Q&A GENMAB

12TH OF AUGUST 2015

WITH JAN VAN DE WINKEL

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Transcript Live Q and A Genmab with Jan Van de Winkel, the 12th of August 2015

investor1989	This session starts in about 10 minutes
Jan Van de Winkel	I am here with David Eatwell, Genmab's CFO, and looking forward to this Q & A.
investor1989	Great. Nice to have you back here
investor1989	Can you start with giving us an update on the most important Developments in the Q2 ?
Jan Van de Winkel	Certainly - the filing of the BLA for daratumumab mono therapy, two regulatory submissions for ofatumumab....
Jan Van de Winkel	...achieved a USD 10 Mn for dara progress in Phase 3, positive results for a Phase 3 in relapsed CLL for ofa....
Jan Van de Winkel	...and entered a commercial agreement with BioNTech in the field of immuno oncology for DuoBody.
Jan Van de Winkel	and of course, encouraging early clinical data for HuMax-TF-ADC, as well as another set of strong financial results.
investor1989	Okay. thats great. You said this morning in the radio that arzerra competition in europe was hard because Ibrutinib was giving out for free. Can you clarify that ?
Jan Van de Winkel	Yes, we have heard that in certain European countries Ibrutinib is made available for free, to patients that may benefit.
troldmanden	Can you shed some light on the actually timeline for FDA dara review. The 60 days review time is that from the date thepriority review is given or is that for the date the final submission was sent in? And second could you repeat the average review time for BTD seen so fare?
Jan Van de Winkel	The process is that we will hear within 60 days from July 9th when we completed the submission...
Jan Van de Winkel	if we get a priority review, then the FDA commits to finalising the review within 6 months ie March 2016.
investor1989	The free Ibrutinib. Is that Jannsen/PCYC that are providing that or are the drug paid by someone else ?
Jan Van de Winkel	The average review time for BTD products is 176 days with a range from 75 days to 315 days.
Jan Van de Winkel	It is Janssen/PCYC.

Q&A GENMAB

12TH OF AUGUST 2015
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symmetry	Daratumumab outside MM. Do you think you primarily will go after Relapsed/Refrac "Orphan" indications there? Or are J&J considering developing Dara more broadly (frontline etc.) outside MM to ?
Jan Van de Winkel	It is too early to say, but the first clinical study that is scheduled is the relapsed refractory setting and will involve FL, MCL and DLBCL patients. ...
Jan Van de Winkel	..Preclinically we have obtained very strong data with daratumumab also in AML, Burkitt's Lyphoma and CLL.
troldmanden	Regarding DARA. Is there any milestones related to 1) filing in Europe 2) first sale in Europe. And if so would it be fair to speculate that those milestones would be a bit north of half the milestones for US?
Jan Van de Winkel	We stated in our Guidance that there is a filing milestone in Europe...
Jan Van de Winkel	...it is reasonable to expect there may be a milestone linked to first commercial sale in Europe, and reasonable to expect that both those may be lower than the milestones in the US.
troldmanden	What timeline do you see for possible approval of DARA in Japan?
Jan Van de Winkel	We cannot comment on timings for possible approvals. Janssen has however, recently started a second study in Japan to support potential future filings there.
bongobob	Regarding Humax-TF. Did you reach 54 patients before closing recruitment for study redesign. When is you partner Seattle obligated to take a in/out decision, after the first Phase one study or the new one
Jan Van de Winkel	We presented data on 24 patients at ASCO, and we have expanded the Phase 1 study with extra patients for a total study patient number of approx. 110 patients...
Jan Van de Winkel	...Seattle will make their opt in decision at the end of Phase 1.
investor1989	But the current study is a phase I/II study with the 24 patients the phase I part and the 110 the phase II part. So can they wait until after the 110 patients ?
investor1989	I think bongobob was referring to clinical trials where the study now is "closed for recruitment"
Jan Van de Winkel	The entire study will enroll approx. 110 patients and it is the completion of the entire study which triggers their final opt in obligation.
troldmanden	You have stated that you want to take Humax TF-ADC longer in the clinic before doing any potential partnership, so that you can retain at least 50% of the value. Just to give us some insight we can relate to. How much of the Dara value would you say have retained in your deal with Jansen?

