

Dealdoc

Licensing agreement for daratumumab (updated)

Genmab Janssen Biotech

Aug 30 2012

Licensing agreement for daratumumab (updated)

Companies:

Announcement date: Amendment date: Deal value, US\$m:

- Details
- Financials
- <u>Termsheet</u>
- Press Release
- Filing Data
- <u>Contract</u>

Financials

Details

Announcement date:	Aug 30 2012
Amendment date:	Nov 15 2017
	Bigbiotech
Industry sectors:	Bigpharma
	Biotech
	Pharmaceutical
Brand name:	Darzalex
Compound name:	Daratumumab / HuMax-CD38
Asset type:	Compound
Therapy areas:	Oncology » Leukemia » Acute myelogenous leukemia
	Oncology » Multiple myeloma
Technology types:	Antibodies » Monoclonal antibodies » Human mAb
	Biological compounds
Deal components:	Development
	Licensing
	Preclinical
Stages of development:	Phase I
	Phase II
	Phase III
Geographic focus:	Worldwide
Deal value, US\$m:	1135 : sum of upfront, milestone and equity payments
Upfront, US\$m:	55 : upfront payment
	1000 : Sum of development, regulatory and sales milestones
Milestones, US\$m:	8 : first milestone payment for clinical development on November 2013
	22 : second milestone payment for clinical development on March 2014
	25 : third milestone payment for clinical development on July 2014
	10 : fourth milestone payment for progress in phase III study on Oct
	2014
	10 : fifth milestone payment for progress in phase III study received on
	April 17 2015
	15 : milestone payment for submission of Biologic License Application to
	the FDA on July 2015
Royalty rates, %:	n/d : tiered double digit royalties

<u>Genmab</u>

Janssen Biotech Aug 30 2012 Nov 15 2017 1135 : sum of upfront, milestone and equity payments Equity, US\$m:

Funding, US\$m:

80 : subscribe for 5.4 million new shares of Genmab at a price of DKK 88 per share

n/d : Janssen will be fully responsible for all costs associated with developing and commercializing daratumumab going forward, including the costs of two ongoing Phase I/II studies

Termsheet

November 2017

Genmab announced that the first commercial sale of DARZALEX (daratumumab) in Japan has taken place, triggering USD 25 million in milestone payments from Janssen Biotech.

The milestone was mentioned at the time of the September 2017 announcement of the approval of DARZALEX for the treatment of adults with relapsed or refractory multiple myeloma in Japan.

10 July 2015

Genmab announced its licensing partner Janssen Biotech has completed the rolling submission of the Biologics License Application to the U.S. Food and Drug Administration for daratumumab.

The completion of the submission triggers a milestone payment of USD 15 million to Genmab from Janssen.

17 April 2015

Genmab has reached the fifth milestone in its daratumumab collaboration with Janssen Biotech.

The USD 10 million milestone payment was triggered by progress in the ongoing Phase III study ("Alcyone" MMY3007) which compares daratumumab in combination with bortezomib, melphalan and prednisone (VMP) to bortezomib, melphalan and prednisone alone as front line treatment for patients who are not considered candidates for stem cell transplantation (SCT).

24 October 2014

Genmab has reached the fourth milestone in its daratumumab collaboration with Janssen Biotech.

The USD 10 million milestone payment was triggered by progress in the ongoing Phase III study of daratumumab in combination with bortezomib and dexamethasone alone for the treatment of relapsed or refractory multiple myeloma.

07 July 2014

Genmab has reached the third milestone in its daratumumab collaboration with Janssen Biotech.

The USD 25 million milestone payment was triggered by progress in the ongoing Phase III study of daratumumab in combination with lenalidomide and dexamethasone versus lenalidomide and dexamethasone alone for the treatment of relapsed or refractory multiple myeloma.

26 March 2014

Genmab has reached the second milestone in its daratumumab collaboration with Janssen Biotech.

The \$22 million milestone payment was triggered by progress in the ongoing Phase II study of daratumumab in multiple myeloma patients who have received at least three different lines of therapy, including both a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD), or who are double refractory to a PI and an IMiD.

26 November 2013

Genmab has reached the first milestone in its daratumumab collaboration with Janssen Biotech.

The milestone was triggered by progress in the clinical development of daratumumab.

Genmab will receive a USD 8 million milestone payment from Janssen in connection with this event.

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30 August 2012 Genmab announced a global license and development agreement for daratumumab (HuMax-CD38), a human CD38 monoclonal antibody with Janssen Biotech.

Daratumumab is currently in development for multiple myeloma and may have potential in other cancer indications such as acute myeloid leukemia.

Genmab will grant Janssen an exclusive worldwide license to develop and commercialize daratumumab as well as a backup human CD38 antibody.

