Q&A GENMAB

16. maj 2012

Med CEO Jan Van de Winkel

Transcript Live Q and A Genmab CEO Jan Van de Winkel, 16. maj 2012

Akademikeren	Welcome to this Q&A Session. We are very proud to once again welcome Jan van de Winkel from Genmab for an indepth questions and answers session about the latest quarter. Are you there Jan?
Jan Van de Winkel	Yes, I am here, I also have David Eatwell and Rachel Gravesen with me.
Akademikeren	It looks like Genmab is constantly improving QoQ. Can you run us through the highlights of this Quarter
Jan Van de Winkel	We saw a small improvement in revenue, lower costs year on year and a 29% improvement in operating loss.
Jan Van de Winkel	We also saw good progress on our business milestones.....
Jan Van de Winkel	Arzerra net sales up 32% and a NDA for ofatumumab in Japan was submitted.
Akademikeren	Ok I will let the users in right away
Johny	You have registered ofatumumab in Japan. When do you expect that filing to be decided upon by the authorities? And is there a milestone attached to that?
Jan Van de Winkel	OK. Feel free to ask several questions at once
Akademikeren	We will then take a bunch of questions regarding Arzerra /Ofab
Johny	You say that the date for primary data on the Head-to-head study has been moved forward. When do you expect the primary data to be announced?
Sukkeralf	Could you in more detail explain the reason for submission of protocol amendment for ofatumumab phase III in DLBCL (removing the DVP-arm and keeping the DHAP-arm) – what did the futility analysis show you and when do you assume to get an answer from FDA ?
Sukkeralf	Which CD20 antibodies do you see Arzerra compete against in the future (Rituxan, Obinutuzumab/GA101, Zevalin or others) ?
Jan Van de Winkel	We dont have an exact timing for acceptance of the filing. Yes there is a small milestone attached to acceptance. If all goes well the drug maybe approved in Japan Q1 2013.
Akademikeren	How is the arzerra sales stacking up against your expectations?
Jan Van de Winkel	After the protocol amendment we potentially may have the primary data by early 2014 in the head to head Phase 3 vs rituximab
Jan Van de Winkel	The protocol has been amended to focus the chemo regimen on the most commonly used chemotherapy regimes internationally and we increased the number of patients on the DHAP regime.
Jan Van de Winkel	The futility analysis indicates that the Independent data monitoring committee were comfortable with the way the study is progressing and therefore the study is recommended that it should continue as planned.
Akademikeren	How do you see the future development / uptake of Arzerra in the market. What are the key data the next 2 years?
Jan Van de Winkel	We see ofatumumab as a well differentiated drug from other CD20 antibodies including rituximab and GA101. Ofatumumab has shown to be very effective in killing cancer cells in preclinical tests and we hope this will be validated from the results of our head to head studies - the first one of which may read out in early 2014.

