Q&A GENMAB

8. november 2012

Med CEO Jan Van de Winkel

Transcript Live Q and A Genmab CEO Jan Van de Winkel, 8. november 2012

Akademikeren	Today we present Genmabs CEO, Jan Van de Winkel, in a Q&A Session at 14.00
Akademikeren	You can enter your questions and then we will post them at the time of the live session.
Akademikeren	We will start this session in 5 minutes
Akademikeren	First of all I would like to Welcome Jan Van de Winkel, CEO of Genmab. Congratulations on your 3rd upgrade this year. We have a lot of ground to cover today. I will try to group in 2 or 3 sets on each topic. But first Welcome Jan.
Jan Van de Winkel	Thank you - very nice to be 'speaking' with you again
Akademikeren	We appreciate your time. First we have a range of questions concerning the factory.
Investor1989	Do the 320 mio. Kr. for the facility sale match with the actual prices you discuss with potential buyers or are that just an estimate for the book value of the facility right now?
Leoloo	Mn Facility. Among investors here it has been an issue of much discussion and in general we are of course very disappointed with the huge write off, the yearly costs and that it seems so hard to get it out of the way. I hope you can give us some more information on this. I am interested in knowing if the write off reflects 1) the price you are willing to sell at 2) overcapacity on the market or 3)if the facility is no longer “state of the art” looking at todays and near future production methods
Akademikeren	----
Jan Van de Winkel	The fair value is based on benchmarks including sales of similar facilites, replacement cost and advice from our sales agent. However, while a potential buyer may be interested in what it cost to build or our book value....
Jan Van de Winkel	to the buyer will be based on their specific calculations ie what they will use it for and their best next alternative and how well it fits their need.
Jan Van de Winkel	It is an excellent facility built to a very high quality, although as we have said before it is a specialised facility ....
Akademikeren	It seems very optimistic still to be expecting the sale this year. Are you still confident in that?
Jan Van de Winkel	and it takes patience to find the right buyer...
Jan Van de Winkel	but we have been encouraged by activity over the last few months.
Jan Van de Winkel	We are still very focused on resolving the issue in the near term.
Akademikeren	Ok. Thank you. Lets turn to Arzerra
Leoloo	Arzerra sales. You state that the Q2/3 sales increase comes from ROW clinical trials and that the numbers are not reflecting the commercial demand going forward. At the same time we have seen the US numbers stalling for 5 straight quarters. Looking ahead towards your 4th year on the US market, can you give us your thoughts on why Arzerra uptake is not progressing there and why we still see no J-code effect. I understand the challenge of operating in a small indication, and that off label has not

