EUROPEAN COMMISSION
DG Competition

Case M.10165 - ASTRAZENECA / ALEXION PHARMACEUTICALS

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 05/07/2021

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PUBLIC VERSION

In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EC) No 139/2004 concerning non-disclosure of business secrets and other confidential information. The omissions are shown thus […]. Where possible the information omitted has been replaced by ranges of figures or a general description.

AstraZeneca plc
1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge CB2 0AA
UK

Subject: **Case M.10165 – ASTRAZENECA/ALEXION PHARMACEUTICALS**
Commission decision pursuant to Article 6(1)(b) of Council Regulation No 139/2004[1] and Article 57 of the Agreement on the European Economic Area[2]

Dear Sir or Madam,

(1) On 31 May 2021, the Commission received notification of a proposed concentration pursuant to Article 4 of the Merger Regulation by which AstraZeneca plc ("AstraZeneca", UK) acquires sole control of Alexion Pharmaceuticals Inc. ("Alexion", US), (the "Transaction").[3] AstraZeneca is referred to as the "Notifying Party" and, together with Alexion, the "Parties".

1 OJ L 24, 29.1.2004, p. 1 (the "Merger Regulation"). With effect from 1 December 2009, the Treaty on the Functioning of the European Union ("TFEU") has introduced certain changes, such as the replacement of "Community" by "Union" and "common market" by "internal market". The terminology of the TFEU will be used throughout this decision.

2 OJ L 1, 3.1.1994, p. 3 (the "EEA Agreement").

3 Publication in the Official Journal of the European Union No C 215, 07.06.2021, p. 10.

1. THE PARTIES AND THE OPERATION

(2) **AstraZeneca** is a UK-based global pharmaceutical company. It focuses on developing and marketing treatments for common diseases with large addressable patient populations, with three core therapy areas: (i) oncology; (ii) cardiovascular, renal, and metabolism; and (iii) respiratory and immunology.

(3) **Alexion** is a US-based biopharmaceutical company focusing on rare and ultra-rare diseases for which there is high unmet medical need. Alexion currently markets only five drugs, including Soliris, a blockbuster drug for the treatment of several rare diseases ([…]).

(4) On 12 December 2020, the Parties entered into a definitive merger agreement pursuant to which AstraZeneca agreed to acquire all of the shares of Alexion. Following completion of the Transaction, AstraZeneca will thus acquire sole control of Alexion. Therefore, the Transaction constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

2. UNION DIMENSION

(5) The undertakings concerned have a combined aggregate worldwide turnover of more than EUR 5 000 million (AstraZeneca: EUR 23 338 million; Alexion: EUR 5 322 million).[4] Each of them has a Union-wide turnover in excess of EUR 250 million (AstraZeneca: EUR […] million; Alexion: EUR […] million), but they do not achieve more than two-thirds of their aggregate Union-wide turnover within one and the same Member State. The notified operation therefore has a Union dimension pursuant to Article 1(2) of the Merger Regulation.

3. GENERAL CONSIDERATIONS

3.1. Overview of the Parties' overlapping activities

(6) AstraZeneca and Alexion are both active in the development and commercialisation of pharmaceutical products. Their activities are highly complementary: AstraZeneca focuses on prescription drugs for common diseases while Alexion is only active in the rare and ultra-rare disease space.[5] Consequently, the Transaction only gives rise to a limited number of pipeline-to-pipeline overlaps with respect to three indications, namely (i) lupus nephritis ("LN"); follicular lymphoma ("FL"); and (iii) peripheral T-cell lymphoma ("PTCL").

(7) Moreover, AstraZeneca manufactures *inebilizumab* for its former subsidiary Viela Bio, Inc. ("Viela"), controlled by Horizon Therapeutics PLC ("Horizon") since March 2021. This creates a vertical relationship with Alexion's activities in the treatment of neuromyelitis optica spectrum disorder ("NMOSD") and generalized myasthenia gravis ("gMG"), where Viela and Alexion are competitors.

3.2. General considerations on market definition

(8) When defining relevant product markets in past decisions dealing with pharmaceutical products in development (also called pipeline products),[6] the Commission has generally

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4 Turnover calculated in accordance with Article 5 of the Merger Regulation.

5 The European Commission defines a rare disease as one that affects less than 5/10 000 people – see https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/rare-diseases_en.

6 In the pharmaceutical industry, pipeline drugs go through several development stages, starting with preclinical trials in laboratories and on animals, and later moving on to clinical trials in humans (so called "Phase I", "Phase II" and

envisaged market definitions based on the indication, the mode of action ("MoA") and, where relevant, the line of treatment ("LoT"),[7] but ultimately left open the exact delineation of the market definition.[8] The Commission added that when research and development ("R&D") activities are assessed in terms of importance for future markets, the product market definition can be less clearly defined than for marketed products, reflecting the intrinsic uncertainty in analysing products that do not exist yet.[9] In terms of geographic scope, the Commission has consistently considered that the markets for pipeline drugs are at least EEA-wide.[10]

(9) The Commission will analyse in Sections 4 and 5 below the relevance of these precedents for the relevant product and geographic market definitions in the present case.

3.3. General approach to competitive assessment

(10) Article 2 of the Merger Regulation requires the Commission to examine whether notified concentrations are compatible with the internal market, by assessing whether they would significantly impede effective competition in the internal market or in a substantial part of it.

(11) The Commission Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings (the "Horizontal Merger Guidelines")[11] specify that concentrations between actual or potential competitors may significantly impede effective competition as a result of the creation or strengthening of a dominant position or the removal of a significant competitive constraint.[12] The Horizontal Merger Guidelines also indicate that mergers involving a potential competitor may restrict effective competition by ways of horizontal anti-competitive effects, either coordinated or non-coordinated.[13]

(12) In this framework, "competition" is understood to mean product and price competition (actual or potential), but also innovation competition.[14] In this respect, the Commission assesses innovation competition in relation to (i) the parties' ongoing pipeline products, assessing the risk of significant loss of innovation competition resulting from the discontinuation, delay or redirection of the overlapping pipelines (including early stage

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"Phase III" clinical trials), which are strictly regulated to ensure the protection of trial subjects and the reliability of the results. The phases of clinical development for pipeline products can be described as follows. Phase I starts with the initial administration of a new drug to humans, with trials carried out on a small number of people (*e.g.* in oncology, the sample size is usually in the low tens). The focus of Phase I trials is to confirm that the drug is safe to use in humans and identify the appropriate dosage and exposure-response relationship. Phase II usually starts with the initiation of studies to explore therapeutic efficacy in patients. Studies in Phase II are typically conducted on a small group of patients (generally around 20 to 50 up to some hundreds per cohort or treatment arm) that are selected based on stricter criteria for indications. Phase III trials aim to demonstrate or confirm therapeutic benefit in a larger group of patients (Phase III trials will typically have hundreds of patients and may have over a thousand, for example for autoimmune diseases). Studies in Phase III are designed to confirm the preliminary evidence accumulated in Phase II that a drug is safe and effective for use in the intended indication and recipient population. Usually, Phase III trials will involve a comparison of the investigational agent with a placebo or the standard of care therapy. These studies are also intended to provide an adequate basis for marketing approval. Phase IV begins after drug approval to monitor possible adverse reactions and/or new side effects over time.

