EUROPEAN COMMISSION
DG Competition

# *Case M.10629 - CSL / VIFOR PHARMA*

Only the English text is available and authentic.

## REGULATION (EC) No 139/2004
## MERGER PROCEDURE

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Article 6(1)(b) NON-OPPOSITION
Date: 31/05/2022

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EUROPEAN COMMISSION

Brussels, 31.5.2022
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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 Where possible the information omitted has been replaced by ranges of figures or a general description.

CSL Limited
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Australia

**Subject:** **Case M.10629 – CSL / VIFOR PHARMA**
**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 26 April 2022, the European Commission received notification of a proposed concentration pursuant to Article 4 of the Merger Regulation by which CSL Limited ("CSL", Australia), through its subsidiary CSL Behring AG ("CSL Behring"), will acquire sole control of Vifor Pharma Ltd. ("Vifor Pharma", Switzerland) (the "Transaction").[3] CSL and Vifor Pharma are together referred to as 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 180, 03.05.2022, p. 14.

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## 1. THE PARTIES AND THE OPERATION

(2) **CSL** is an Australia-based biotechnology company with a portfolio of life-saving medicines, including those that treat hemophilia and immune deficiencies (through CSL Behring), as well as vaccines to prevent influenza (through its subsidiary Seqirus UK Limited). In addition, CSL Plasma, a division of CSL Behring, operates a plasma collection network.

(3) **Vifor Pharma** is a Swiss-based pharmaceutical company active worldwide in the development, manufacturing, and marketing of pharmaceutical products for the treatment of iron deficiency, nephrology (kidney care), and cardio-renal therapies.

(4) The Transaction is effected by way of a public tender offer to acquire all of Vifor Pharma's publicly held shares, pursuant to a transaction agreement entered into by CSL and Vifor Pharma on 14 December 2021 (the "Transaction Agreement"). Pursuant to the terms of the Transaction Agreement, CSL will acquire Vifor Pharma's shares for USD 179.25 (approximately EUR 158) per share for a total cash purchase price of approximately USD 11.7 billion (approximately EUR 10.37 billion).

(5) Pursuant to the Transaction Agreement, CSL will acquire up to 100% and at least 80% of the share capital of Vifor Pharma. Following the completion of the Transaction, CSL will thus acquire sole control of Vifor Pharma, and the Transaction constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

## 2. UNION DIMENSION

(6) The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million (CSL: EUR 8 717 million; Vifor Pharma: EUR 1 593 million).[4] Each of them has a Union-wide turnover in excess of EUR 250 million (CSL: […] million; Vifor Pharma: […] 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. General considerations on market definition in relation to pipeline products

(7) When defining relevant product markets in past decisions dealing with pharmaceutical products in development (also called pipeline products),[5] the

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

5 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. Clinical trials in humans (so called "Phase I", "Phase II" and "Phase III" clinical trials) 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. A Phase I clinical trial starts with the initial administration of a new drug to humans, with trials carried out on a small number of people (e.g. in

Commission has generally envisaged market definitions based on the indication, the mode of action ("MoA"), the mode of delivery ("MoD") and, where relevant, the line of treatment ("LoT"),[6] but ultimately left open the exact delineation of the market definition.[7] The Commission also found 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.[8] In terms of geographic scope, the Commission has consistently considered that the markets for pipeline drugs are at least EEA-wide.[9]

(8) The Commission will analyse in Sections 4.1.2 and 4.2.2 below the relevance of these precedents for the relevant product and geographic market definitions in the present case.

### 3.2. General approach to competitive assessment

(9) 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.

(10) The Commission Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings (the "Horizontal Merger Guidelines")[10] 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.[11] The Horizontal Merger Guidelines also indicate that

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oncology, the sample size is usually in the low tens). The focus of a Phase I trial is to confirm that the drug is safe to use in humans and identify the appropriate dosage and exposure-response relationship. A Phase II clinical trial 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 clinical trials aim to demonstrate or confirm the therapeutic benefit in a larger group of patients (Phase III clinical 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 clinical 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 by the regulatory agencies. There are also Phase IV clinical trials, but they begin only after drug approval to monitor possible adverse reactions and/or new side effects over time.

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

7 See e.g. case M.10165 – *Astrazeneca/Alexion Pharmaceuticals*, para. 8 and case M.9294 – *BMS/Celgene*, para. 14.

8 See e.g. cases M.10165 – *Astrazeneca/Alexion Pharmaceuticals*, para. 8. M.9294 – *BMS/Celgene*, para. 16, and M.7275 - *Novartis/GSK Oncology*, para. 26.