Genmab will receive an upfront license fee of \$55 million (approximately DKK 327 million) and Johnson & Johnson Development Corporation (JJDC) will invest DKK 475 million, (approximately \$80 million) to subscribe for 5.4 million new shares of Genmab at a price of DKK 88 per share.

Genmab's closing share price on August 29, 2012 was DKK 67.85.

Genmab could also be entitled to up to \$1 billion in development, regulatory and sales milestones, in addition to tiered double digit royalties.

Janssen will be fully responsible for all costs associated with developing and commercializing daratumumab going forward, including the costs of two ongoing Phase I/II studies.

Press Release

November 2017

Genmab Achieves \$25M Milestone for First Commercial Sale of DARZALEX® (daratumumab) in Japan and Updates Financial Guidance

First commercial sale of DARZALEX in Japan triggers USD 25 million in milestone payments from Janssen

Financial guidance updated

Copenhagen, Denmark; November 14, 2017 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today that the first commercial sale of DARZALEX (daratumumab) in Japan has taken place, triggering USD 25 million in milestone payments from Janssen Biotech, Inc. (Janssen). The milestone was mentioned at the time of the September 2017 announcement of the approval of DARZALEX for the treatment of adults with relapsed or refractory multiple myeloma in Japan. As a result of this milestone, Genmab is updating its 2017 financial guidance.

"We're pleased that DARZALEX is now commercially available for patients with relapsed or refractory multiple myeloma who are living in Japan," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

OUTLOOK

MDKK Revised Guidance Previous Guidance Revenue 2,110 - 2,310 + 2,310 - 2,150 Operating expenses (1,000) - 1,100) (1,000) – (1,100) Operating income 1,060 - 1,260 + 2,000 - 1,100 Cash position at end of year >4,900 >4,500 Cash, cash equivalents, and marketable securities Genmab is improving its 2017 financial guidance last published on November 8, 2017 due to the inclusion of the DARZALEX milestones totaling USD 25 million associated with first commercial sale of DARZALEX in Japan.

Operating Result We expect our 2017 revenue to be in the range of DKK 2,110 – 2,310 million, an increase of DKK 160 million compared to the previous guidance. We have increased our projected daratumumab milestones to DKK 960 million (previously DKK 800 million) due to inclusion of USD 25 million in milestone payments triggered by the first commercial sale of DARZALEX in Japan. We expect DARZALEX royalties to remain in the range of DKK 930 – 1,100 million, which are based on an estimated USD 1,100 – 1,300 million of DARZALEX sales in 2017. The remainder of the revenue mainly consists of Arzerra® royalties, DuoBody® milestones, and non-cash amortization of deferred revenue.

We anticipate that our 2017 operating expenses will remain in the range of DKK 1,000 -1,100 million.

As a result of the increased revenue, we now expect the operating income for 2017 to be approximately DKK 1,060 - 1,260 million, compared to DKK 900 - 1,100 million in the previous guidance.

Cash Position As a result of the above and proceeds from the exercise of warrants during the year, we are now projecting a cash position at the end of 2017 of greater than DKK 4,900 million.

Outlook: Risks and Assumptions In addition to factors already mentioned, the estimates above are subject to change due to numerous reasons, including but not limited to the achievement of certain milestones associated with our collaboration agreements; the timing and variation of development activities (including activities carried out by our collaboration partners) and related income and costs; DARZALEX and Arzerra sales and corresponding royalties to Genmab; fluctuations in the value of our marketable securities; and currency exchange rates. The financial guidance does not include any potential proceeds from future warrant exercises and also assumes that no significant agreements are entered into during 2017 that could materially affect the results.

About DARZALEX® (daratumumab) DARZALEX® (daratumumab) injection for intravenous infusion is indicated in the United States in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy; in combination with pomalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor (PI); and as a monotherapy for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy, including a PI and an immunomodulatory agent, or who are double-refractory to a PI and an immunomodulatory agent.1 DARZALEX is the first monoclonal antibody (mAb) to receive U.S. Food and Drug Administration (FDA) approval to treat multiple myeloma. DARZALEX is indicated in Europe for use in combination with lenalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma, whose prior therapy included a PI and an immunomodulatory agent and who have demonstrated disease progression on the last therapy. In Japan, DARZALEX is approved in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a PI and an immunomodulatory agent and who have demonstrated disease progression on the last therapy. In Japan, DARZALEX is approved in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for treatment of adults with relapsed or refractory multiple myeloma. DARZALEX is the first human CD38 monoclonal antibody to reach the market. For more information, visit www.DARZALEX.com.