7 Line of treatment refers to the setting for which a specific drug is indicated. For example, a drug indicated for second-line of treatment should be used only after another therapy (the first-line of treatment) has proven ineffective or if this other therapy cannot be prescribed to a specific patient.

8 See case M.9294 – *BMS/Celgene*, para. 14.

9 See cases M.9294 – *BMS/Celgene*, para. 16; and M.7275 - *Novartis/GSK Oncology*, para. 26.

10 See most recently, case M.9461 – *AbbVie/Allergan*, para. 13.

11 OJ C31, of 5 February 2004, p. 5.

12 Horizontal Merger Guidelines, paras. 24-25.

13 Horizontal Merger Guidelines, paras. 22 and 58-59. Section 4 (Horizontal analysis) focuses on horizontal non-coordinated effects as the Transaction does not give rise to horizontal coordinated effects.

14 See case M.8084 - *Bayer/Monsanto*, para. 48.

pipelines); and (ii) the capability to innovate in certain innovation spaces, assessing the risk of a significant loss of innovation competition resulting from a structural reduction of the overall level of innovation.[15]

(13) The Commission Guidelines on the assessment of non-horizontal mergers under the Council Regulation on the control of concentrations between undertakings (the "Non-Horizontal Merger Guidelines")[16] distinguish between two main ways in which vertical mergers may significantly impede effective competition, namely input foreclosure and customer foreclosure.[17]

(14) For a Transaction to raise input foreclosure competition concerns, the merged entity must have a significant amount of market power upstream.[18] In assessing the likelihood of an anticompetitive input foreclosure strategy, the Commission has to examine whether (i) the merged entity would have the ability to substantially foreclose access to inputs, (ii) whether it would have the incentive to do so, and (iii) whether a foreclosure strategy would have a significant detrimental effect on competition downstream.[19]

(15) The Commission will analyse the horizontal overlaps and vertical links arising from the Transaction against this framework in Sections 4 and 5 below.

4. HORIZONTAL ANALYSIS

4.1. Lupus nephritis ("LN")

4.1.1. Introduction

(16) LN is a severe and rare renal complication of systemic lupus erythematosus ("SLE"), in which deposits of immune complexes accumulate in the kidney and lead to renal injury. LN is developed by around 30% of the SLE patients. LN is characterised by a high unmet medical need, a large number of LN patients being refractory to treatments and progressing to end-stage renal disease ("ESRD", *i.e.* a stage where the kidneys cease to function on a permanent basis) requiring dialysis and kidney transplant. LN severity can be classified based on the classification of the International Society of Nephrology (ISN): Class I & II (mild disease); Class III & IV (severe and proliferative focal and diffuse disease); Class V (membranous disease, slower progression); Class VI (ESRD – no treatment available).

(17) In the EEA, the current treatment algorithm for LN (Class III-V) consists of (i) a combination of steroids (glucocorticoids) with immunosuppressants (*e.g.* mycophenolate

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15 See in the pharmaceutical sector case M.9294 – *BMS/Celgene*, para. 22. In the present case, the Transaction does not raise competition concerns in relation to (ii) since the Parties are not active in the same R&D spaces. Alexion's R&D mainly focuses on rare diseases and, in particular, on the complement pathway (*i.e.* a specific pathway of the immune system). Apart from a few isolated pipeline drugs, AstraZeneca is not present in those R&D spaces, which was confirmed by market investigation (see notably responses to question 52.1 of questionnaire Q1 to competitors: "*we are not aware of any presence of AstraZeneca in relation to the complement pathway"* and "*Alexion currently has a strong position with respect to rare diseases in the inflammation field. (…) We are not aware of any activity of AstraZeneca in this area*"). Moreover, the rare diseases and complement pathway R&D spaces appear rather competitive, with many players, including *e.g.* Roche, Takeda Shire, Sanofi and Apellis Pharmaceuticals (see responses to question 53.4 of questionnaire Q1 to competitors).

16 OJ L24, 29.1.2004, p. 1.

17 Section 5 (Vertical analysis) focuses on input foreclosure as the Transaction does not give rise to customer foreclosure concerns.

18 Non-horizontal Merger Guidelines, para. 35.

19 Non-horizontal Merger Guidelines, para. 32. Each of these points will be analysed separately although the Commission recognises that they are intertwined.

mofetil ("MMF") or cyclophosphamide ("CYC")) as frontline treatments; and (ii) a combination of steroids with rituximab or calcineurin inhibitors for refractory LN.[20]

4.1.2. Market Definition

(A) Product market definition

(18) In the absence of Commission precedents for LN treatments, the Notifying Party considers that all marketed and pipeline treatments for LN compete against each other and that the market should not be further segmented. In any event, the Notifying Party submits that this question can be left open as no competition concerns arise under any plausible market definitions.[21]

(19) The market investigation was not conclusive as to whether the treatments for LN should be sub-segmented notably because many of the LN drugs are still at the development stage and there is an intrinsic level of uncertainty in assessing their future characteristics and market positioning. In particular, based on the results of the market investigation, it is not clear whether the following potential segmentations are warranted:

i. *Segmentation based on the MoA*: LN drugs with different MoAs target different pathways and, thus, may translate into distinct efficacy and safety profiles, which are key factors for physicians when prescribing drugs.[22] However, at this stage, given the limited available data, the exact efficacy and safety profile of the various LN pipeline drugs remains uncertain. Moreover, all the competitors expect LN pipeline drugs based on different MoAs to compete with one another and generally consider that the MoA is not an important criterion for physicians;[23]

ii. *Segmentation based on the LoT*: albeit some of the Parties' internal documents distinguish LN drugs depending on their LoT and suggest limited competition between drugs belonging to different LoTs,[24] the results of the market investigation were not as clear. In particular, KOLs stressed that the "*place of LN pipeline drugs in the treatment algorithm is unclear*"[25] and the feedback received from competitors regarding the competition between LN drugs belonging to different LoTs was rather mixed.[26]

(20) In any event, for the purposes of this decision, the Commission concludes that the exact scope of the market for treatments of LN can be left open since the Transaction does not give rise to serious doubts as to its compatibility with the internal market and the functioning of the EEA Agreement under any plausible market definitions (*i.e.* segmentations by MoA and by LoT).

(B) Geographic Market Definition

(21) As regards the geographic market definition, the Commission has consistently considered the markets for pipeline drugs to be at least EEA-wide in scope.[27] The Notifying Party does

20 Responses to question 4 of questionnaire Q1 to competitors and Non-confidential minutes of a call with a LN Key Opinion Leader ("KOL") dated 21.04.2021 (1).