Sukkeralf	Is there a milestone connected to the approval of Arzerra in Japan next year ?
Sukkeralf	Will GSK/Genmab still give us an update on Arzerra in autoimmune indications this year ?
Akademikeren	----------
Jan Van de Winkel	Currently the label for Arzerra is very narrow. However, we expect sales growth to be driven by data from the robust pivotal studies, that will start reading out next year.
Jan Van de Winkel	In the coming 20 months we expect data from 5 pivotal studies that should trigger label expansion and increase sales.
Jan Van de Winkel	Yes we have a small milestone connected to aproval in Japan.
Jan Van de Winkel	GSK is in charge of the autoimmune programs but it is reasonable to expect that they could update on data from the MS program next year .
Akademikeren	you have raised guidance for arzerra, but you are saying that Q4 is going to be smaller than Q3. Can you shed some light over that? Is the current label getting any commercial sales as of now?
Solsen	When do you expect GSK to bring an update on ofatumumab in RRMS – this year or next year ?
Sukkeralf	Looking ahead for one of the big milestones in 2013 - the frontline fase III topline data for Ofatumumab in combination with chlorambucil in CLL. What kind of improvement i PFS (O vs OC) do you hope for and how important is it that can get an approval before Roche (Rituxan/GA101) ?
Akademikeren	----------
Jan Van de Winkel	As we mentioned on the call, Q3 sales were boosted by purchases by other companies running clinical studies. We do not have visibility into future needs for Arzerra for clinical studies by third parties.
Jan Van de Winkel	We have not publically disclosed the powering or the expectations of the frontline CLL pivotal study.
Jan Van de Winkel	This is an important trial, it is a frontline study and as these phase 3s readout over the next 2 years, we very much hope that these drive label expansion.
Sukkeralf	What impact will the withdrawal of Alemtuzumab/Campath have on the Arzerra label and sales in the future ?
Akademikeren	----------
Jan Van de Winkel	This unprecendented situation and with GSK we are keeping a very close eye on developments. We will work with regulatory authorities on potential action when appropriate.
Akademikeren	Thank you. Now we have some questions regarding Zalutumumab.
Solsen	The DAHACA trial is to be made public next year. What could investors expect from Zalutumumab – do you belive in better luck this time hence the patients is naive to prior treatments.
Leoloo	Also I would like to know if anything could make you change your mind in selling i.e taking a product all the way to the market yourself, or perhaps a package deal combined with a clinical candidate or even Zalutumumab? Also is there anything else to report about the Zalutumumab status?
Akademikeren	-------
Jan Van de Winkel	We very much look forward to seeing the data for zalutumumab from DAHANCA, but at Genmab we do not expect to further invest in zalutumumab as disclosed last year.
Jan Van de Winkel	We expect to file an IND next year for our HuMax-TF-ADC which is performing excellently in preclinical and tox studies...
Jan Van de Winkel	we believe the way to create value in Genmab is to maintain 50% or more of the rights of a product in the future, but only after achieving profitability. HuMax-TF-ADC could be a contender for us to take further.

Akademikeren	What would the market potential be for this new drug?
Akademikeren	---
Jan Van de Winkel	Tissue Factor is expressed on multiple solid cancers. It is too early to discuss specific indications.
Akademikeren	So should we view it more as a new technology, approach to deliver treatment?
Akademikeren	---
Jan Van de Winkel	HuMax-TF-ADC is a product. It is a so called antibody drug conjugate where an antibody is linked to a highly potent chemotherapeutic. ADCs are expected to catalyse a revolution in cancer therapy.
Akademikeren	Ok. Thank you. I need to read up on that. We have a quick followup question on Arzerra.
Collersteen	Re: Arzerra. Hi Jan, thanks for doing this Q&A. Are the arzerra used by other companies in clinical studies sold at full price? And how do you see that particular type of sale going forward? Any new planned studies you are aware of?
Akademikeren	---
Jan Van de Winkel	Arzerra sales to other companies is sold at a commercial price. It is difficult to project accurately the clinical trial supplies on a forward basis.
Jan Van de Winkel	We are pleased to see the increased interest by other pharma in combining Arzerra with new candidate therapeutics...
Jan Van de Winkel	this because most cancer patients are treated by a combination of drugs. If Arzerra becomes part of future combination regimens, that should further impact sales.
Akademikeren	Now lets turn to the exciting present with Duobody & Daratumumab. Congratulations on some surprisingly good deals for Genmab. Lets do Duobody first.
Solsen	Dear Mr Winkel First regarding duobody. Together with Janssen two or more duobodies are activated for which Janssen paid $175.000 each. Is this the final payment or do you expect more before you are delivering the duobody to them ? And when do you expect to hand over the first duobody for further clinical trial ?
Investor1989	I think I heard on the conference call yesterday that you received 3*750.000 $ from Janssen from 3 Duobody programs. Is that right? Can you give an update on those 3 programs? And is it possible more of the 10 programs will be chosen in the future?
Sukkeralf	What defines a program in the DuoBody collaborations with Janssen/ Novatis - is it a disease or a combination of targets ? Any limitations regarding having the "same program" with two different partners ?
Sukkeralf	Any news on the DuoBody-ADC collaboration with the secret top 10 pharma partner - are we going to see a license agreement in 2013 or is it to early to say ?
Sukkeralf	You seem quite satisfied with the Seattle Genetics collaborations - any plans to go for a DuoBody-ADC ?
Akademikeren	-------sorry there were so many
Jan Van de Winkel	With Janssen DuoBody agreement we got USD 3.5 million upfront payment and two new bispecific product reservation payments of USD 750.000 each....
Jan Van de Winkel	There are three active bispecific programs and we are optimistic that they will select all ten covered by the agreement....
Jan Van de Winkel	furthermore all three initial programs progress well.
Jan Van de Winkel	A bispecific program is defined by a certain target combination. Our partners get an options for a short exclusivity period in exchange for a payment.