Daratumumab is a human IgG1k monoclonal antibody (mAb) that binds with high affinity to the CD38 molecule, which is highly expressed on the surface of multiple myeloma cells. Daratumumab triggers a person's own immune system to attack the cancer cells, resulting in rapid tumor cell death through multiple immune-mediated mechanisms of action and through immunomodulatory effects, in addition to direct tumor cell death, via apoptosis (programmed cell death).1,2,3,4,5

Daratumumab is being developed by Janssen Biotech, Inc. under an exclusive worldwide license to develop, manufacture and commercialize daratumumab from Genmab. A comprehensive clinical development program, including multiple Phase III studies, is ongoing with daratumumab in relapsed and frontline multiple myeloma settings, and additional studies are ongoing or planned to assess its potential in other malignant and pre-malignant diseases on which CD38 is expressed, such as smoldering myeloma, NKT-cell lymphoma, amyloidosis, myelodysplastic syndromes and solid tumors. Daratumumab has received two Breakthrough Therapy Designations from the U.S. FDA, for multiple myeloma, as both a monotherapy and in combination with other therapies.

About Genmab Genmab is a publicly traded, international biotechnology company specializing in the creation and development of differentiated antibody therapeutics for the treatment of cancer. Founded in 1999, the company has two approved antibodies, DARZALEX® (daratumumab) for the treatment of certain multiple myeloma indications, and Arzerra® (ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications. Daratumumab is in clinical development for additional multiple myeloma indications, other blood cancers, and solid tumors. A subcutaneous formulation of ofatumumab is in development for relapsing multiple sclerosis. Genmab also has a broad clinical and pre-clinical product pipeline. Genmab's technology base consists of validated and proprietary next generation antibody technologies - the DuoBody® platform for generation of bispecific antibodies, and the HexaBody® platform which creates effector function enhanced antibodies. The company intends to leverage these technologies to create opportunities for full or co-ownership of future products. Genmab has alliances with top tier pharmaceutical and biotechnology companies. For more information visit www.genmab.com.

10 July 2015

Genmab A/S (GEN.CO) Announces Completion Of Rolling Submission Of Biologics License Application For Daratumumab In Multiple Myeloma And Achievement Of A USD 15 Million Milestone

Submission of rolling BLA to US FDA for daratumumab in multiple myeloma completed by Janssen Biotech, Inc. Completion of submission triggers USD 15 million milestone payment to Genmab COPENHAGEN K, Denmark, July 9, 2015 (GLOBE NEWSWIRE) -- Genmab A/S (OMX: GEN) announced its licensing partner Janssen Biotech, Inc. has completed the rolling submission of the Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for daratumumab. The submission is for daratumumab as a treatment for patients with multiple myeloma who have received at least three prior lines of therapy including both a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD) or who are double refractory to a PI and an IMiD. In May, 2013, daratumumab was granted a Breakthrough Therapy Designation (BTD) in this population. The completion of the submission triggers a milestone payment of USD 15 million to Genmab from Janssen. The milestone was included in Genmab's financial guidance for 2015, which was updated on May 20, 2015. In August 2012, Genmab granted Janssen Biotech, Inc. an exclusive worldwide license to develop, manufacture and commercialize daratumumab.

A request for Priority Review has been submitted by Janssen with this BLA. The FDA will inform Janssen whether a Priority Review has been granted by calendar day 60 of their review starting today. If the FDA grants Priority Review the review period may not exceed 6 months from that date.

If daratumumab receives FDA approval, Genmab will receive a milestone payment from Janssen of USD 45 million associated with the first commercial sale of the product in the United States. However, it is not possible to precisely predict the timing of a potential marketing approval and first commercial sale; therefore, this milestone has not been included in the 2015 financial guidance at this time.

"The rapid completion of the BLA submission brings us a significant step closer to the potential regulatory approval of daratumumab," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. "Daratumumab received Breakthrough Therapy Designation from the FDA for this indication for multiple myeloma patients who have no other treatment options available, and we are proud that our partner Janssen has completed the submission in record time."

The submission includes data from the Phase II study (Sirius MMY2002) of daratumumab in multiple myeloma patients who have received at least three prior lines of therapy including both a PI and an IMiD, or who are double refractory to a PI and an IMiD. However, safety and efficacy data from the Phase I/II study (GEN501) and safety data from three other studies have also been included in the BLA submission.