21 Form CO, paras. 206 and ff.

22 Responses to question 6 of questionnaire Q1 to competitors.

23 Responses to questions 6 and 12 of questionnaire Q1 to competitors.

24 See *e.g.* the Parties' reply to RFI 1, Annex 17, p. 4: "*[…]*" (emphasis added).

25 Non-confidential minutes of a call with a LN KOL dated 21.04.2021 (12:15 pm CET).

26 Responses to question 5 of questionnaire Q1 to competitors. For instance, a competitor stated that although "*by definition of refractory LN, patients would need to fail the frontline treatment […] [i]n the case of relapse, either frontline treatment or novel drug could be used*".

27 See Section 3.2 above.

not contest the above. Nothing in the market investigation suggests that the Commission should depart from its previous practice in the present decision with respect to LN.

4.1.3. The Parties' products

(22) The Parties' pipeline drugs for the treatment of LN are detailed in Table 1 below. The Parties have no marketed treatment for LN in the EEA.

Table 1 – Parties' pipeline products for LN

Party	Product	Clinical Trial Stage	MoA	(targeted) LoT	(expected) EEA launch
AstraZeneca	*anifrolumab*	Phase III *(not started yet)*	type 1 IFN receptor	[…]	[…]
Alexion	Ultomiris	Phase II	anti-C5	[…]	[…]
	[…]	[…]	[…]	[…]	[…]
	ALXN2050	Phase II (*not started yet*)	anti-Factor D	[…]	[…]

Source: Form CO

(23) AstraZeneca is developing *anifrolumab*, a Type-1 IFN inhibitor which has recently completed Phase II trials and is expected to reach the EEA markets in […].

(24) Alexion has several pipeline products targeting LN, including […], namely Ultomiris and […], which are undergoing respectively Phase II and […] trials. […]. In addition, Alexion has a third pipeline product for LN, *i.e.* ALXN2050, a complement pathway inhibitor, which is about to start Phase II trials and is expected to be launched […] at the earliest.

(25) Therefore, in the market for LN treatments (including in the potential segment for […]), the Transaction gives rise to pipeline-to-pipeline overlaps between (i) AstraZeneca's *anifrolumab*, on the one hand, and (ii) Alexion's Ultomiris/[…] and ALXN2050, on the other hand. No overlap arises if the market is segmented based on MoAs.

4.1.4. Competitive assessment

(26) The Notifying Party argues that no competition concerns arise in LN under any plausible market delineations given notably (i) the early development stage and the uncertain development status of their products, (ii) their differentiated MoAs, and (iii) the fact that they face strong competition from several competing drugs, including promising pipelines.[28]

(27) The market investigation generally confirms the Notifying Party's claims and, for the reasons set out below, allows the Commission to exclude serious doubts as to the compatibility of the Transaction with the internal market and the functioning of the EEA Agreement resulting from the overlaps between the Parties' activities in LN.

(28) *First*, KOLs and competitors do not generally see the Parties' LN pipeline drugs as being particularly promising.[29] In particular, a KOL noted that "*anifrolumab's Phase II study yielded negative results for lack of efficacy*" and, thus, indicated that it was "*unclear*" whether AstraZeneca would actually pursue the development of *anifrolumab,* irrespective of the Transaction.[30] As regards Alexion's LN pipeline drugs, a number of competitors stressed that their MoAs are "*unproven*" and that their "*clinical relevance [...] is less well*

28 See notably Form CO, paras. 220 and ff.

29 Responses to question 13 of questionnaire Q1 to competitors. See also Non-confidential minutes of calls with LN KOLs dated 21.04.2021 (12:15 pm CET and 3:30 pm CET).

30 Non-confidential minutes of a call with a LN KOL, dated 21.04.2021 (3:30 pm CET). Similarly, a competitor noted that *anifrolumab* "*missed the endpoint in Phase 2 for LN*" (Response to question 15 of questionnaire Q1 to competitors).

established".[31] KOLs also stressed that, due to the early stage of development of the Parties' pipelines ([…]),[32] very limited data is available and that, in this context, their prospects and exact profiles remain uncertain and speculative.[33]

(29) Second, the Parties' pipeline drugs are differentiated in terms of MoA and, thus, are not expected to closely compete.[34] In particular, a KOL stated that "*Alexion's complement pathway (C5 inhibitors) represents a different treatment strategy* [compared to other LN pipeline drugs, including AstraZeneca's]*, acting as a direct replacement for glucocorticoids to stop acute inflammations (short-term treatment).*"[35] Consequently, a number of respondents consider that, post-Transaction, the merged entity would have incentives to pursue in parallel the development of their respective drugs.[36]

(30) Third, the Parties face many competing drugs for the treatment of LN (see Table 2 below),[37] including two drugs under registration for approval in the EU and at least 11 pipeline drugs in Phase II or III (*i.e.* a stage of development similar to or more advanced than the Parties'). KOLs and competitors generally consider that the LN pipeline is rather competitive, stressing that "*there are many promising pipeline products currently undergoing trials for the treatment of LN*", including a number of drugs expected to be launched in the EEA within the next three years, namely Benlysta (GSK), Lupkynis (Aurinia) and Gazyva (Roche).[38]

Table 2 – Main competitors in LN[39]

Party	Product	Marketed / pipelines	MoA	(expected) EEA launch
GSK	Benlysta (*belimumab*)	Registration (*ongoing*)	anti-B-Lys	2021
Aurinia	Lupkynis (*voclosporin*)	Registration (*ongoing*)	anti-IL2	2021
Roche	Gazyva (*obinutuzumab*)	Pipeline (*Ph. III*)	anti-CD20	2024
Novartis	Cosentyx (*secukinumab*)	Pipeline (*Ph. III*)	anti-IL17A	2026
J&J	Tremfya (*guselkumab*)	Pipeline (*Ph. III*)	anti-IL23	2027
Novartis	CFZ533 (*iscalimab*)	Pipeline (*Ph. II*)	anti-CD40	2026/2027
BI/AbbVie	BI-655064	Pipeline (*Ph. II*)	anti-CD40	2026
Eledon	AT-1501	Pipeline (*Ph. II*)	anti-CD40L	2027/2028
BMS	BMS-986165 (*deucravacitinib*)	Pipeline (*Ph. II*)	anti-TYK2	2027
BeiGene	*zanubrutinib*	Pipeline (*Ph. II*)	anti-BTK	2027
Omeros	OMS721 (*narsoplimab*)	Pipeline (*Ph. II*)	anti-MASP2	2026
ChemoCentryx	Avacopan	Pipeline (*Ph. II*)	anti-C5a	2025/2026
Kezar	KZR-616	Pipeline (*Ph. II*)	anti-immunoproteasome	2026
Equillium	*itolizumab*	Pipeline (*Ph.I*)	anti-CD6	2027/2028

Source Form CO

31 Responses to question 15 of questionnaire Q1 to competitors.

32 *Anifrolumab*'s Phase III trials have not started yet.

