Q&A GENMAB

8. maj 2013

Med CEO Jan Van de Winkel

Transcript Live Q and A Genmab CEO Jan Van de Winkel, 8. maj 2013

Akademikeren	We have the pleasure of presenting Genmab Q1 report and Q&A session with CEO Jan van de Winkel at 14.00.
Akademikeren	Ok we will open this Session. Are you with us Jan?
Jan Van de Winkel	Good afternoon, Jan van de Winkel here, and I am joined by David Eatwell, Genmab's CFO.
Akademikeren	Thank you. We will start off with some questions on hexabody which we hope you can shed some light on.
Akademikeren	We are interested in trying to find out whether this could yield a deal this year already or should we be more patient?
Solsen	Dear mr Winkel. As an investor Iam very pleased with your steady progress. Regarding Hexabody it seems like a deal is in d evelopment. Could you bring some expectations to this deal ? And second where do you se the potential with the platform in infectious diseases ? Thanks !
Investor1989	- You said 2013 was the year of “data and deals”. So far you hasn’t made any deals. Any progress on new HexaBody or DuoBody deals? And is this because you have “reached the bar” to make more lucrative deals then the one with Janssen (you said after the Janssen deal that you expected the next deals to be even more lucrative).
Akademikeren	----
Jan Van de Winkel	to take the first question first. The early deals with HexaBody are likely to be research agreements. All agreements with big pharma take time to negotiate to a point where they are signable, and therefore we would suggest deals to be visible from next year rather than this year.....
Jan Van de Winkel	Re infectious diseases, yes this could be an important disease area for a HexaBody enhanced therapeutic approach. In the lab we are currently validating the approach....
Jan Van de Winkel	As we said, deals take time to negotiate and finalise, but we have significant interest from both pharma and biotech companies for access to DuoBody as well as HexaBody.....
Akademikeren	A followup questions. Are Genmab at all entertaining the idea of combing hexabody and zalutumab in a package deal to a partner?
Jan Van de Winkel	In principle HexaBody can be used to repurpose all sorts of antibodies and we clearly consider a number of options of how to best use our technology platforms to create differentiated antibody therapeutics.
Akademikeren	Thank you lets turn to your other compound arzerra.
Sukkeralf	How do se see the topline Phase II results in relapsed CLL with Ofatumumab in combination with Bendamustine compared to results with Rituximab plus Bendamustine in the same patients ?
Collersteen	Hi mr. Winkel. First of all congratulations on the fine turnaround of Genmab since you took over. Can you comment on the recent phase II clinical study topline results (ofatumumab+bendamustine in patients with untreated or relapsed CLL) compared to the similar clinical studies of Rituximab in the same indication?
Akademikeren	----------

Jan Van de Winkel	Thank you for the compliment, we are very pleased with the strong data. It is always difficult to compare data between trials, as this Phase 2 combination study was not set up as a head to head study...
Jan Van de Winkel	...however we believe these data to be very strong on two fronts, 1. the magnitude and deepness of the clinical effects induced....and 2.....
Jan Van de Winkel	the way the combination treatment was tolerated in both relapsed and untreated patients. We saw 87% of the relapsed patients complete the full treatment course, and in the untreated patients we saw an even higher compliance bodes well for the potential of ofatumumab in combination regiments.
Akademikeren	you have 5 pivotal studies reading out in 15 months. the first in 2 month. how soon will we see a label expansion thereafter. Can you explain the procedure and timeline. Its a whole new application proces?
Jan Van de Winkel	On average it takes 4 to 6 months to compile and organise the data package and submit these to the authorities, and another 6 to 10 months to get a potential label expansion.....
Jan Van de Winkel	so in summary one can assume a year from the topline data to the potential label expansion and increased sales. The good thing is that we already have Arzerra on the market in over 2 dozen countries and the sales force is already in place and ready to expand.
Akademikeren	you said yesterday that the "rest of world" demand for Arzerra was driven by research and not commercial demand. Is it the same case with the US demand or has it found some commercial demand in refrac cll?
Jan Van de Winkel	In addition expanding a label is usually more straightforward than applying for a new label.
Jan Van de Winkel	The purchase of material for other companies' clinical trials mainly impacted the RoW sales in Q1 2013 - there was little impact, if any, on the US numbers.
Akademikeren	Ok. Thanks. We will continue with more clinical arzerra questions.
Solsen	Arzerra in autoimmune diseases are still alive according to you yesterday. The sc version is likely the best competitive formulation. Are your expectations to the futher development in the sc version and potent ially when could arzerra be offered to patients with RRMS ? As I recall the results in RRMS with iv was outstanding. Is there any chance that a ph2 could be basis for a NDA ?
Sukkeralf	Regarding the phase III study in frontline CLL with Ofatumumab + Chlorambucil vs Chlorambucil are you cleaning data right now or still waiting for the last events to happen ?
Akademikeren	----------
Jan Van de Winkel	GSK is responsible for the Autoimmune indications and we anticipate an update from them on the results of the MS phase 2 clinical study and on potential other plans in autoimmune indications.
Jan Van de Winkel	We anticipate being able to release topline data in the coming months for the frontline Phase 3 study in CLL.
Akademikeren	Lets turn to other potential blockbuster Daratumumab, which continues to impress us.
Sukkeralf	Any interest/plans/discussions/ with Janssen (and Celgene or Onyx) to combine daratumumab with Carfilzomib or Pomalidomide for treating Multiple Myeloma ?
Investor1989	- Regarding Daratumumab. With Breakthrough designation, can the ongoing phase I/II study be used as a registration study in R/R MM patients?
Akademikeren	--------

