lot of questions here. The final one from Collersteen
collersteen	Hi. I assume you have seen the recent Dendreon news and their missed sales forecast. One issue seems to have been reimbursements via the Q-code. Are you seeing the same issues with the j-code or is there another reason as to why there Does not seem to be any j-code effect in the US-arzerra sales? Thanks.
Jan Van de Winkel	We continue to receive positive feedback from GSK on interest for Arzerra. We are confident that sales will increase now reimbursement has been put into place in the US. We also look forward to future growth as more clinical data becomes available, there are currently 61 studies on clinicaltrials.gov of which 48 are active or recruiting.
akademikeren	Ok. I would like to thank Genmab and our users for this Q&A session. Thank you for coming to ProInvestor, Jan. And thanks for all the good answers and questions
akademikeren	It will be exciting to follow the company through the uptake of Arzerra and your efforts to bring new drugs to the market
Jan Van de Winkel	Thanks for the very good questions. We look forward to an exciting 2H 2011 and to be able to answer your questions again In the future.

Q&A Retail

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