33 Non-confidential minutes of calls with LN KOLs, dated 21.04.2021 (12:15 pm CET and 3:30 pm CET).

34 Responses to questions 14 and 15 of questionnaire Q1 to competitors. For instance, a competitor stated that "*these drugs have different mechanisms of actions which are likely to result in different benefit-risk profile*" (Response to question 12.1 of questionnaire Q1 to competitors).

35 Non-confidential minutes of a call with a LN KOL, dated 21.04.2021 (3:30 pm CET).

36 Responses to question 14.1 of questionnaire Q1 to competitors. See also Non-confidential minutes of a call with a LN KOL, dated 21.04.2021 (12:15 pm CET): "*the Parties would have commercial incentives to develop both [Alexion and AstraZeneca's pipeline products] as they could likely treat different patient populations (due to their different mechanisms of action).*"

37 As explained in Section 4.1.2(A), the place of LN pipeline drugs in the treatment algorithm is rather unclear. Therefore, the LoT targeted by competing pipeline drugs is generally not known or uncertain.

38 Responses to questions 10, 11 and 13 of questionnaire Q1 to competitors. See also Non-confidential minutes of calls with LN KOLs, dated 21.04.2021 (12:15 pm CET and 3:30 pm CET).

39 Table 2 includes only drugs specifically approved or developed for LN. Other drugs are also used off-label.

(31) *Finally*, none of the KOLs and competitors expressed concerns about the impact of the Transaction on the market for LN treatments in the EEA and the potential discontinuation, re-orientation and delay of the Parties' pipeline drugs.[40]

4.1.5. Conclusion

(32) In view of the above considerations, the Commission concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market and the functioning of the EEA Agreement as regards its impact on competition in the market for the treatments of LN (and its plausible sub-segmentations).

4.2. Follicular Lymphoma ("FL")

4.2.1. Introduction

(33) FL is a rare and indolent subtype of Non-Hodgkin lymphoma (blood cancer), which leads to abnormal B-cells building up in the lymph nodes or other body parts. FL affects mainly older patients (the median age at diagnosis is above 60 years old) and progresses slowly (the median time from diagnosis to death in FL is over 20 years). Ultimately, 30-40% of the FL cases transform into diffuse large B-cell lymphoma, a more aggressive type of lymphoma. There are different degrees of gravity ranging from stage I to IV: Stage I (the disease is located in a single region, *e.g.* a lymph node); Stage II (the disease is located in two separate regions confined to one side of the diaphragm); Stage III (the disease involves both sides of the diaphragm) and Stage IV (diffuse disease).

(34) In the EEA, the current treatment algorithm for FL (stage III-IV) consists of (i) a combination of chemotherapy (*e.g.* CHOP)[41] with immunotherapy (typically CD20 inhibitors, such as *rituximab*) as first-line treatments for young/fit patients (no chemotherapy for old/unfit patients, *e.g. rituximab* monotherapy); (ii) a combination of chemotherapy with immunotherapy as second-line treatments (either repetition of the first-line combined treatment or another combination); and (iii) PI3K inhibitors (*e.g. Idelalisib*) or novel agents (*i.e.* enrolment in clinical trials) for third-line treatments.[42]

4.2.2. Market definition

(A) Product market definition

(35) In the absence of Commission precedents for FL treatments, the Notifying Party submits that all marketed and pipeline treatments for FL belong to the same product market and should not be further segmented. In any event, according to the Notifying Party , this question can be left open as no competition concerns arise under any plausible market definitions.[43]

(36) The market investigation was not conclusive as to whether the treatments for FL should be sub-segmented, notably because many of the FL drugs are still at the development stage and there is an intrinsic level of uncertainty in assessing their future characteristics and market positioning. In particular, based on the results of the market investigation, it is not clear whether the following potential segmentations are warranted:

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40 Responses to questions 17 and 18 of questionnaire Q1 to competitors. See also Non-confidential minutes of calls with LN KOLs, dated 21.04.2021 (12:15 pm CET and 3:30 pm CET).

41 Chemotherapy combination of *cyclophosphamide*, *hydrodaunorubicin*, *oncovin* and *prednisone*.

42 Responses to question 20 of questionnaire Q1 to competitors and Non-confidential minutes of a call with FL KOL, dated 21 April 2021.

43 Form CO, paras. 329 and ff.

i. *Segmentation based on the MoA*: FL drugs with different MoAs target different pathways and, thus, may translate into distinct efficacy and safety profiles, which are key factors for physicians when prescribing drugs.[44] However, at this stage, given the limited available data, the exact profile of the various FL pipeline drugs remains uncertain. Moreover, all the competitors expect FL pipeline drugs based on different MoAs to compete with one another;[45]

ii. *Segmentation based on the LoT*: on the one hand, some evidence in the file, including the Parties' internal documents[46] and the responses provided by some respondents,[47] suggest limited competition between drugs belonging to different LoTs. In this respect, a KOL noted that "*FL drugs authorized for specific line of treatment cannot be used for other lines of treatment*" and that "*novel agents currently developed for FL […] are expected to be labelled for relapse and refractory FL*"[48] (the latter point is also corroborated by the Parties' internal documents).[49] However, on the other hand, half of the respondents stressed that FL drugs may be used or approved for various LoT.[50]

(37) In any event, for the purposes of this decision, the Commission concludes that the exact scope of the market for FL treatments can be left open since the Transaction does not give rise to serious doubts as to its compatibility with the internal market and the functioning of the EEA Agreement under any plausible market definitions (*i.e.* segmentations by MoA and by LoT).

(B) Geographic Market Definition

(38) As regards the geographic market definition, the Commission has consistently considered the markets for pipeline drugs to be at least EEA-wide in scope.[51] The Notifying Party does not contest the above. Nothing in the market investigation suggests that the Commission should depart in the present decision from its previous practice with respect to FL.

4.2.3. The Parties' products

(39) The Parties' pipeline drugs for the treatment of FL are detailed in Table 3 below. They have no marketed treatments for FL in the EEA.

Table 3 – Parties' pipeline products for FL

Party	Product	Clinical Trial Stage	MoA	(targeted) LoT	(expected) launch year
AstraZeneca	*Capivasertib* (AZD5363)	Phase II	anti-AKT	[…]	[…]
Alexion	*Cerdulatinib*	Phase I/IIa ([…])	anti-SYK/JAK	[…]	[…]

Source: Form CO

44 Responses to question 22 of questionnaire Q1 to competitors.

45 Responses to question 28 of questionnaire Q1 to competitors.

46 See *e.g.* [Extract from an RFI response containing information from an internal document] (emphasis added).

47 Responses to question 21 of questionnaire Q1 to competitors.

48 Non-confidential minutes of a call with a FL KOL, dated 21.04.2021.

49 See *e.g.* […] (emphasis added).

50 Responses to question 21 of questionnaire Q1 to competitors (*e.g.* "*frontline FL treatments may compete with or potentially displace treatments in the relapsed or refractory setting*" and "*Rituximab is used in frontline […] as well as relapsed/refractory setting […]. Obinutuzumab is also approved in combination with chemotherapy in the frontline as well as relapsed/efractory setting*").