9 See most recently, case M.10165 – *Astrazeneca/Alexion Pharmaceuticals*, para. 8.

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

11 Horizontal Merger Guidelines, paras. 24-25.

mergers involving a potential competitor may restrict effective competition by ways of horizontal anti-competitive effects, either coordinated or non-coordinated.[12]

(11) In this framework, "competition" is understood to mean product and price competition (actual or potential), but also innovation competition.[13] 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 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.[14]

(12) The Commission will analyse the horizontal overlaps arising from the Transaction against this framework in Sections 4.1 and 4.2 below.

## 4. COMPETITIVE ASSESSMENT

(13) The Transaction gives rise to only a limited number of pipeline-to-pipeline overlaps with respect to two indications: (i) sickle cell disease ("SCD") and (ii) hidradenitis suppurativa ("HS").[15]

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12 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.

13 See recently case M.10165 – *Astrazeneca/Alexion Pharmaceuticals*, para. 12 and case M.8084 - *Bayer/Monsanto*, para. 48.

14 See also e.g. the pharmaceutical sector case M.9294 – *BMS/Celgene*, para. 22. In the present case, the Transaction does not give rise to serious doubts as to possible competition concerns in relation to (ii) the capability to innovate in certain innovation spaces. The Parties are generally not active in the same R&D spaces and to a large extent the parties' activities are complementary. CSL's R&D capabilities are focused on plasma fractionation, recombinant technology, gene and cell therapy and vaccines, while Vifor Pharma's activities are focused on iron deficiency, nephrology and rare diseases. In the majority of the limited broad therapeutic areas where the Parties' R&D activities could be considered as potentially overlapping (immunology, haematology, cardiovascular and metabolic, and transplants), competitors confirm that none of the Parties are considered to be strong R&D players in the development of pharmaceutical products. The only overlapping therapeutic area where one of the Parties, namely Vifor Pharma, could potentially be considered a strong player at R&D level is nephrology. However, CSL has no marketed products in the nephrology area and competitors confirm that CSL could not be considered a strong R&D player in nephrology (see responses to questions 37.1. of questionnaire Q1 to competitors), and that nephrology is a competitive therapeutic area with many large players active, including AstraZeneca, Roche, Fresenius, Baxter, and Terumo (see responses to questions 37.2. of questionnaire Q1 to competitors). In addition, in all the overlapping therapeutic areas, including, responding competitors consider that a sufficient number of companies will remain active (see responses to questions 39 of questionnaire Q1 to competitors).

15 For the sake of completeness, it should also be noted that the Transaction also gives rise to two potential overlaps between marketed/late stage pipeline products of Vifor Pharma and early stage products (Phase I) of CSL because those pipeline products could potentially be developed for the same indications in the future, namely: (i) anti-neutrophil cytoplasmic auto-antibody ("ANCA")-associated vasculitis ("AAV") and (ii) IgA nephropathy (IgAN).

As regards AAV, Vifor Pharma markets avacopan (Tavneos®), an approved and marketed drug for AAV in the EEA. CSL develops the pipeline product […], with AAV as […]. At this stage, it remains uncertain whether AAV will be one of the indications for […]. Even if […] is developed and approved for AAV, the Parties' products are likely to be differentiated ([products are differentiated on a number of relevant

## 4.1. Sickle cell disease ("SCD")

### *4.1.1. Introduction*

(14) SCD is a group of inherited red blood cell disorders. It is a genetic condition present at birth. Due to nucleotide mutation in the β-globin gene, red blood cells carry abnormal haemoglobin, which makes them prone to rupture, causing the adhesion of sickle cells and inflammatory cells to the blood vessels. This ultimately leads to an obstruction of blood flow and organ damage. People with SCD start to have signs of the disease during the first year of life, usually around 5 months of age. Symptoms and complications of SCD are different for each person and can range from mild to severe. SCD is a disease that worsens over time.[16]

(15) There are several types of SCD depending on the sickle cell genes a person inherits from his/her parents. In all types of SCD, at least one of the two abnormal genes causes a person's body to make haemoglobin S. Hemoglobin S (Hgb S) is an abnormal type of hemoglobin that can be inherited. Hgb S causes red blood cells to become stiff and abnormally shaped. Instead of having a normal round, disk shape, these red blood cells become sickle-shaped, or crescent-shaped. These cells don't live as long as normal red blood cells. Because of their shape, they get stuck inside small blood vessels. These problems cause symptoms of sickle cell disease. The most common types of SCD are:

- sickle cell trait ("SCT"), which occurs in people who inherit one sickle cell gene ("S") from one parent and one normal gene ("A") from the other parent;

- sickle cell anaemia ("SCA"), which is when a person has two haemoglobin S gene (hemoglobin SS) and is the most common and often most severe type of SCD; and

- haemoglobin SC disease and haemoglobin Sβ (sickle beta) thalassemia are two other common types of SCD.[17]

(16) One of the most common and severe complications of SCD is a vaso-occulsive crisis ("VOC"). VOC occurs when sickled red blood cells block blood flow to the point that tissues are deprived of oxygen. This in turn sets in motion an inflammatory response as the body tries to rectify the problem. The result is substantial pain, which

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factors]). Moreover, there are many marketed (6) and pipeline products currently in development for AAV, including at a late stage of development.

[…] could also be considered for IgAN indication, and Vifor Pharma is developing Sparsentan (Phase III clinical trial) for that same indication. However, for the same reasons as for AAV, given that […] is not yet determined for IgAN and the pipeline appears competitive (there are more than 20 assets in clinical and pre-clinical development, some advanced in Phase II/III clinical trial), it is unlikely that the Transaction will give rise to competition concerns in this respect. These overlaps are therefore not further discussed in this decision.

16 Form CO, para. 123.

17 In addition to these types of SCD, there are much less common types, such as haemoglobin SD, haemoglobin SE, and haemoglobin SO.

can affect any part of the body, but most commonly occurs in the back, chest, or extremities.[18]

(17) In the EEA, the current treatment algorithm for the *prevention* of SCD complications generally refers to prophylactic medication to prevent VOC and other acute complications. Hydroxyurea is a frontline prophylactic medication for SCD. Daily Hydroxyurea reduces the frequency of painful crises and might reduce several complications of SCD and prevent VOC. In case of lack of responsiveness/adherence, physicians would usually prescribe either chronic blood transfusions or a secondary prophylactic medication (e.g. Adakveo and Oxbryta) to be taken as an alternative or in combination with Hydroxyurea.[19]

(18) There is no specific treatment algorithm for the *treatment* of VOC.[20] The current standard of care treatment of VOC is limited to supportive care with intravenous fluids and symptomatic (pain-relief) management with analgesics.[21]

(19) For patients severely affected with SCD, hematopoietic stem cell transplantation can provide curative therapy, but its utilization is limited due to the limited availability of suitable donors and the significant risks and expense of the procedure.[22] In addition, there are several potential genetic therapies currently under development as, one-time, possibly curative treatments of SCD with the goal to fix the mutations that cause sickle cell through the use of cutting-edge gene editing technologies. There is no currently approved form of gene therapy for SCD in the EEA.[23]

*4.1.2. Market Definition*

(A) Product Market

(20) In the absence of Commission precedents for SCD treatments, the Notifying Party considers that a segmentation of the market could be envisaged according to the severity of the disease and the LoT, as follows: (i) durable curative treatments (i.e. stem-cell transplants and, in the future, gene therapies); (ii) prophylaxis treatments (prevention of VOC and other SCD symptoms); and (iii) treatments of VOC and other SCD complications (acute (on-demand) treatment).[24] However, the Notifying Party considers that a segmentation by subtype of SCD or by MoA is not appropriate.[25] The Notifying Party does not give its view as to whether the market should be segmented based on the MoD. In any event, the Notifying Party submits that this question can be left open as no competition concerns arise under any plausible market segmentation.[26]

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18 Form CO, para. 124-125.