About multiple myeloma

Multiple myeloma is an incurable blood cancer that starts in the bone marrow and is characterized by an excess proliferation of plasma cells.1 Multiple myeloma is the third most common blood cancer in the United States (U.S.), following only leukemia and lymphoma.2 Approximately 26,850 new patients will be diagnosed with multiple myeloma and approximately 11,240 people will die from the disease in the U.S. in 2015.3 Globally, it is estimated that 114,251 people will be diagnosed and 80,019 will die from the disease.4 While some patients with multiple myeloma have no symptoms at all, most patients are diagnosed due to symptoms which can include bone problems, low blood counts, calcium elevation, kidney problems or infections.5

About daratumumab

Daratumumab is an investigational human IgG1k monoclonal antibody (mAb) that binds with high affinity to the transmembrane ectoenzyme, CD38, on the surface of multiple myeloma cells. It induces rapid tumor cell death through diverse mechanisms of action. Five Phase III clinical studies with daratumumab in relapsed and frontline settings are currently ongoing. Additional studies are ongoing or planned to assess its potential in other malignant and pre-malignant diseases on which CD38 is expressed, such as smoldering myeloma and non-Hodgkin's lymphoma. Daratumumab has been granted Breakthrough Therapy Designation from the US FDA.

About Genmab

Genmab is a publicly traded, international biotechnology company specializing in the creation and development of differentiated human antibody therapeutics for the treatment of cancer. Founded in 1999, the company currently has one marketed antibody, Arzerra(r) (ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications and daratumumab in clinical development for multiple myeloma and non-Hodgkin's lymphoma, in addition to other clinical programs, and an innovative pre-clinical pipeline. Genmab's technology base consists of validated and proprietary next generation antibody technologies - the DuoBody(r) platform for generation of bispecific antibodies, and the HexaBody(r) platform which creates effector function enhanced antibodies. Genmab's deep antibody expertise is expected to provide a stream of future product candidates. Partnering of selected innovative product candidates and technologies is a key focus of Genmab's strategy and the company has alliances with top tier pharmaceutical and biotechnology companies. For more information visit www.genmab.com.

17 April 2015

Genmab A/S (GEN.CO) Achieves USD 10 Million Milestone In Daratumumab Collaboration With Janssen Biotech Inc. (JNJ)

Genmab to receive USD 10 million milestone payment from Janssen Milestone triggered by progress in the Phase III study in patients with multiple myeloma of daratumumab in combination with bortezomib, melphalan and prednisone COPENHAGEN, Denmark, April 16, 2015 (GLOBE NEWSWIRE) -- Genmab A/S (Copenhagen:GEN) announced today it has reached the fifth milestone in its daratumumab collaboration with Janssen Biotech, Inc. (Janssen). The USD 10 million milestone payment was triggered by progress in the ongoing Phase III study ("Alcyone" MMY3007) which compares daratumumab in combination with bortezomib, melphalan and prednisone (VMP) to bortezomib, melphalan and prednisone alone as front line treatment for patients who are not considered candidates for stem cell transplantation (SCT).

"We are pleased with the progress being made in the daratumumab Alcyone study for multiple myeloma. Multiple myeloma is the most common type of blood cancer in the US and second most common in Europe and we hope that the combination of daratumumab with other myeloma therapies will provide another treatment option for patients in the future," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

Today's news does not impact Genmab's 2015 financial guidance.

About the MMY3007 study

This Phase III study is a randomized, open-label, multicenter study and will include approximately 700 newly diagnosed, chemotherapy naive multiple myeloma patients ineligible for stem cell transplantation (SCT). Patients will be randomized to receive 9 cycles either daratumumab combined with bortezomib (a proteasome inhibitor), melphalan (an alkylating chemotherapeutic agent) and prednisone (a corticosteroid), or bortezomib, melphalan and prednisone alone. In the daratumumab treatment arm, patients will receive 16 mg/kg of daratumumab once weekly for six weeks (cycle 1; 1 cycle = 42 days), followed by once every three weeks (cycles 2-9). Following the 9 cycles, patients in the daratumumab treatment arm will continue to receive 16 mg/kg of daratumumab once every four weeks until disease progression. The primary endpoint of the study is progression free survival (PFS).

About daratumumab

Daratumumab is a human CD38 monoclonal antibody with broad-spectrum killing activity. Daratumumab is in clinical development for multiple myeloma (MM) and non-Hodgkin's lymphoma (NHL). Daratumumab targets the CD38 molecule which is highly expressed on the surface of multiple myeloma cells. Daratumumab may also have potential in other cancers on which CD38 is expressed, including diffuse large B-cell

lymphoma, chronic lymphocytic leukemia, acute lymphoblastic leukemia, plasma cell leukemia, acute myeloid leukemia, follicular lymphoma and mantle cell lymphoma. Daratumumab has been granted Breakthrough Therapy Designation from the US FDA. In August 2012, Genmab granted Janssen Biotech, Inc. an exclusive worldwide license to develop and commercialize daratumumab.