51 Section 3.2 above.

(40) AstraZeneca is developing *capivasertib*, an AKT inhibitor, which is targeting patients that […] and only recently started Phase II trials for FL (in May 2021). If the trials are successful, *capivasertib* is expected to reach the EEA market at the earliest in […].

(41) Alexion is developing *cerdulatinib*, a dual SYK/JAK inhibitor currently undergoing Phase I/IIa trials for Non-Hodgkin Lymphoma, including FL (and PTCL), […]. *Cerdulatinib* was acquired by Alexion […] in July 2020 in the context of a broader transaction (*i.e.* Alexion's acquisition of Portola Pharmaceuticals) […]. Since then, [Alexion's plans for *cerdulatinib*].[52]

(42) Therefore, in the market for FL treatments (including in the potential segment for […]), the Transaction gives rise to a pipeline-to-pipeline overlap between AstraZeneca's *capivasertib* and Alexion's *cerdulatinib*. No overlap arises if the market is segmented by MoA.

4.2.4. Competitive assessment

(43) The Notifying Party argues that no competition concerns arise in FL under any plausible market delineations given notably (i) the early development stage and the uncertain development status of the Parties' pipeline products, (ii) their different MoAs, (iii) [Alexion's plans for *cerdulatinib*], and (iv) the existence of many competing drugs.[53]

(44) The market investigation generally confirms the Notifying Party's claims and, for the reasons set out below, allows the Commission to exclude serious doubts as to the compatibility of the Transaction with the internal market and the functioning of the EEA Agreement resulting from the overlap between the Parties' activities in FL.

(45) *First*, the Parties' FL pipeline drugs are not seen by KOLs as being particularly promising and the Parties are not perceived as major players in FL.[54] In particular, a KOL stressed that "*the first preliminary data for the Parties' pipeline drugs is not very promising*".[55] The market participants also generally note that the exact profiles and prospects of these drugs remain uncertain due to their early stage of development and the limited available data.[56]

(46) *Second*, AstraZeneca's and Alexion's pipeline products have different MoAs and, thus, are developed, they are not expected to closely compete (should they both reach the market).[57]

(47) *Third*, as illustrated in Table 4 below, and irrespective of the exact scope of the market,[58] the Parties face a large number of competing (marketed and pipeline) drugs. In this respect, market participants generally consider that the FL pipeline is very competitive, including drugs that are more advanced and more promising than the Parties'.[59] For instance, a

52 Form CO, paras. 326-328.

53 Form CO, paras. 357 and ff.

54 See notably Responses to question 29 of questionnaire Q1 to competitors.

55 Non-confidential minutes of a call with a FL KOL, dated 21.04.2021.

56 Responses to question 29 of questionnaire Q1 to competitors. See also non-confidential minutes of a call with a FL KOL, dated 21.04.2021.

57 Responses to question 31 of questionnaire Q1 to competitors.

58 As explained in Section 4.2.2(A), the novel agents currently in the FL pipeline are expected to be mainly prescribed after the failure of frontline treatments (similarly to the Parties' drugs).

59 Responses to questions 26, 27 and 29 of questionnaire Q1 to competitors. See also Non-confidential minutes of a call with a FL KOL, dated 21.04.2021 identifying bispecific antibodies CD20 and CD3 (such as Regeneron's pipeline drug) and CAR T cell therapies (currently under development by Novartis and BMS) as the most promising pipeline drugs based on the currently available data.

competitor stated that "*there is a healthy diversity of other pipeline therapies under development by other pharmaceutical companies*".[60]

Table 4 – Main competitors in FL[61]				
Party	**Product**	**Marketed / Pipeline**	**MoA**	**(expected) EEA launch**
Roche	Gazyva (*obinutuzumab*)	Marketed	anti-CD20	2014
Roche	Rituxan (*rituximab*)	Marketed	anti-CD20	2008
Pfizer/Celtrion/Sandoz	Rituximab biosimilars (x3)	Marketed	anti-CD20	2017
BMS	Revlimid (*lenalidomide*)	Marketed	multiple	2018
Gilead	Zydelig (*idelalisib*)	Marketed	anti-P13K	2014
Epizyme	Tazverik (*tazemetostat hydrobromide*)	Marketed[62]	anti-EZH2	*n/a*
Secura Bio	Copiktra (*duvelisib*)	Registration	anti-P13K	2021
AbbVie	Venclexta (*venetoclax*)	Pipeline (*Ph. II*)	anti-BCL2	≥ 2021
Roche	Polivy (*polatuzumab*)	Pipeline (*Ph. II*)	anti-CD79	2023
TG Therapeutics	*Umbrasilib*	Pipeline (*Ph. II*)	anti-P13K	≥ 2021
BeiGene	Brukinsa (*zanubrutinib*)	Pipeline (*Ph. II*)	anti-BTK	≥ 2022
Novartis	Kymriah (*tisagenlecleucel*)	Pipeline (*Ph. III*)	CAR T cell	2021
MorphoSys	Monjuvi (*tafasitamab*)	Pipeline (*Ph. III*)	anti-CD19	≥ 2022
BMS	Opdivo (*nivolumab*)	Pipeline (*Ph. II*)	anti-PD1	≥ 2024
Regeneron	odronextamab	Pipeline (*Ph. II*)	anti-CD20/CD3	2025
BMS	Lisocabtagene maraleucel	Pipeline (*Ph. II*)	CAR T cell	≥ 2021
Roche	Tecentriq (*atezolizumab*)	Pipeline (*Ph. I/II*)	anti-PD1	≥ 2024

Source: Form CO

(48) *Fourth*, [Alexion's plans for *cerdulatinib*]. This is corroborated by contemporary internal documents,[63] some KOLs[64] and publicly available data.[65]

(49) *Finally*, none of the KOLs and competitors expressed concerns about the impact of the Transaction on the market for FL treatments in the EEA and the potential discontinuation, re-orientation and delay of the Parties' pipeline drugs.[66]

4.2.5. Conclusion

(50) In view of the above considerations, the Commission concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market and the functioning of the EEA Agreement as regards its impact on competition in the possible market for the treatment of FL (and its plausible sub-segmentations).

60 Responses to question 33.1 of questionnaire Q1 to competitors.

61 Table 4 includes only drugs specifically approved or developed for FL. Other drugs are also used off-label.

62 Tazverik is not currently marketed in the EEA for the treatment of FL. However, on March 2018 it received a marketing authorisation in the EEA for large B-Cell lymphoma and […].