Jan Van de Winkel	We are pleased with the progress to date of Arzerra sales. Q1 2012 saw the highest US quarterly sales since launch. Rather than looking from quarter to quarter though, we focus on the long term potential which should be driven by data and label extensions.
Jan Van de Winkel	There is an increasing number of studies with ofatumumab. At present there are 78 studies on clinicaltrials.gov of which 64 are active or recruiting. From next year on we will see data from large Phase 3 studies reading out. The first one will be frontline CLL in 2013, followed by four different Phase 3 studies in 2014.
Akademikeren	Do you get any feedback from the medical community about how they and their patients percieve Arzerra?
Akademikeren	the sales are in steady uptake, increasing incrementally all the time. Is it repeat treatments or new patients?
Jan Van de Winkel	The broad clinical program means that physicians are becoming more and more familiar with ofatumumab and combinations of ofatumumab with other (new) drugs. There are also a lot of investigator sponsored studies ongoing where physicians will share their experience with ofatumumab.
Jan Van de Winkel	We dont have that level of detail on the sales for Arzerra in existing or new patients. GSK continue to roll out the commercialisation program in new countries.
Akademikeren	Thank you. We will move into 3 Daratumumab questions.
Sukkeralf	How satisfied are you with the clinical results seen so far with Daratumumab in comparison to what you expected from a antibody in MM ?
Tunis	Approximately how much of your cost today is related to Daratumumab?
Akademikeren	And lastly you said last quarter that there was a good interest for partnering Dara. Has there been any exciting developments? Do you still expect a partner during 2012
Jan Van de Winkel	The early clinical data are very encouraging and compare well with the experience with other antibodies evaluated in multiple myeloma (myelomatosis).
Jan Van de Winkel	In 2012 we expect to spend approximately 70 million kroner on the daratumumab program.
Jan Van de Winkel	We have a daratumumab partnership as one of our key 2012 milestones and fully expect to achieve that. We have seen excellent interest in daratumumab.
Akademikeren	Thank you. 3 misc. questions concerning your clinic next.
MadsSkjern	When do You expect DAHANCA19 results to be published - and if significant, is Zalatumumab back in business?
Sukkeralf	What kind of validation (in-virto or in-vivo) are needed for your secret partner (and Genmab) on the Doubody- and ADC technology platform to go from a research collaboration to a license agreement ?
Sukkeralf	When can we expect an update on Genmabs pre-clinical pipeline ?
Jan Van de Winkel	We are in contact with DAHANCA and the flow of data is decided by them. The study continues to recruit according to schedule and should be recruited this year.
Jan Van de Winkel	The undisclosed pharma company will run the DuoBody ADC molecule against a relevant benchmark and may exercise an option to license the product.
Jan Van de Winkel	We intend to organise a post ASH seminar at the end of the year in which we will update the market on our pipeline, preclinical pipeline and technologies.
Akademikeren	Ok. We will dive into 2 financial questions next

Tunis	Your cashburn this quarter seemed particular low. Is this the rate of burn going forward?
Akademikeren	Do you have any costs related to Zalutumumab any more or has this been written off in 2011?
Jan Van de Winkel	The guidance for 2012 is a cash burn of 425-450 million DKK.
Jan Van de Winkel	We have a very small amount in 2012 compared to the 85 million DKK we spent in 2011.
Jan Van de Winkel	What we save on zalutumumab is now invested in daratumumab during 2012.
Akademikeren	what can of read out do you need on Zalutumumab for recomitting ressources on that project?
Jan Van de Winkel	We dont envisage investing further in zalutumumab ourselves.
Tunis	Do you have any update on the factory?
Jan Van de Winkel	The process to find a new owner for the manufacturing facility is active. At this time we can't really say more as we have CDAs in place.
Akademikeren	Ok. Finally there is a couple (2) questions about the future
Johny	I have noticed that GSK has been more active on the M&A side lately. Do you think GSK now is moving more in a direction where they want to acquire new companies?
Jan Van de Winkel	I think that is a question for GSK.
Tunis	Have you noticed any change in their strategy towards genmab?
Jan Van de Winkel	No, we have not seen any change in our relationship which continues to be very productive.
Akademikeren	What should we as investors in Genmab be looking out for in the next quarter? What do you think will be of the greatest importance for Genmab as a company? Do you still envision to turn the clinic into a cashgenerator and will this be done in early stage ?
Akademikeren	I mean by partnering out in early stage phases
Jan Van de Winkel	Rather than looking at the next quarter, let's consider the milestones for 2012. We have set out key objectives including -
Jan Van de Winkel	maximise the value of ofatumumab, complete partnering for daratumumab, enter new collaborations for the DuoBody Platform, and progress our partnered programs.. And finally manage our cash burn and execute the sale of the manufacturing facility.
Jan Van de Winkel	All of these objectives will contribute to building value and confidence in Genmab.
Jan Van de Winkel	We will continue to build a number of partnered programs that will supplement the cost of our research facililty - such as the Lundbeck collaboration.
Akademikeren	One final question.
Akademikeren	How do you see the industry balance between biotech and pharma. Is Biotech getting better deals in their deals with big pharma. Is the pattern cliff beginning to show some increased interest?
Jan Van de Winkel	It is clear that big pharma need biotech to provide innovation and novel pipeline products. They also tend to access both earlier and earlier on....
Jan Van de Winkel	....we see the level of interest from pharma increasing generally which should be positive for the biotech sector.
Akademikeren	Thank you so much for your answers, Jan. We as retail investors really appreciate you taking your time to share the progress of Genmab.
Jan Van de Winkel	Thank you very much for your excellent questions. I appreciate the opportunity to 'speak' with you and look forward to next time.

Q&A Retail

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