19 Non-confidential minutes of a call with a SCD KOL, dated 9 March 2022 (3:00PM CET), paras. 6-8.

20 Form CO para. 130.

21 Form CO, para. 129.

22 Form CO, para. 180 and non-confidential minutes of a call with a SCD KOL, dated 9 March 2022 (3:00PM CET), para. 13.

23 Form CO, para. 168 and 169.

24 Form CO, para 163.

25 Form CO, para 173 and 174.

26 Form CO, para 165.

(21) The market investigation was not conclusive as to whether the treatments for SCD should be sub-segmented by the severity of the disease/LoT, MoA, SCD sub-type or (MoD). However market participants also noted that pipeline treatments are still at the development stage and there is an intrinsic level of uncertainty in assessing their future characteristics and market positioning:

(a) Segmentation based on the severity of the disease/LoT: the responding key opinion leaders (KOLs) generally agree with the treatment algorithm as presented, namely that the three main categories of therapies for SCD as set out above in paragraph (20) can be distinguished based on the severity of the disease.[27] The majority of responding competitors also agree with such treatment categories.[28]

More specifically, the market investigation generally confirms that stem-cell transplants (and gene therapy in the future) do not constitute a direct substitute to the use of therapies for the prevention of VOCs, recognising that treatment for SCD is complex.[29] Stem-cell transplants are generally not available to all patients, are dependent on donors and are considered invasive treatments suitable for the most severe forms of SCD.[30] As for gene therapies, such therapies are in the development stage and there is an intrinsic level of uncertainty in assessing their future characteristics and market positioning.

With regard to the treatment and prevention of SCD complications, responding market participants note that some treatments, in particular pipeline drugs in development, may be developed for both the prevention of SCD complications, namely VOC, and the treatment of such complications.[31] For example, one competitor stated "[t]*here are many mechanisms of treatments being studied in SCD. Certain classes of therapies maybe both relevant to prevention and treatment of VOCs while others are not*."[32] In addition, one KOL explained that "[…] *in principle, all drugs that are used for the prevention of VOC are also able to avoid progression of a vasoocclusive event. Depending on the mechanism of action and on how fast a drug works, its effect may help acutely or not. E.g. I would expect that P-selectin inhibitors also in acute complications through immediate inhibition of p-selectin while hydroxyurea unfolds its effects over a period of some weeks or even months. Thus,* [hydroxyurea] *does not help acutely* [but other drugs may]".[33]

(b) Segmentation based on MoA: SCD drugs with different MoAs target different pathways, and, thus, may translate into distinct efficacy and safety

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27 Responses to question 2 of e-mail questionnaire to KOLs – SCD.

28 Responses to question 4 of questionnaire Q1 to competitors - SCD HS.

29 Responses to question 2(b) of e-mail questionnaire to KOLs – SCD and responses to question 4 of questionnaire Q5 to competitors - SCD HS.

30 Responses to question 5.1 of questionnaire Q1 to competitors - SCD HS; and non-confidential minutes of a call with a SCD KOL, dated 5 April 2022, 11:00AM CET.

31 Response to question 6 of questionnaire Q1 to competitors - SCD HS; and responses to question 2(c) of e-mail questionnaire to KOLs – SCD.

32 Response to question 6.1 of questionnaire Q1 to competitors - SCD HS.

33 Response to question 2(c) of e-mail questionnaire to KOLs – SCD.

profiles, which are the relevant factors for physicians when prescribing drugs.[34] However, at this stage, given the limited available data, the exact efficacy and safety profiles of various SCD pipeline drugs remain highly speculative and it is thus difficult to predict which drugs are likely to compete with one another.[35] As a consequence, the feedback received from market participants regarding the relevance of a segmentation of SCD treatments by MoA was not conclusive.[36]

(c) Segmentation by SCD sub-type: responding KOLs generally agree that all marketed and pipeline drugs are indicated for several or all types of SCD.[37] The market feedback does not support a segmentation of the market by SCD sub-type[38] and in particular noting that at the stage of clinical trials with limited data available, it would not be clear whether pipeline drugs would be more efficacious for a specific SCD sub-type.

(d) Segmentation based on MoD: as the Parties' drugs are differentiated by MoD, the Commission investigated if the market could be segmented based on the MoD of SCD drugs. The majority of responding competitors and KOLs indicated that pipeline drugs with a different MoD (usually oral or IV) are direct substitutes and compete with one another.[39] One competitor confirmed that "[i]*t is expected that marketed and new therapies will directly compete regardless of the mode of delivery. IV and oral therapies are currently on the market and competing with one another*".[40]

(22) In any event, for the purposes of this decision, the Commission concludes that the exact scope of the market for SCD 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 LoT, MoA, SCD sub-type or MoD).

(B) Geographical Market

(23) As regards the geographic market definition, the Commission has consistently considered the markets for pipeline drugs to be global or at least EEA-wide in scope.[41] The Notifying Party does 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 SCD.

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34 Responses to question 4(b) of e-mail questionnaire to KOLs - SCD.