63 […].

64 Non-confidential minutes of a call with a PTCL KOL, dated 19.04.2021: "*irrespective of the Transaction, it is unclear whether Alexion is willing to pursue the development of cerdulatinib*".

65 See *e.g.* the status of Cerdulatinib's clinical trial for PTCL on the public database ClinicalTrials.gov marked as withdrawn since March 2020 further to the "*sponsor decision not to initiate the trials*" (https://clinicaltrials.gov/ct2/show/NCT04021082?term=cerdulatinib&draw=2&rank=4).

66 Responses to questions 33 and 34 of questionnaire Q1 to competitors. See also Non-confidential minutes of a call with a FL KOL, dated 21.04.2021.

4.3. Peripheral T-Cell Lymphoma ("PTCL")

4.3.1. Introduction

(51) PTCL is another rare type of Non-Hodgkin lymphoma (blood cancer), which leads to abnormal T-cells building up in the lymph nodes or other body parts. PTCL is an aggressive disease (the median time from diagnosis to death in PTCL is around three years), which mainly affects older patients (the median age of diagnosis is 60 years old). It is also an heterogeneous disease, with many subtypes, including notably Angio-Immunoblastic T-cell lymphoma ("AITL"), anaplastic large cell lymphoma ("ALCL"), PTCL - not otherwise specified ("PTCL - NOS"). PTCL is characterised by a high unmet medical need, with low overall response rates to the few existing therapies and high mortality rates.

(52) In the EEA, the current treatment algorithm for PTCL consists of (i) chemotherapies (such as CHOP or CHOEP[67]), or a combination of CHOP with the anti-CD30 *brentuximab vedotin* Adcetris (for ALCL only), as frontline treatments, followed by an autologous stem cell transplant for young/fit patients responding to the chemotherapy (consolidation treatment); (ii) no real standard of care for relapse and refractory ("r/r") PTCL, except for ALCL patients who can be treated with Adcetris (monotherapy).[68]

4.3.2. Market definition

(A) Product market definition

(53) In the absence of Commission precedents for PTCL treatments, the Notifying Party considers that all marketed and potential pipeline treatments for PTCL are part of the same product market and should not be further segmented. In any event, the Notifying Party submits that this question can be left open as no competition concerns arise under any plausible market definitions.[69]

(54) The results of the market investigation are not conclusive as to whether the treatments for PTCL should be sub-segmented, notably because many of the PTCL drugs are still at the development stage and there is an intrinsic level of uncertainty in assessing their future characteristics and market positioning. In particular, based on the results of the market investigation, it is not clear whether the following potential segmentations are warranted:

i. <u>*Segmentation based on the MoA*</u>: similarly to the other overlapping indications, the Commission found that PTCL treatments with the same MoA are "*more likely to be seen as close alternatives*",[70] with similar efficacy and safety profiles. That being said, at this stage, given the limited available data, the exact profile of the various PTCL pipeline drugs remains highly speculative[71] and the feedback received from the market regarding the relevance of a segmentation of the PTCL market by MoA was not conclusive.[72] In any event, as illustrated in Tables 5 and 6 below, it appears that "[PTCL] *drugs having the exact same MoA is fairly rare*";[73]

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67 CHOP chemotherapy combination (see fn. 41) with the addition of etoposide.

68 Responses to question 36 of questionnaire Q1 to competitors and Non-confidential minutes of a call with a PTCL KOL, dated 19.04.2021.

69 Form CO, paras. 499 and ff.

70 Non-confidential minutes of a call with a PTCL KOL, dated 29.04.2021.

71 Non-confidential minutes of a call with a PTCL KOL, dated 22.04.2021.

72 Responses to question 45 of questionnaire Q1 to competitors.

73 Non-confidential minutes of a call with a PTCL KOL, dated 05.05.2021.

ii. *Segmentation by subtypes of PTCL*: albeit some drugs target specific subtypes of PTCL (*e.g.* Adcetris, a marketed drug specifically approved for ALCL),[74] a number of respondents stressed that "*at this stage, given the limited available data, it is not clear whether the [PTCL] pipeline drugs [...] would be more efficacious with respect to specific PTCL subtypes*";[75]

iii. *Segmentation based on the LoT*: the Commission found that (i) PTCL drugs are authorized for specific line(s) of treatment (*e.g.* Adcetris is approved by the European Medicine Agency (the "EMA") both as a first-line treatment and as a treatment for relapse and refractory ALCL) and that (ii) a drug authorised for a specific LoT cannot be used for another LoT. The evidence in the file also suggests that all pipeline drugs currently being developed (including the Parties') are targeting relapsed and refractory PTCL.[76] However, some KOLs disagree with the above, stressing that PTCL pipeline drugs are still an early stage of development, with limited available data, and that, it is therefore "*premature to speculate about [...] their place in the treatment algorithm*".[77]

(55) In any event, for the purposes of this decision, the Commission concludes that the exact scope of the market for PTCL treatments can be left open since the Transaction does not give rise to serious doubts as to its compatibility with the internal market and the functioning of the EEA Agreement under any plausible market definitions (*i.e.* segmentations by MoA, by LoT and by subtype of PTCL).

(B) Geographic Market Definition

(56) As regards the geographic market definition, the Commission has consistently considered the markets for pipeline drugs to be at least EEA-wide in scope.[78] The Notifying Party does not contest the above. Nothing in the market investigation suggests that the Commission should depart in the present decision from its previous practice with respect to PTCL.

4.3.3. The Parties' products

(57) The Parties' pipeline drugs for the treatment of PTCL are detailed in Table 5 below. They have no marketed treatment for PTCL in the EEA.

Table 5 – Parties' pipeline products for PTCL

Party	Product	Pipeline	MoA	(targeted) LoT	(expected) EEA launch
AstraZeneca	AZD4573	Phase II *(not started yet)*	anti-CDK9	*r/r*	[…]
AstraZeneca (Dizal)	DZD4205	Phase I/IIa	anti-JAK	*r/r*	[...]
Alexion	*Cerdulatinib*	Phase I/IIa *([...])*	anti-SYK/JAK	*r/r*	≥ […]

Source: *Form CO*

(58) AstraZeneca is developing in-house AZD4573, a CDK9 inhibitor, which is about to start Phase II trials and is expected to reach the EEA market at the earliest in […]. In addition, AstraZeneca's PTCL pipeline includes DZD4205, a drug developed by Dizal, *i.e.*

74 Responses to question 37 of questionnaire Q1 to competitors.

75 Non-confidential minutes of a call with a PTCL KOL, dated 19.04.2021.

76 In this respect a KOL explained that "*given the high rates of refractory patients and relapse, the typical approach when developing drugs for PTCL consists in targeting first the relapse and refractory settings and subsequently pursue the development of a drugs as a frontline treatment only if the pipeline drug shows encouraging and robust Phase 2 data*" (non-confidential minutes of a call with a PTCL KOL, dated 19.04.2021). See also (i) non-confidential minutes of a call with a PTCL KOL, dated 29.04.2021, as well as (ii) the Parties' internal documents: *e.g.* [Extracts from RFI responses containing information from internal documents] (emphasis added).