About Genmab

Genmab is a publicly traded, international biotechnology company specializing in the creation and development of differentiated human antibody therapeutics for the treatment of cancer. Founded in 1999, the company currently has one marketed antibody, Arzerra(r) (ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications and daratumumab in clinical development for multiple myeloma and non-Hodgkin's lymphoma, in addition to other clinical programs, and an innovative pre-clinical pipeline. Genmab's technology base consists of validated and proprietary next generation antibody technologies - the DuoBody(r) platform for generation of bispecific antibodies, and the HexaBody(tm) platform which creates effector function enhanced antibodies. Genmab's deep antibody expertise is expected to provide a stream of future product candidates. Partnering of selected innovative product candidates and technologies is a key focus of Genmab's strategy and the company has alliances with top tier pharmaceutical and biotechnology companies. For more information visit www.genmab.com.

24 October 2014

Cerus Corporation Secures \$30 Million Growth Capital Credit Facility From Oxford Finance Company Announcement

Genmab to receive USD 10 million milestone payment from Janssen Milestone triggered by progress in the Phase III study of daratumumab in combination with bortezomib and dexamethasone COPENHAGEN, Denmark, Oct. 23, 2014 (GLOBE NEWSWIRE) -- Genmab A/S (Copenhagen:GEN) announced today it has reached the fourth milestone in its daratumumab collaboration with Janssen Biotech, Inc. ("Janssen"). The USD 10 million milestone payment was triggered by progress in the ongoing Phase III study ("CASTOR" MMY3004) of daratumumab in combination with bortezomib and dexamethasone compared to bortezomib and dexamethasone alone for the treatment of relapsed or refractory multiple myeloma.

"We are very pleased with the firm progress being made in the daratumumab development program under the direction of our strategic partner Janssen. At Genmab we are committed to developing differentiated therapeutics to fight cancer, and it is therefore rewarding to see one of our antibodies moving rapidly through clinical development," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

This milestone payment is included in Genmab's 2014 financial guidance as published on August 13, 2014.

About the study This Phase III study will include approximately 480 patients who have relapsed or refractory multiple myeloma. Patients will be randomized to receive either daratumumab combined with bortezomib (a unique type of chemotherapy, called a proteasome inhibitor) and dexamethasone (a corticosteroid), or bortezomib and dexamethasone alone. The primary endpoint of the study is progression free survival (PFS).

07 July 2014

Genmab Reaches USD 25 Million Milestone in Daratumumab Collaboration with Janssen

Company Announcement

Genmab to receive USD 25 million milestone payment from Janssen Milestone triggered by progress in the Phase III study of daratumumab in combination with lenalidomide and dexamethasone in relapsed or refractory multiple myeloma Copenhagen, Denmark; July 7, 2014 – Genmab A/S (OMX: GEN) announced today it has reached the third milestone in its daratumumab collaboration with Janssen Biotech, Inc. ("Janssen"). The USD 25 million milestone payment was triggered by progress in the ongoing Phase III study of daratumumab in combination with lenalidomide and dexamethasone versus lenalidomide and dexamethasone alone for the treatment of relapsed or refractory multiple myeloma.

"Since our partnership with Janssen began in October 2012, we have made very significant progress with the development of daratumumab, announcing five new clinical studies and reporting data from two ongoing studies in multiple myeloma. Today's milestone marks another important step, as patients are now receiving treatment in the first Phase III study of daratumumab in multiple myeloma," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

The milestone payment is included in Genmab's 2014 financial guidance published on May 1, 2014.

About daratumumab Daratumumab is a human CD38 monoclonal antibody with broad-spectrum killing activity. Daratumumab is in clinical development for multiple myeloma (MM). Daratumumab targets the CD38 molecule which is highly expressed on the surface of multiple myeloma cells. Daratumumab may also have potential in other cancers on which CD38 is expressed, including diffuse large B-cell lymphoma, chronic lymphocytic leukemia, acute lymphoblastic leukemia, plasma cell leukemia, acute myeloid leukemia, follicular lymphoma and mantle cell lymphoma. Daratumumab has been granted Breakthrough Therapy Designation from the US FDA for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD) or who are double refractory to a PI and an IMiD. In August 2012, Genmab granted Janssen Biotech, Inc. an exclusive worldwide license to develop and commercialize daratumumab.

About Genmab A/S Genmab is a publicly traded, international biotechnology company specializing in the creation and development of differentiated human antibody therapeutics for the treatment of cancer. Founded in 1999, the company currently has one marketed antibody, Arzerra® (ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications, a clinical pipeline with both late and early stage programs, and an innovative pre-clinical pipeline. Genmab's technology base consists of validated and proprietary next generation antibody technologies - the DuoBody® platform for generation of bispecific antibodies, and the HexaBody[™] platform which creates effector function enhanced antibodies. Genmab's deep antibody expertise is expected to provide a stream of future product candidates. Partnering of selected innovative product candidates and technologies is a key focus of Genmab's strategy and the company has alliances with top tier pharmaceutical and biotechnology companies. For more information visit www.genmab.com.

