Q&A GENMAB

15. AUGUST 2013

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Transcript Live Q and A Genmab med Jan Van de Winkel, d. 15. August 2013

akademikeren	Hej og velkommen til. Vi afholder en online Q&A session med Genmabs direktør Jan Van de Winkel kl. 14.00 ovenpå Genmabs regnskab igår. Bemærk at sessionen foregår på engelsk.
akademikeren	Du kan skrive dine spørgsmål i dette felt nu eller løbende når sessionen er igang.
akademikeren	Alle kan deltage. Husk at stil spørgsmål på engelsk
akademikeren	This session will start in 10 minutes
akademikeren	Dear Jan, Welcome to this Q&A Session. We appreciate your time. First of all congratulations on a great Quarter again.
Jan Van de Winkel	We are here and ready, nice to be talking to you again. I am here with David Eatwell Genmab CFO
Jan Van de Winkel	We are looking forward to your questions....
akademikeren	Since there are lots of questions I will skip my usual introductory questions about last quarter and jump straight into the investor questions concerning your pipeline.
Sukkeralf	Jan do you still se blockbuster potential in autoimmune diseases with ofatumumab and can we still expect an update from GSK later this year with phase II data (RRMS)? Is it unwisely still to hope for a phase III study sc dosing in RRMS ?
Jan Van de Winkel	Development of autoimmune indications are of course the responsibility of GSK....
Jan Van de Winkel	we were very pleased to see the start of the PV Phase 3 before the summer. We still expect Phase 2 MS data to become available this half.
JørgenVarnæs	Dear Jan, Ibrutinib is showing great promise in many indications. Do you have any insights into the potency of combination treatments with CD20 antibodies? Do you think these combination treatments will become the new gold standard in cancer treatment?
Jan Van de Winkel	We believe that 90% of cancer patients will be treated with combination therapy and Ibrutinib will likely play an important role in the treatment landscape in the future.
JørgenVarnæs	Dear Jan, FDA has given GA101 an action date on 20 Dec later this year. With the impressive data Arzerra is showing, can Arzerra be eligible for an equally speedy application- and review process? And when do you see a possible action date for Arzerra?
Jan Van de Winkel	We saw ISS data at ASCO 2012 which was very encouraing in terms of combining Ofatumumab and Ibrutinib, showing 100% overall responses in CLL.

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Jan Van de Winkel	Ofatumumab is already on the market for a narrow indication, and therefore we are looking to expand the label as data becomes available. Therefore the frontline data application would be an sBLA rather than a new application.
Solsen	Could a CD20 antibody be eligible for auristatin or PBD warhead. We have seen some work with auristatin and Arzerra ?
Jan Van de Winkel	Our current focus is to try to expand the label following data readouts from the ongoing Phase 3 trials and expanding development by novel combinations.
Solsen	Mr Winkel. If FDA is impressed with the Arzaerra ph3 like you (and us) and they also belive its a better drug than GA101 - wouldnt it be natu ral to give Arzerra BTD as well as GA101 recived BTD ?
Jan Van de Winkel	We believe we have a very efficacious antibody with excellent tolerability and we very much hope to present the full data set from the Frontline CLL Phase 3 study being presented at ASH.
Sukkeralf	Any chance for Genmab/GSK to get BTD for Ofatumumab in combination with Chlorambucil like Roche did with GA101 ?
Jan Van de Winkel	We cant comment whether GSK has or will apply for BTD.
Sukkeralf	Any presentation of ofatumumab phase II (Bendamustine) or phase III (Chlorambucil)data at the International Workshop on CLL (iwCLL) in Colo gne, Germany this September ?
Jan Van de Winkel	The Ofatumumab plus bendamustine data will be presented at the IWCLL meeting in September in Cologne. We very much hope the CLL frontline data will be presented at ASH in December.
akademikeren	Concerning the recent data we got in Phase 3 what is the approximate timeline for filing and hopefully expansion of the label?
Jan Van de Winkel	Our partner GSK is working hard to send in the sBLA soon.
akademikeren	can we expect around 6 month after filing?
Jan Van de Winkel	The timing of the review is up to the authorities, the US tends to be slightly quicker than the EU authorities as a general rule.
akademikeren	Ok thank you lets turn to Daratumumab
Solsen	We are all eagerly awainting news about the develop plans for daratumumab. Could we possibly se FDA accept a NDA filing on the ph 1/2 monotrial ?
Jan Van de Winkel	BTD gives us good access to the FDA so we can discuss development plans with the