77 See notably Non-confidential minutes of a call with a PTCL KOL, dated 22.04.2021.

78 See Section 3.2 above.

[confidential summary of why Dizal's product is attributed to AstraZeneca for purposes of EU merger control assessment]. DZD4205 is a selective JAK1 and JAK3 inhibitor currently undergoing Phase I/II trials. At this stage, none of AstraZeneca's pipeline drugs targets a specific PTCL subtype. All AstraZeneca's pipeline drugs for the treatment of PTCL target relapse and refractory patients.

(59) Alexion is developing *cerdulatinib*, a dual SYK/JAK inhibitor, targeting both the JAK and SYK pathways (as opposed to AstraZeneca's DZD4205, which is a more selective JAK inhibitor, targeting only the JAK pathway). Cerdulatinib is currently undergoing Phase I/IIa trials and does not target a specific PTCL subtype. It also targets relapse and refractory patients. Moreover, as explained in Section 4.2.2(A), [Alexion's plans for *cerdulatinib*].[79]

(60) Therefore, in the market for PTCL treatments (including if the market is segmented by LoT), the Transaction gives rise to pipeline-to-pipeline overlaps for the treatment of PTCL between (i) AstraZeneca's AZD4573 and Alexion's *cerdulatinib*; and (ii) Astrazeneca's DZD4205 and Alexion's *cedulatinib*. No overlaps arise if the market is segmented by MoA and by subtypes of PTCL (since none of the Parties' pipeline products is developed for a specific PTCL subtype).

4.3.4. Competitive assessment

(61) The Notifying Party argues that no competition concerns arise in PTCL under any plausible market delineations given notably the fact that the Parties' pipeline products (i) are still at an early stage of development, (ii) have differentiated MoAs and (iii) face strong competition from a number of drugs. The Notifying Party also submits that (iv) [Alexion's plans for *cerdulatinib*] and (v) Dizal (*i.e.* the Chinese company controlled by AstraZeneca developing a PTCL pipeline) is subject to an ongoing Initial Public Offering (*i.e.* a public offering in which shares of a company are sold to investors; "IPO").[80]

(62) The market investigation generally confirms the Notifying Party's claims and, for the reasons set out below, allows the Commission to exclude serious doubts as to the compatibility of the Transaction with the internal market and the functioning of the EEA Agreement resulting from the overlaps between the Parties' activities in PTCLtreatments.

(63) *First*, the Parties' PTCL pipeline drugs are not seen by KOLs and market participants as being particularly promising.[81] For instance, a KOL noted that the "*interest in SYK inhibition within the context of T-Cell Lymphomas […] has recently declined*" and stated that he was "*pessimistic about the likelihood of the Parties getting licenses for treatments in PTCL*".[82] Another KOL explained that the limited preliminary data available for *cerdulatinib* in PTCL did not suggest a significant improvement compared to the current standard of care.[83] The respondents also generally stressed that the Parties' products are early stage pipeline drugs, with highly uncertain prospects.[84]

(64) *Second*, the Commission received rather mixed feedback from the market about the differentiation between the Parties' pipelines, in particular between AstraZeneca's DZD4205 and Alexion's *cerdulatinib*. On the one hand, some KOLs explained that these two drugs have the potential to closely compete with each other because of their similar MoAs (JAK inhibitor

79 Form CO, paras. 326-328.

80 Form CO, paras. 512 and ff.

81 Responses to question 46 of questionnaire Q1 to competitors.

82 Non-confidential minutes of a call with a PTCL KOL, dated 05.05.2021.

83 Non-confidential minutes of a call with a PTCL KOL, dated 19.04.2021.

84 Non-confidential minutes of calls with PTCL KOLs, dated 19.04.2021 and 22.04.2021.

vs. SYK/JAK inhibitor), which "*overlap to some extent as they both target the JAK pathway*".[85] On the other hand, other KOLs stressed that a pure JAK inhibitor is more selective than a combined SYK/JAK inhibitor, with potentially less side effects: "*although the mechanisms of action of DZD4205 (JAK inhibitor) and cerdulatinib (SYK/JAK inhibitor) overlap to some extent […], the two drugs do not target the exact same pathways and DZD4205 is more selective than cerdulatinib […] at this stage, it is not obvious that these pipeline drugs will have similar efficacy and safety profiles*".[86] Consequently, some respondents consider the new entity "*may have incentives to pursue in parallel the development of the Parties' respective PTCL pipeline drugs (notably because these drugs may in fine be used in different settings)*".[87] That said, respondents generally emphasize the fact that, given the limited available data, it is too early to assess the closeness of competition between these drugs without speculating.[88]

(65) *Third*, as illustrated in Table 6, and irrespective of whether the market is segmented by LoT,[89] the Parties face several drugs specifically approved or developed for PTCL, including one marketed drug recently approved (Adcetris)[90] and many competing pipelines currently in Phase II (*i.e.* a stage of development similar to or more advanced than the Parties'). In this respect, the evidence in the file suggests that the PTCL pipeline is increasingly competitive (*e.g.* a KOL stressed the "*rising number pipeline treatments targeting PTCL*")[91] and includes drugs that are seen as being more promising than the Parties', such as Affimed's AFM13 (anti-CD30/CD16A) and SecuraBio's Copiktra (anti-PI3K).[92]

85 Non-confidential minutes of a call with a PTCL KOL dated 19.04.2021.See also Non-confidential minutes of a call with a PTCL KOL, dated 29.04.2021 stating that, in theory, "*two treatment with the same or similar modes of action are more likely to be seen as close alternatives"* but that "*there is no definitive answer*" as to whether AstraZeneca's DZD4205 and Alexion's *cerdulatinib* would closely compete (emphasis added).

86 Non-confidential minutes of a call with a PTCL KOL dated 22.04.2021. See also Non-confidential minutes of a call with a PTCL KOL dated 19.04.2021: "*DZD4205 is a more selective JAK inhibitor than cerdulatinib, which could potentially translate into a better safety and tolerability profile*".

87 Non-confidential minutes of a call with a PTCL KOL dated 22.04.2021.

88 Non-confidential minutes of call with PTCL KOLs dated 19.04.2021, 22.04.2021 and 29.04.2021. See also Responses to question 47 of questionnaire Q1 to competitors.

89 As explained in Section 4.3.2(A) above, the evidence in the file suggests that all pipeline drugs currently being developed (including the Parties') are targeting relapsed and refractory PTCL.