26 March 2014

Genmab A/S (GEN.CO) Reaches \$22 Million Milestone In Daratumumab Collaboration With Janssen Biotech Inc. (JNJ)

Genmab Reaches \$22 Million Milestone in Daratumumab Collaboration with Janssen

COPENHAGEN, Denmark, March 26, 2014 (GLOBE NEWSWIRE) -- Genmab A/S (GEN.CO) announced today it has reached the second milestone in its daratumumab collaboration with Janssen Biotech, Inc. ("Janssen"). The \$22 million milestone payment was triggered by progress in the ongoing Phase II study of daratumumab in multiple myeloma patients who have received at least three different lines of therapy, including both a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD), or who are double refractory to a PI and an IMiD. This is the same indication for which daratumumab was granted Breakthrough Therapy Designation from the FDA in May 2013.

"The daratumumab development program continues to move forward successfully under our productive collaboration with Janssen and we are pleased to reach this second milestone in the agreement," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

The milestone payment is included in Genmab's 2014 financial guidance published on March 4, 2014.

About daratumumab

Daratumumab is a human CD38 monoclonal antibody with broad-spectrum killing activity. Daratumumab is in clinical development for multiple myeloma (MM). Daratumumab targets the CD38 molecule which is highly expressed on the surface of multiple myeloma cells. Daratumumab may also have potential in other cancers on which CD38 is expressed, including diffuse large B-cell lymphoma, chronic lymphocytic leukemia, acute lymphoblastic leukemia, plasma cell leukemia, acute myeloid leukemia, follicular lymphoma and mantle cell lymphoma. Daratumumab has been granted Breakthrough Therapy Designation from the US FDA. In August 2012, Genmab granted Janssen Biotech, Inc. an exclusive worldwide license to develop, manufacture and commercialize daratumumab.

About Genmab A/S

Genmab is a publicly traded, international biotechnology company specializing in the creation and development of differentiated human antibody therapeutics for the treatment of cancer. Founded in 1999, the company's first marketed antibody, ofatumumab (Arzerra(r)), was approved to treat chronic lymphocytic leukemia in patients who are refractory to fludarabine and alemtuzumab after less than eight years in development. Genmab's validated and next generation antibody technologies are expected to provide a steady stream of future product candidates. Partnering of innovative product candidates and technologies is a key focus of Genmab's strategy and the company has alliances with top tier pharmaceutical and biotechnology companies. For more information visit www.genmab.com.

26 November 2013

Genmab Reaches First Milestone in Daratumumab Collaboration With Janssen & Improves 2013 Financial Guidance

COPENHAGEN, Denmark, Nov. 26, 2013 (GLOBE NEWSWIRE) -- Genmab A/S (GEN.CO) announced today it has reached the first milestone in its daratumumab collaboration with Janssen Biotech, Inc. ("Janssen"). The milestone was triggered by progress in the clinical development of daratumumab. Genmab will receive a USD 8 million milestone payment from Janssen in connection with this event.

"Since the inception of our agreement with Janssen, we have reported encouraging data from two clinical studies of daratumumab and have started one new study. We are pleased to reach the first milestone in this productive collaboration and look forward to making further progress with daratumumab," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

Continuing Operations

Due the achievement of the USD 8 million daratumumab milestone, approximately DKK 44 million, we are improving the revenue guidance, which is now expected to be in the range of DKK 595 -- 635 million compared to DKK 550 -- 590 million in the previous guidance.

There is no change to the operating expense guidance, which remains at DKK 600 -- 625 million.

As a result of the improved revenue, we now project an operating result between an operating income of DKK 35 million and an operating loss of DKK 30 million.

Cash Position

As of December 31, 2012, we had a cash position of DKK 1,516 million and now, with the inclusion of the daratumumab milestone, we are projecting a cash burn from operations in 2013 of DKK 180 - 230 million, an improvement from the previous guidance of DKK 225 -- 275 million. With the proceeds from warrant exercises we are now projecting an improved cash position at the end of 2013, including the facility sale at DKK 52 million, of DKK 1,475 -- 1,525 million. This compares with the previous guidance of DKK 1,430 -- 1,480 million.

The estimates above are subject to change for numerous reasons, including but not limited to, the timing and variation of development activities (including activities carried out by our collaboration partners) and related income and costs; achievement of certain milestones associated with our collaboration agreements; Arzerra sales and corresponding royalties to Genmab; fluctuations in the value of our marketable securities; and currency exchange rates. The financial guidance also assumes that no significant agreements are entered into during 2013 that could materially affect the results.