Jan Van de Winkel	Regarding the undisclosed pharma partnership, it is progressing well and we will update on this in the future.
Jan Van de Winkel	We have already a existing DuoBody-ADC collaboration with the undisclosed pharma. It is an exciting opportunity to combine DuoBody with ADC technology.
Akademikeren	Before we turn the attention to Daratumumab. I would like to ask, how all these deals are transforming Genmab? Can you shed some light on the cash burn situation which looks so much different now?
Akademikeren	---
Jan Van de Winkel	We've worked very hard to reduce the cash burn over the last few years. We are now in an unusual position for a biotech company in that we have a cash runway of more than 4 years based on our current cash burn level.
Akademikeren	thank you. Lets turn to the Daratumumab situation
Investor1989	Regarding Daratumumab, you have stated earlier that you are discussing protocol with the FDA. Are you trying to get a SPA on a registration study?
Investor1989	You mentioned that J&J (Janssen) will do several phase III studies with Daratumumab. Will all of those be registration studies? And will it all be in MM monotherapy in different settings as relapsed, frontline etc
Akademikeren	--------
Jan Van de Winkel	We disclosed that we discussed design of monotherapy studies with regulatory bodies. At present we have no plans to file an SPA.
Jan Van de Winkel	The phase 3 studies are all potential pivotal studies. They will be both monotherapy and combination studies.
Sukkeralf	In the Q3 CC you mentioned that we will see multiple studies with Daratumumab in mutiple myeloma next year - what about clinical studies in other indications in 2013 ?
Jan Van de Winkel	In MM we are making plans for pivotal studies in frontline, secondline and third line, that will all be started in parallel in the coming time.
Solsen	Janssen did recently enter an agreement with Pharmacyclics on Ibrutinib. Can we se similarities in this deal regarding milestones compared to the daratumumab deal ex significant milestones when treatment begin in trials ? Is there any milestones related when the daratumumab safety trial enters part 2 ?
Jan Van de Winkel	We have not disclosed which studies will start in 2013 in daratumumab program.
Akademikeren	-------
Jan Van de Winkel	The structure of the deals are different. Pharmacyclics is funding a significant part of the studies. Our deal is de risked, in that Janssen is fully funding all the costs including our own FTEs working on daratumumab going forward.
Jan Van de Winkel	We have not disclosed specifics about milestones, albeit they are nicely spread over different events and indications.
Akademikeren	Thank you very much Jan. I have a final question for you.
Akademikeren	As a longterm investor its quite hard to keep up with the progress of Genmab, especially these 2 past quarters, so what should we be looking at in Q4?
Jan Van de Winkel	One of the key events in Q4 will be our Post ASH seminar planned for December 17th - this will be webcasted (and details put on our website before the event)....
Akademikeren	--
Jan Van de Winkel	At this event we will update on our preclincal and clinical pipeline, and cover data presented at ASH. Presenters will include world renowned experts in hematology who will give their perspective on our clinical data.

Akademikeren	will that include new guidance for Genmab 2013 or will it be on the clinical side alone?
Jan Van de Winkel	We will publish our guidance as usual, along with the year end results in the New Year.
Akademikeren	Thank you for your time, Jan. And congratulations on an excellent quarter. We hope to hear from you again
Jan Van de Winkel	Thank you very much, and again, thank you for the opportunity to interact here on ProInvestor. Some excellent questions!
Akademikeren	- This Q&A Session is finished -

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