90 In the EEA, to the exception of Adcetris, there is currently no drug specifically approved for relapse and refractory PTCL. In the US, three drugs, namely Folotyn (pralatextrate), Istodax (romidepsin) and Beleodaq (belinostat), have been approved by the FDA and are currently available on the market for relapse and refractory PTCL. However, given their limited proven clinical benefits, these drugs were considered as falling short of the EMA's requirement for a drug to be approved and, thus, are not available in Europe.

91 Non-confidential minutes of a call with a PTCL KOL dated 19.04.2021.

92 Non-confidential minutes of calls with PTCL KOLs dated 19.04.2021 and 22.04.2021.

Table 6 – Main competitors in PTCL[93]				
Party	**Product**	**Marketed / Pipeline**	**MoA**	**(expected) EEA launch**
Takeda	Adcetris *(brentuximab vedotin)*	Marketed	anti-CD30	2020
Merck	Keytruda (*Pembrolizumab)*	Pipeline (*Ph. II*)	anti-PD1	2022
Affimed	AFM13	Pipeline (*Ph. II*)	anti-CD30/CD16A	≥ 2023
BeiGene/Novartis	*tislelizumab*	Pipeline (*Ph. II*)	anti-PD1	≥ 2023
Secura Bio	Copiktra *(duvelisib)*	Pipeline (*Ph. II*)	anti-PI3K	≥ 2023
Daiichi Sankyo	DS-3201b (*valemetostat*)	Pipeline (*Ph.II*)	anti-EZHI1/EZHI2	≥ 2025
Innate Pharma	IPH4102 (*lacutamab)*	Pipeline (*Ph. II*)	anti-KIR3D L2	≥ 2025
Legend	LB1901	Pipeline (*Ph. I*)	anti-CAR T	≥ 2025
Kura Oncology	Zanestra (*tipifarnib*)	Pipeline (*Ph. II*)	anti-FTI	*n.a.*
Karyopharm/Antogene	Xpovio ATG-010	Pipeline (*Ph. II*)	anti-XPO1	*n.a.*
BMS	Revlimid (*lenalidomide*)	Pipeline (*Ph. II*)	multiple	*n.a.*

Source: Form CO

(66) *Fourth*, as previously explained,[94] [Alexion's plans for *cerdulatinib*].

(67) *Fifth*, the Commission notes that Dizal (*i.e.* the company controlled by AstraZeneca and developing one its PTCL pipeline) is subject to an ongoing IPO. The IPO was initiated on 10 March 2021 and […].[95]

(68) *Finally*, no respondents to the market investigation expressed concerns about the impact of the Transaction on the market for PTCL treatments in the EEA and the potential discontinuation, re-orientation and delay of the Parties' pipeline drugs.[96]

4.3.5. Conclusion

(69) In view of the above considerations, the Commission concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market and the functioning of the EEA Agreement with respect to the overlaps between the Parties' pipeline drugs for the treatment of PTCL.

5. VERTICAL ANALYSIS

5.1. Market definition

(70) Neuromyelitis optica spectrum disorder ("NMOSD") is a rare autoimmune disease in which the immune system mistakenly attacks own body cells in the spinal cord and optic nerves. Generalized myasthenia gravis ("gMG") is also a rare autoimmune disease in which antibodies block or destroy nicotinic acetylcholine receptors at the junction between the nerve and muscle, thus preventing nerve impulses from triggering muscle contractions.

(71) The Commission has not previously considered the relevant markets for NMOSD and gMG. However, for the reasons explained below, the exact scope of the markets would have no impact on the Commission's assessment of the vertical link at stake and, therefore, can be left open.

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93 Table 6 includes only drugs specifically approved or developed for PTCL. Other drugs are also used off-label.

94 See para. (48) above.

95 Form CO, paras. 435 and ff.

96 Response to questions 50 and 51 of questionnaire Q1 to competitors. See also non-confidential minutes of calls with a PTCL KOL, dated 19.04.2021, 22.04.2021 and 22.04.2021.

5.2. The Parties' activities and products

(72) AstraZeneca manufactures *inebilizumab* for its former subsidiary Viela Bio, Inc. ("Viela", controlled by Horizon since March 2021). This creates a vertical relationship with Alexion's activities in the treatment of NMOSD and gMG, where Viela and Alexion are competitors.

(73) Viela (a spin-off of AstraZeneca acquired by Horizon in 2021) markets in the US[97] Uplizna (*inebilizumab*), a drug used for the treatment of NMOSD. Uplizna is also undergoing Phase III clinical trials for the treatment of gMG. Viela sources manufacturing services related to Uplizna from AstraZeneca. Uplizna directly competes with some of Alexion's marketed drugs and pipeline projects. In particular, (i) Alexion's product Soliris (*eculizumab*) is marketed, among others, for the treatment of NMOSD and gMG in the EEA; and (ii) Alexion's pipeline product Ultomiris (*ravulizumab*) is in Phase III clinical trials for the treatment of NMOSD and gMG.[98]

5.3. Competitive assessment

(74) As previously indicated, the Transaction gives rise to a potential vertical relationship between the manufacture (upstream) and the sales (downstream) of drugs for the treatment of NMOSD and gMG.

(75) […], competition concerns have been raised in relation to the above vertical link on the ground that the new entity would have the ability and the incentive to implement an input foreclosure strategy by discontinuing or degrading the manufacture of Uplizna so as to favour Alexion's products for the treatment of NMOSD and gMG. Consequently, […], the supply agreement between AstraZeneca and Horizon concerning Uplizna has been amended[99] to prevent the above risk.[100]

(76) In this respect, the Commission notes that the amended supply agreement includes provisions (i) to avoid the risk of supply disruption […] and (ii) to facilitate the transfer of the technology and the manufacture of Uplizna […]. Moreover, Horizon expressly confirmed to the Commission that it is satisfied with the amendments and that as revised, the supply agreement provides sufficient safeguards to secure the manufacture of Uplizna.[101]

5.4. Conclusion

(77) In view of the above considerations, the Commission concludes that the vertical link arising in relation to NMOSD and gMG does not give rise to serious doubts as to the compatibility of the Transaction with the internal market and the functioning of the EEA Agreement.

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97 Uplizna is not yet commercialised in the EEA. Horizon anticipates an EMA approval for NMOSD by the end of 2021. Horizon does not yet have a timeline for the marketing of Uplizna for gMG in the EEA.

98 Ultomiris is expected to be launched in the EEA in […] for NMOSD and […] for gMG.

99 […].

100 […].

101 Non-confidential minutes of a call with Horizon, dated 30.04.2021.

6. CONCLUSION

(78) For the above reasons, the Commission has decided not to oppose the notified operation and to declare it compatible with the internal market and with the EEA Agreement. This decision is adopted in application of Article 6(1)(b) of the Merger Regulation and Article 57 of the EEA Agreement.

For the Commission

(Signed)
Margrethe VESTAGER
Executive Vice-President