About daratumumab

Daratumumab is a human CD38 monoclonal antibody with broad-spectrum killing activity. Daratumumab is in clinical development for multiple myeloma (MM). Daratumumab targets the CD38 molecule which is highly expressed on the surface of multiple myeloma cells. Daratumumab may also have potential in other cancers on which CD38 is expressed, including diffuse large B-cell lymphoma, chronic lymphocytic leukemia, acute lymphoblastic leukemia, plasma cell leukemia, acute myeloid leukemia, follicular lymphoma and mantle cell lymphoma. Daratumumab has been granted Breakthrough Therapy Designation from the US FDA. In August 2012, Genmab granted Janssen Biotech, Inc. an exclusive worldwide license to develop and commercialize daratumumab.

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Genmab is a publicly traded, international biotechnology company specializing in the creation and development of differentiated human antibody therapeutics for the treatment of cancer. Founded in 1999, the company's first marketed antibody, ofatumumab (Arzerra(R)), was approved to treat chronic lymphocytic leukemia in patients who are refractory to fludarabine and alemtuzumab after less than eight years in development. Genmab's validated and next generation antibody technologies are expected to provide a steady stream of future product candidates. Partnering of innovative product candidates and technologies is a key focus of Genmab's strategy and the company has alliances with top tier pharmaceutical and biotechnology companies. For more information visit www.genmab.com.

30 August 2012

Genmab Enters Worldwide Agreement with Janssen for Daratumumab

Genmab licenses daratumumab to Janssen Biotech, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson

\$55 million upfront payment to Genmab

Johnson & Johnson Development Corporation invests DKK 475 million (approx. \$80 million) in new Genmab shares

Total potential agreement value including upfront payment, equity investment and milestones in excess of \$1.1 billion

Copenhagen, Denmark; August 30, 2012 — Genmab A/S (OMX: GEN) announced today a global license and development agreement for daratumumab (HuMax®-CD38), a human CD38 monoclonal antibody with Janssen Biotech, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen). Daratumumab is currently in development for multiple myeloma and may have potential in other cancer indications such as acute myeloid leukemia. Under the terms of the agreement, Genmab will grant Janssen an exclusive worldwide license to develop and commercialize daratumumab as well as a backup human CD38 antibody.

Under the terms of the agreement, Genmab will receive an upfront license fee of \$55 million (approximately DKK 327 million) and Johnson & Johnson Development Corporation (JJDC) will invest DKK 475 million, (approximately \$80 million) to subscribe for 5.4 million new shares of Genmab at a price of DKK 88 per share. Genmab's closing share price on August 29, 2012 was DKK 67.85. Genmab could also be entitled to up to \$1 billion in development, regulatory and sales milestones, in addition to tiered double digit royalties. Janssen will be fully responsible for all costs associated with developing and commercializing daratumumab going forward, including the costs of two ongoing Phase I/II studies.

"Janssen was one of the first companies to recognize the power and promise of monoclonal antibodies and today is a world leader in biologics; we look forward to applying that same expertise to daratumumab to help meet the needs of patients with multiple myeloma," said William N. Hait, M.D., Ph.D., Head of Janssen Research & Development, LLC. "Daratumumab is an exciting, innovative compound, and we are delighted to add it to our portfolio."

"We are very pleased to partner with Janssen on another Genmab innovation and look forward to working with them to accelerate the development of daratumumab and to maximize the value of this product," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. "This agreement significantly strengthens our financial position, ensuring that Genmab can continue to develop much needed differentiated antibody therapeutics to help cancer patients in the future."

The transaction is subject to customary closing conditions, including approval of a prospectus by the Danish Financial Supervisory Authority and clearance by the US antitrust authorities under the Hart-Scott-Rodino Act, and will become final as soon as these conditions have been met.

OUTLOOK MDKK Revised Guidance August 30, 2012 Previous Guidance August 15, 2012 Revenue 435 — 460 375 — 400 Operating expenses (600) — (625) (600) — (625) Operating loss continuing operations (140) — (190) (200) — (250) Discontinued operation (40) (40) Cash position beginning of year 1,105 1,105 Cash used in operations (375) — (400) (375) — (400) Cash from license agreement & share subscription agreement

800

- Cash position at end of year excl. MN sale 1,505 - 1,530 705 - 730 Facility sale 320 320 Cash position at end of year 1,825 - 1,850 1,025 - 1,050 Cash, cash equivalents, and marketable securities Dependent on closing of the transaction with Janssen and JJDC

Continuing Operations We expect our 2012 revenue to now be in the range of DKK 435 — 460 million, an improvement of DKK 60 million from the previous DKK 375 — 400 million. The increased revenue is primarily due to the daratumumab license agreement and share subscription agreement entered into with Janssen and JJDC, respectively. The agreements include reimbursement of certain research and development costs and the amortization of the upfront payment and a part of the share premium which initially is recognized as deferred income and allocated as revenue over a number of years.