35 Non confidential minutes of a call with a SCD KOL, dated 9 March 2022 (3:00PM CET), para. 15.

36 Responses to question 9 of questionnaire Q1 to competitors and Responses to question 4(a) of e-mail questionnaire to KOLs - SCD.

37 Responses to question 2(b) of e-mail questionnaire to KOLs – SCD.

38 Responses to questionnaire Q1 to competitors - SCD HS.

39 Responses to question 9.2 of questionnaire Q1 to competitors - SCD HS. Responses to question 4(b) of e-mail questionnaire to KOLs – SCD.

40 Responses to question 9.2.1 of questionnaire Q1 to competitors - SCD HS.

41 See cases M.8955 - *Takeda/Shire*, decision of 20.11.2018, recital 56; M.8401 – *J&J/Actelion*, decision of 9.7.2017, recital 31; M.7275 – *Novartis/GlaxoSmithKline oncology business*, recitals 33 and 72; M.7872 – *Novartis/GlaxoSmithKline*, recital 29; and M.7559 – *Pfizer/Hospira*, recital 30.

*4.1.3. The Parties' products*

(24) The Parties' pipeline drugs for the treatment of SCD are detailed in Table 1 below. The Parties have no marketed SCD products.

**Table 1 – Parties' pipeline products for SCD**

| Party | Product | Pipeline | MoA | (expected) EEA launch |
|---|---|---|---|---|
| CSL | CSL889 (Hemopexin) | Phase I | Hemopexin replacements | […] |
| Vifor Pharma | Vamifeport (VIT-2763) | Phase IIa | Oral inhibitor of ferroportin | […] |

*Source: Form CO, Table 8*

(25) Vifor Pharma's Vamifeport (VIT-2763), a small molecule, is a novel oral inhibitor of ferroportin investigated for the treatment of diseases with ineffective production of red blood cells and iron overload such as SCD.[42] Ferroportin is an enzyme essential for the body's transport of iron and it plays a key role in regulating iron uptake and distribution in the body. Vamifeport binds to ferroportin and blocks it to prevent excessive iron release into the blood. Vamifeport is currently in Phase IIa clinical stage for SCD, […].[43]

(26) CSL's CSL889 is a plasma-derived hemopexin, a naturally occurring protein produced in the body, the levels of which are decreased in patients with SCD. It is depleted in patients with SCD and other haemolytic disorders, permitting accumulation of toxic cell-free heme. CSL889 diminishes activation of the innate immune system by preventing heme binding to TLR4, which leads to decreased expression of adhesion molecules.[44] CSL889 is currently in Phase I clinical stage, being developed for the treatment of acute VOC, a severe and painful complication in SCD patients.[45] […].[46]

(27) Therefore, in the broader market for all SCD treatments, the Transaction gives rise to pipeline-to-pipeline overlaps between (i) Vifor Pharma's Vamifeport, on the one hand, and (ii) CSL's CSL889, on the other hand. No overlap arises if the market is segmented based on MoAs or on MoDs.

*4.1.4. Competitive Assessment*

(28) The Notifying Party argues that no competition concerns arise in SCD under any plausible market delineations given notably (i) the Parties' pipeline products are not close alternatives (ii) they have differentiated MoAs, and (iii) there are numerous existing or pipeline alternatives that exert competitive constraints on the Parties.[47]

(29) The market investigation confirmed 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

42 Form CO, para. 137.
43 Form CO, para. 140.
44 Form CO, para. 141.
45 Form CO, para. 189.
46 Form CO, para. 159
47 Form CO, paras. 167-179.

EEA Agreement resulting from the overlaps between the Parties' pipeline treatments for SCD.

(30) *First*, the Parties' SCD pipeline drugs are not considered by the market participants as particularly close alternatives, for a number of reasons. Based on current development strategies of the Parties,[48] whilst still at the early stages of development, the two pipeline drugs (Vamifeport and CSL889) are being developed for different phases of the SCD. This is also confirmed by market feedback, with one competitor explaining: "[t]*hese therapies are targeting different disease phases. Hemopexin would be used during acute VOCs to minimize VOC severity/duration or prevent acute VOC complications. Vamifeport would be used prophylactically to minimize the occurrence of VOCs. The efficacy and safety endpoints these therapies will be expected to establish must be different for their respective disease phases*."[49] Another competitor, whilst noting limited public clinical data to date, noted that "[the two Parties'] *products appear distinct in terms of potential usage, as while vamifeport is being trialed for the prevention of SCD complications, CSL889 is being trialed for the treatment of SCD complications. They also have different mechanisms of action*."[50]

