GSK and Genmab Announce Top-line Results from a Pivotal Head to Head Study of Ofatumumab in Combination With Chemotherapy vs. Rituximab in Combination with Chemotherapy for the Treatment of Relapsed or Refractory Diffuse Large B-cell Lymphoma

Company Announcement

- **No statistically significant difference in progression free survival in ofatumumab plus chemotherapy treatment arm compared to rituximab plus chemotherapy**
- **Detailed data will be presented at an upcoming medical conference**

London, UK and Copenhagen, Denmark; May 19, 2014 – GlaxoSmithKline plc (LSE: GSK) and Genmab A/S (OMX: GEN) announced today that the Phase III study (ORCHARRD) of ofatumumab (Arzerra™) plus chemotherapy versus rituximab plus chemotherapy to treat relapsed or refractory diffuse large B-cell lymphoma (DLBCL) did not meet its primary endpoint as there was no statistically significant difference in progression free survival (PFS) between the treatment arms.

There were no differences in adverse events (AEs) leading to treatment discontinuation, Grade ≥3 AEs, severe adverse events (SAEs) or fatal SAEs between the treatment arms. However, there were more dose interruptions and delays due to infusion reactions and increased serum creatinine in the ofatumumab plus chemotherapy arm, which require further analysis.

"We are disappointed that the ORCHARRD study did not meet its primary endpoint. We will further analyze these results to better understand the findings and how they add to our collective knowledge of this disease," said Dr. Rafael Amado, Head of Oncology R&D, GlaxoSmithKline.

"We plan to submit detailed data from the ofatumumab ORCHARRD study in DLBCL for presentation at a medical conference later this year, which we hope will provide further clarity on today's headline results. Based on today's results we are unlikely to move forward with a regulatory filing," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

About the ORCHARRD study

This pivotal Phase III randomized study included 447 patients who were refractory to, or had relapsed following, first-line treatment with rituximab in combination with a chemotherapy regimen containing anthracycline or anthracenedione, and were eligible for autologous stem cell transplant (ASCT). Patients in the study were randomized 1:1 to receive three cycles of either ofatumumab or rituximab in combination with DHAP (dexamethasone, cytarabine and cisplatin) salvage chemotherapy. After the third treatment cycle, patients who obtained a complete or partial response received high dose chemotherapy followed by ASCT. The primary endpoint of the study was progression free survival.

The ORCHARRD study was conducted in collaboration with the following research groups:

- HOVON-Dutch-Belgian Cooperative Trial Group for Hematology-Oncology
- Grupo Español de Linfomas/Trasplante Autólogo de Médula Ósea (GELTAMO)
- National Cancer Research Institute Lymphoma Clinical Studies Group
- Nordic Lymphoma Group
- Polish Lymphoma Research Group
- The All Ireland Cooperative Oncology Research Group

About DLBCL

DLBCL is the most common form of non-Hodgkin lymphoma (NHL), and is an aggressive (fast-growing) lymphoma or cancer of the B-cells.[1] DLBCL is the most common lymphoid malignancy in adults, accounting for 30% of all NHL in the Western world.[2] Approximately 38,000 new cases of DLBCL occur annually in the US, Japan and five major European markets.[3]

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About Ofatumumab (Arzerra)
Ofatumumab—a human monoclonal antibody which targets an epitope on the CD20 molecule encompassing parts of the small and large extracellular loops—is not approved or licensed anywhere in the world for the treatment of DLBCL.[4]

For the approved indications and full **U.S. Prescribing Information, including Boxed Warning, visit https://www.gsksource.com/gskprm/htdocs/documents/ARZERRA.PDF**. For the approved indications and European Union (EU) Summary of Product Characteristics (SPC) visit http://health.gsk.com/.

Ofatumumab is being developed under a co-development and collaboration agreement between Genmab and GSK. Arzerra is a trademark of the GSK group of companies.

GSK – one of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com.

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.

GSK enquiries:

UK Media enquiries:	David Mawdsley	+44 (0) 20 8047 5502	(London)
	Simon Steel	+44 (0) 20 8047 5502	(London)
	David Daley	+44 (0) 20 8047 5502	(London)
	Catherine Hartley	+44 (0) 20 8047 5502	(London)
	Sarah Spencer	+44 (0) 20 8047 5502	(London)
US Media enquiries:	Bernadette King	+1 215 778 3027	(Philadelphia)
	Anna Padula	+1 215 751 4271	(Philadelphia)
	Melinda Stubbee	+1 919 483 2510	(North Carolina)
	Karen Collins	+1 919 483 2527	(North Carolina)
	Stephen Rea	+1 215 751 4394	(Philadelphia)
Analyst/Investor enquiries:	Ziba Shamsi	+44 (0) 20 8047 5543	(London)
	Kirsty Collins (SRI & CG)	+44 (0) 20 8047 5534	(London)
	Tom Curry	+ 1 215 751 5419	(Philadelphia)
	Gary Davies	+44 (0) 20 8047 5503	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)

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Lucy Singah +44 (0) 20 8047 2248 (London)

Genmab enquiries:
Rachel Curtis Gravesen, Senior Vice President, Investor Relations & Communications
T: +45 33 44 77 20; M: +45 25 12 62 60; E: r.gravesen@genmab.com

Forward Looking Statement for Genmab
This Company Announcement contains forward looking statements. The words "believe", "expect", "anticipate", "intend" and "plan" and similar expressions identify forward looking statements. Actual results or performance may differ materially from any future results or performance expressed or implied by such statements. The important factors that could cause our actual results or performance to differ materially include, among others, risks associated with pre-clinical and clinical development of products, uncertainties related to the outcome and conduct of clinical trials including unforeseen safety issues, uncertainties related to product manufacturing, the lack of market acceptance of our products, our inability to manage growth, the competitive environment in relation to our business area and markets, our inability to attract and retain suitably qualified personnel, the unenforceability or lack of protection of our patents and proprietary rights, our relationships with affiliated entities, changes and developments in technology which may render our products obsolete, and other factors. For a further discussion of these risks, please refer to the risk management sections in Genmab's most recent financial reports, which are available on www.genmab.com. Genmab does not undertake any obligation to update or revise forward looking statements in this Company Announcement nor to confirm such statements in relation to actual results, unless required by law.

Cautionary statement regarding forward-looking statements
GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described under Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2013.

Registered in England & Wales:
No. 3888792

Registered Office:
980 Great West Road
Brentford, Middlesex
TW8 9GS

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[4] Teeling et al, *J Immunol* 2006; 177:362-371