Our revenue consists primarily of non-cash amortization of deferred revenue totaling DKK 250 million (previous guidance was DKK 230 million) and royalties on sales of Arzerra, which still are expected to be in the range of DKK 90 — 100 million.

We anticipate that our 2012 operating expenses from continuing operations will remain the same as the previous guidance at DKK 600 — 625 million.

With the increase in revenue and no change to the operating expense guidance, the operating loss also improves. We expect the operating loss from continuing operations for 2012 to be approximately DKK 140 — 190 million, an improvement of DKK 60 million over the previous guidance of DKK 200 — 250 million.

Discontinued Operation The discontinued operation guidance of DKK 40 million relates to the ongoing running costs of maintaining the Minnesota manufacturing facility in a validated state and represents a full 12 months of activity. This expense could be lower if the facility is sold before the end of the year.

The fair value of the facility less cost to sell is currently estimated to be USD 58 million, approximately DKK 320 million at an assumed exchange rate of USD 1.00 = DKK 5.50. As of August 29, 2012, the exchange rate between USD and DKK was 5.9388. We remain focused on entering a sales agreement and anticipate the sale of the facility in 2012.

Cash Position As of December 31, 2011, we had a cash position of DKK 1,105 million and are still projecting a cash burn from operations in 2012 of DKK 375 — 400 million as the reimbursement of certain research and development costs under the daratumumab license agreement will be received in early 2013.

We are now projecting a cash position at the end of 2012, excluding the facility sale, of DKK 1,505 — 1,530 million, an increase of DKK 800 million compared to the previous guidance of DKK 705 — 730 million. The improvement is due to the equity investment and upfront payment related to the daratumumab license agreement and share subscription agreement. Taking into account the planned sale of the facility, the projected cash position at the end of 2012 would increase by DKK 320 million to DKK 1,825 — 1,850 million, compared to the previous guidance of DKK 1,025 — 1,050 million.

In addition to factors already mentioned, the estimates above are subject to change for numerous reasons, including but not limited to, closing of the transaction with Janssen and JJDC, the timing and variation of development activities (including activities carried out by our collaboration partners) and related income and costs; the successful completion of the manufacturing facility sale; fluctuations in the value of our marketable securities; Arzerra sales and corresponding royalties to Genmab; and currency exchange rates. The financial guidance also assumes that no significant new agreements are entered into during 2012 that could materially affect the results.

Conference Call Genmab will hold a conference call in English to discuss this news today, Thursday August 30, 2012, at 9:00 am CEST, 08:00 am BST (3:00 am EDT). The dial in numbers are:

+1 718 354 1226 (US participants) and ask for the Genmab conference call +44 207 509 5139 (international participants) and ask for the Genmab conference call

A live and archived webcast of the call and relevant slides will be available at www.genmab.com.

About daratumumab Daratumumab is a human CD38 monoclonal antibody with broad-spectrum killing activity. Daratumumab is in clinical development for multiple myeloma (MM). Daratumumab targets the CD38 molecule which is highly expressed on the surface of multiple myeloma cells. Daratumumab could also have potential in other tumors on which CD38 is expressed.

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About Genmab A/S Genmab is a publicly traded, international biotechnology company specializing in the creation and development of differentiated human antibody therapeutics for the treatment of cancer. Founded in 1999, the company's first marketed antibody, ofatumumab (Arzerra®), was approved to treat chronic lymphocytic leukemia in patients who are refractory to fludarabine and alemtuzumab after less than eight years in development. Genmab's validated and next generation antibody technologies are expected to provide a steady stream of future product candidates. Partnering of innovative product candidates and technologies is a key focus of Genmab's strategy and the company has alliances with top tier pharmaceutical and biotechnology companies. For more information visit www.genmab.com.

30 August 2012

Genmab Surges On Johnson & Johnson Cancer Pact: Copenhagen Mover

Genmab A/S (GEN), a Danish biotechnology company, rose the most in more than a year after it said Johnson & Johnson (JNJ) licensed its experimental treatment for multiple myeloma.

Genmab shares rose as much as 25 percent, the biggest intraday gain since Aug. 9, 2011, and were up 20 percent to 81 kroner as of 10:25 a.m. in Copenhagen.

The agreement with J&J's Janssen unit for daratumumab may be worth at least \$1.1 billion, including an upfront payment of \$55 million, milestone payments, and an \$80 million equity investment, Genmab said in a statement today. Daratumumab is a monoclonal antibody that may have potential in treating other types of cancers such as acute myeloid leukemia, Genmab said.

"Much had been anticipated from a licensing deal for daratumumab and we believe this deal has more than met the expectation," Nomura Code analyst Samir Devani said in a note to investors today.

Genmab shares have more than doubled this year, giving the Copenhagen-based company a market value of 3.62 billion kroner.

Filing Data

Not available.

Contract

Not available.