Jan Van de Winkel	Daratumumab has generated excellent preclinical data in combination with Revlimid and Velcade, even with tumor cells from patients who are refractory to these drugs. It is an obvious combination partner for other IMiDs and Proteasome Inhibitors. We anticipate better visibility on the robust clinical plans in the second half of this year.
Jan Van de Winkel	It is very exciting to have received breakthrough therapy designation for daratumumab and Janssen will actively work with the FDA to optimise and accelerate the development plan for this drug...
Jan Van de Winkel	we may add new patients to the existing monotherapy study or alternatively plan a new monotherapy study to serve as the basis for a product application.
Akademikeren	You have said to MedWatch that Daratumumab could be on the market in 2016. What needs to happen in order to do this so fast? And can we presume that break through designations paves the way for more milestones and faster?
Akademikeren	i.e in 2013
Akademikeren	---------
Jan Van de Winkel	Breakthrough designation is a very new process at the FDA however, it is intended to accelerate the availability of fundamentally new drugs where there is an unmet medical need.
Jan Van de Winkel	We have not included any milestones from daratumumab in our current 2013 guidance.
Akademikeren	Could "BTD" at all affect the pace of milestones?
Akademikeren	----
Jan Van de Winkel	We do expect meaningful milestones over the next 3 or 4 years. BTD does potentially accelerate the timelines.
Akademikeren	Thank you Jan, Great. Lets turn to the duobody platform
Investor1989	- The last time we heard from you about DuoBody deals Janssen had activated 3 programs and reached proof of concept in one of those. Is this still the status? (And have Novartis activated programs?)
Akademikeren	------
Jan Van de Winkel	Janssen has activated a fourth DuoBody program which triggered a 750,000 payment and is also making significant progress in the other active programs...
Jan Van de Winkel	Novartis has currently one program active, which is progressing nicely.
Akademikeren	Before turning to your surprisingly strong financial results we have 2 more clinical questions
Sukkeralf	Could you elaborate on the reason for stopping HuMax-CD74-ADC program - any chance for a "Hexaboost" of the antibody candidate or back-ups for this target ?
Investor1989	- Regarding Inclacumab. Are Roche waiting for more data readouts? Or are they now in consideration of starting a phase III study?
Jan Van de Winkel	Excellent....
Akademikeren	-------
Jan Van de Winkel	The CD74 program has been moved back to preclinical because of complications related to the biology of the target...
Jan Van de Winkel	we will continue to work on the potential targetting of CD74.
Jan Van de Winkel	Regarding Inclacumab Roche intends to report data from a second large phase 2 study, that has finished recruitment, in the coming months...and we then expect to hear on next steps for this exciting antibody.
Akademikeren	Some time ago you said you would turn the clinic from a cashburner to a cashgenerator. We have certainly seen the effect of this in this quarter.
Akademikeren	I think we are all surprised with your progress. Can you tell us why you are still guiding a loss for 2013?
Akademikeren	-------

Jan Van de Winkel	As we said at the AGM in April, our goal is to be sustainably profitable.
Akademikeren	And just to clarify. When you and David speak of sustainainability, you meen revenue generated from royalty?
Jan Van de Winkel	In the first quarter the revenue was a little high due to the inclusion of a GSK milestone for the approval in Japan, the expenses were also a little light in the Q1. We still expect to be within guidance for the year.
Jan Van de Winkel	Yes, an important milestone for us is when Arzerra reaches 500 mn USD which would generate 100 mn USD in royalty, which will fully cover all of Genmab's expense base.
Akademikeren	Ok. Thanks for your time Jan. I think I speak for a lot of private investors when I thank you and David for an excellent quarter. Its really impressive what you have done in a short amount of time. We see the institutional players being more interested as well. Good work!
Jan Van de Winkel	Thank you very much for that comment - and for the very thoughtful questions today. We very much look forward to an excellent year and to talking with you again soon.
Collersteen	Thank you Jan.
PKjellmann	Thanks for the interesting Q&A, Jan.
Akademikeren	---this session has ended----

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