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	authorities. We hope to give more colour on the development plans later this year.
investor1989	you said yesterday at CC that you have changed the protocol in the Daratumumab monotherapi study some times. Are this because of the FDA BTD feedback, do you want to use this study as a registration ?
Jan Van de Winkel	It is quite normal in a Phase I-II trial to amend the protocol in order to find the optimal treatment framework.
akademikeren	Is it right to presume that you don´t update the market on every milestone you get in the Daratumumab cooperation with Jansen? If so is there a minimun threshold value?
Jan Van de Winkel	Milestones will be communicated by company announcements and for smaller amounts not considered material, we would include them in our quarterly reports.
akademikeren	Thank you. Lets go for some DuoBody.
Sukkeralf	Janssen is probably your most involved partner in creating bispecific antibodies (DouBody technology platform) - has it anything to do with them knowing the Ultimab technology ? Who delivers the naked antibodies for the fab-arm exchange - you or Janssen or both ?
Jan Van de Winkel	Janssen has a lot of experience with antibodies and have a lot of antibodies available to be evaluated as bispecifics. Many of them come from the UltiMab technology.
investor1989	You got 2 mio. $ for a proof of concept on 11/12 2012 from Jannsen on DuoBody. But in the Q2 you are stating that the first proof of concept got 500.000 $ in juli, whats the difference here ?
Jan Van de Winkel	The first 2 million dollars were for a technical proof of concept, the new milestone is for in vivo proof of concept, so two different types of milestones...
Jan Van de Winkel	I hope that answers the question.
akademikeren	We still have some questions coming. I will hurry
Jan Van de Winkel	Very good, we have another 15 minutes .
TheNote	Hexabody - are we near any chance of "validation" ?
Jan Van de Winkel	We are making great progress on HexaBody and have submitted abstracts to conferences on the technology platform.
akademikeren	can you tell us when we might expect them to be presented ?
Jan Van de Winkel	We very much aim to present during this year.
akademikeren	Great. Thanks.

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Solsen	Yesterday you disclosed that we can expect news from the pipeline at the end of this year. Is your goal still one IND pr year or could your more robust finansial situation give you the opportunity to bring more candidates in Clinic ?
Jan Van de Winkel	Genmab has filed 14 INDs in its 14 year history. However, what matters is the quality of the products not the mere number.
akademikeren	do you expect to continue the strategy with early stage partnerships going forward?
Jan Van de Winkel	We intend to actively close partnership agreements, both early and late stage....
Jan Van de Winkel	however we have the ambition to retain a larger part of the product rights on select products to build the next stage of our company.
akademikeren	In respect to that answer, how would you categorize Humax-TF?
Jan Van de Winkel	HuMax-TF-ADC is a program where Seattle Genetics has an option to co own the program following end of Phase I evaluation. ...
Jan Van de Winkel	costs and profits would be shared 50-50 upon their opt in.
Sukkeralf	Jan could you explain the reason for the new Phase I study with Inclacumab (differencies between Japanese and Caucasian healthy volunteers) ?
Jan Van de Winkel	This is a normal procedure in drug development to evaluate a new drug in a different ethnic population....
Jan Van de Winkel	on top of that the regulatory process in Japan is quite different from the US and EU process.
investor1989	It is now over 12 months since the latest DuoBody deal (Jannsen) - (i Know you got the collaboration with Kirin to).. Are DuoBody intereset falling or do you still expect to get better deals than the Jannsen deal in 2013 ?
Jan Van de Winkel	We are still in active partnering mode with the DuoBody platform. We anticipate further interest as the technology becomes further validated.
akademikeren	Ok. Thanks. One final question.
collersteen	From a strictly financial point of view, what kind of upside or downside "events" do you see in the 2nd half of 2013, i.e. milestone triggers?
Jan Van de Winkel	Our new guidance is realistic. As mentioned on the CC call yesterday we have not included any daratumumab milestones in the new guidance.
akademikeren	Thank you very much for your time Jan. We appreciate it. Congratulations on your Quarter to you and your team.

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Jan Van de Winkel	Thank you very much, as always it is a pleasure to take your questions. We look forward to Q3.
akademikeren	------ this session has ended --------

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