Q&A GENMAB

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Jan Van de Winkel	Part one of the study is complete (dose escalation) we are now in Part 2.
Jan Van de Winkel	These two deals are very different. In the dara deal we have up to a billion USD of milestones and double digit royalties at no cost. In the HuMax-TF-ADC programme we fund all studies currently and there is an opt in potential for Seattle Genetics for a 50/50 cost and profit sharing.
symmetry	Ofatumumab and Daratumumab (assumed approval in 2016) took 7-8 years from IND to approval. Do you expect you can continue this track record with Humax-TF-ADC and other products, or is it just harder to develop drugs in solid tumors?
Jan Van de Winkel	Depends on the drug and the indication - there are many variables in drug development, but we work as quickly as possible in Genmab.
sertolicell	Dr. Van de Winkel, I have some questions regarding more long-term immunotherapy visions and goals: Genmab acquired an anti-CD19 Ab early this year. The CD19 area is rapidly evolving regarding new technolgies such as CART/CTL019 (Novartis/U-Penn). Is Genmab considering to go into adoptive T cell transfer/CART/TILs at a later stage - either with anti-CD19 or other mAbs (eg. anti-CD38?)
Jan Van de Winkel	At present Genmab is firmly focused on antibody therapeutic approaches. This means that CAR-approaches for cancer fall outside of our current focus.
troldmanden	Could you perhaps give a general update on the Hexabody development. How many programs do you have and how does the interest for potential partners look here 3 years after the reveal of the technology
Jan Van de Winkel	We have multiple HexaBody programs in the Genmab proprietary pipeline - HexaBody candidates represent over 10 percent of our preclinical candidates....
Jan Van de Winkel	...there is significant interest by both large pharma and biotech companies for access to HexaBody, both for cancer and non cancer therapeutic approaches.
Helge Larsen/PI-redaktør	Genmab has a large sum marked for buying up in the market. Which special medical remedies do you find especially interesting to add to your business?
Jan Van de Winkel	We are very focused on Immuno Oncology, one of the hottest areas in oncology at the time, and have already three partnerships in this area.
symmetry	You have promissed we would get a broader look into your preclinical pipeline sometime this year. Is that still your expectations?
Jan Van de Winkel	Absolutely, we would hope that our R&D update seminar in December (following the ASH conference in Orlando) will provide an opportunity to discuss some of the exciting preclinical programs we are working on.

Q&A GENMAB

12TH OF AUGUST 2015
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troldmanden	How much data do you think you would need to have, before you can get a deal where you retain 50% of the value. Phase 3 data?
Jan Van de Winkel	We are signing deals now where we retain 50% of the value of products, such as the exciting BioNovion and BioNTech deals.
symmetry	Do you still expect more IND this year? and do you expect duobody IND either from J&J or from your own products?
Jan Van de Winkel	In addition to the two INDs already filed for Genmab created antibodies in 2015 we would anticipate additional filings from partners.
investor1989	The Pierre Fabre Duobody is new. Who are they, and what target is that for ?
Jan Van de Winkel	This is a well established French pharma company, with a strong cancer therapeutic pipeline...
Jan Van de Winkel	...they are experienced in antibody therapeutics and very excited to work with DuoBody.
investor1989	And maybe are broad question to end with. A big chunk of your stock price is linked to Daratumumab. You have gone away from partnering products early on with upfront and milestones. But how should investors value your preclinical pipelines now when they do not have partnership agreements to look at
Jan Van de Winkel	We now have the strongest pipeline in our company's history which will fill the clinical portfolio with wonderful differentiated therapeutic candidates in the coming years....
Jan Van de Winkel	...combined with the fact that we can hold on to an increasingly larger share to product rights, these should create more value for shareholders.
investor1989	And maybe just one for David. The intangible assets on the balance sheet. What is the amortization period for those ?
Jan Van de Winkel	This relates to some of the new assets we have been acquiring such as DR5 and CD19 antibodies. Each assets is looked at individually but typical amortization over 5-7 years.
investor1989	That was all we had for you this time. Hope to see you again after the Q3 report.
Jan Van de Winkel	Thank you. We very much look forward to speaking with you all next time.
investor1989	--- This Session has now ended ---

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