DLBCL advisory board 21 november 2018

Work-title: Obtain advice on the positioning of polatuzumab vedotin in DLBCL in the Netherlands and on the Roche global polatuzumab vedotin clinical development plan (CDP)

Participants:

- Dr. Beeker, Spaarne Hospital, Haarlem
- Dr. Chamuleau, VUMC, Amsterdam
- Dr. De Heer, Flevoziekenhuis, Almere
- Dr. De Kruif, OLVG, Amsterdam
- Dr. Lugtenburg, Erasmus MC, Rotterdam
- Dr. Zijlstra, VUMC, Amsterdam

Location:

- Centrally in the Netherlands (Green Village, Nieuwegein)
- Diner during AdBoard

Goals:

- Obtain advice on treatment choices within DLBCL and respective outcomes
- Obtain advice on positioning of polatuzumab vedotin in DLBCL in the Netherlands in R/R DLBCL, non-transplant eligible patients
- Obtain advice on Roche global development-strategy polatuzumab vedotin/CDP

Pre-reads:

- GO29365-data presented at EHA: https://learningcenter.ehaweb.org/eha/2018/stockholm/214489/laurie.sehn.adding.polatuzumab.vedotin.28pola29.to.bendamustine.and.rituximab.html?f=ce_id=1346*ot_id=19046*media=3*search=polatuzumab%20vedotin*listing=1*browseby=8

- Requirements:
    - Service agreement with members for their advice (1 hour pre-read, 3,5 hours AdBoard). For HOVON-members potentially an additional 0,5 hours for alignment within HOVON on positioning.
    - Hospitality as per offer of location

AGENDA:

Time	Subject	Moderator
18.00-18.45 PART I - Introduction, MEDICAL		
18.00-18.15	Introductory round AdBoard members/Roche	Marc Hilkhuijsen, Medical Manager, the Netherlands
18.15-18.45	INTRO/SETTING THE SCENE of new compound Polatuzumab vedotin: - Polatuzumab vedotin-strategy Roche/Genentech - GO29365 set-up and published efficacy/safety data - POLARIX set-up: first-line DLBCL	Marc Hilkhuijsen, Medical Manager, the Netherlands
18.45-19.15 PART 2 - Patient flow R/R DLBCL patients, MEDICAL		
18.45-19.15	What is your advice on the drafted patient flow for R/R DLBCL-patients? Is this patient flow accurate based on published data and own experience?	Marc Hilkhuijsen, Medical Manager, the Netherlands
19.15-20.00 PART 3 - Positioning of polatuzumab vedotin, MEDICAL		
19.15-19.30	Roche-view on position polatuzumab vedotin after launch (Q3 2019-Q1 2020) - Local proposal for position polatuzumab vedotin (Marc Hilkhuijsen, MM Roche Netherlands)	Marc Hilkhuijsen, Medical Manager, the Netherlands
19.30-20.00	#1 Personal view per adboard member: obtaining advice/exploring different views and opinions on the local positioning of polatuzumab vedotin #2 HOVON view polatuzumab vedotin: Dutch DLBCL treatment-landscape current and future (upcoming 3-5 years) – obtaining advice/exploring HOVON view and opinion on the local positioning based on HOVON DLBCL-vision (dr. Lugtenburg, prof. Kersten?) - Advice question: what differences do AdBoard-members identify in Roche-proposed position vs. individual/HOVON position and what advice do AdBoard-members have for Roche?	Individual AdBoard members
20.00 - 20.45 PART 4 - Advice required on implications of study designs and limited polatuzumab-experience in the Netherlands, MEDICAL		
20.00-20.45	**GO29365 / R/R DLBCL** What advice do you provide Roche on: - additional expertise required by centres to prescribe polatuzumab vedotin? - ensuring that polatuzumab vedotin will be used properly in the Netherlands?	Marc Hilkhuijsen, Medical Manager, the Netherlands

	- impact of GO29365, as a randomised, phase 2-trial with n = 80?
	  - For the AdBoard members?
	  - For patients?
	  - For patient access?
	- R-benda as chemotherapy backbone in the GO29365-trial? Dutch national DLBCL guideline only advises R-PECC.
	- generating additional evidence with polatuzumab in the Netherlands?
	- providing Dutch hematologists with hands-on experience in trials? And if yes, how?
	- education regarding use of polatuzumab vedotin to Dutch hematologists in terms of:
	  - Mode of Action?
	  - Toxicity?
	  - Efficacy?
	- any other evidence/knowledge gaps?	

20.45 - 21.30 PART 5 - Discussion on potential access-barriers for patients, ACCESS		
21.00-21.30	Access, INTRO/SETTING THE SCENE: Roche NL presents overview of road map for access to polatuzumab e.g. reimbursement route national, and decentralized agreements (overview of potential access challenges). Participants give advice on: - key challenges in prescribing new medicines in hematology (budgets and choices) - must-haves in new product launches to accelerate financing processes? - requirements to be able to prescribe polatuzumab to the right patients? - the value of making decentralized agreements on the appropriate use and financing of new products? (e.g. Round Table-HOVON). When is the outcome of a decentralized arrangement a success?	Gert-Jan van Uem, Health Policy & Access Manager, Roche Netherlands