(31) The Parties' pipeline drugs are also differentiated in terms of MoA and MoD. CSL is developing an IV drug, namely CSL889 (Hemopexin) and Vifor Pharma is developing an oral inhibitor of ferroportin (Vamifeport). Hemopexin is a heme scavenger which is depleted in SCD due to intravascular hemolysis. […].[51] By contrast, Vamifeport has a different mode of action, it is a ferroportin inhibitor that binds ferroportin, and blocks it to prevent excessive iron release into the blood. If developed, Vifor Pharma's drug would most likely be used to […], while CSL's drug would be used […]. In addition, the majority of responding competitors did not expect the SCD drugs currently being developed by CSL and Vifor Pharma to have similar efficacy and safety profiles.[52]

(32) *Second*, irrespective of whether the market is segmented further, there are numerous existing marketed drugs or pipeline alternatives (including in Phase II or Phase III clinical trials), as illustrated in Table 2 below. The market investigation feedback confirmed that the SCD pipeline is increasingly competitive and includes drugs that would be expected to compete closer with each Party's pipeline drugs than the Parties' pipeline drugs between them.[53] This is further supported by internal documents of the Parties.[54]

48 Internal documents, e.g. […].
49 Response to question 13.1 of questionnaire Q1 to competitors - SCD HS.
50 Response to question 13.1 of questionnaire Q1 to competitors - SCD HS.
51 Form CO, para. 173.
52 Responses to question 13 of questionnaire Q1 to competitors - SCD HS.
53 Response to question 12 of questionnaire Q1 to competitors - SCD HS.
54 Internal documents, for example, […].

| Table 2 – Main competitors in SCD (non-gene therapies)[55, 56] | | | | | |
|---|---|---|---|---|---|
| **Party** | **Product** | **Marketed / pipelines** | **MoA** | **MoD** | **(expected) EEA launch** |
| Nova Laboratories Ireland Limited | Hydroxyurea / Xrome / Siklos (hydroxy-carbamide) | Marketed | Ribonucleotide reductase inhibitors | Oral | Marketed |
| Emmaus Medical | Xyndari (L-glutamine) | Marketed (US only) | Antioxidants; Protein synthesis modulators | Oral | MAA withdrawn 2019 |
| Novartis | Adakveo (crizanlizumab) | Marketed | P selectin inhibitors | i.v. injection | Marketed |
| Global Blood Therapeutics | Oxbryta (Voxelotor) | Marketed | Hemoglobin oxygen-affinity modulator | Oral | Pending |
| Global Blood Therapeutics & Roche | Inclacumab[57] | Phase III | Fully Human Anti-P-Selectin Antibody | Quarterly infusion | >2024 |
| Forma Therapeutics | FT-402 (etavopivat) | Phase II/III | Multimodal. Pyruvate kinase stimulants | Oral | >2028 |
| Takeda | TAK-755 (rADAMTS13) | Phase I | ADAM protein replacements | i.v. injection | Not yet available |
| Fulcrum Therapeutics | FTX6058 | Phase I | • Globin stimulant<br>• EED inhibitor | Oral | Not yet available |
| Agios Pharmaceuticals | Mitapivat (AG-348 sulfate hydrate) | Phase II/III | Pyruvate kinase stimulants | Oral | Not yet available |
| EpiDestiny & Novo Nordisk | EPI01 (Decitabine, tetrahydrouridine) | Phase I | DNA methyl-transferase enzyme 1 and cytidine deaminase inhibitor | Oral | >2028 |
| Pfizer | PF-07209326 | Phase I | E-selection inhibitor | injectable | Not yet available |
| Global Blood Therapeutics[58] | GBT601 | Phase I | Hemoglobin oxygen-affinity modulator | Oral[59] | Not yet available |

*Source: Form CO, Table 8*

55 In the Form CO Table 8, the parties state that the gene therapy pipeline includes: one pipeline drug in Phase III clinical trial, six pipeline drugs in Phase I/II clinical trials, and one pipeline drug in Phase I. In addition, one competitor confirmed one more gene therapy drug in development (Phase I/II), see response to question 1.1 of questionnaire Q1 to competitors - SCD HS.

56 With respect to the potential LoT of individual pipeline drugs, this cannot be determined with certainty. The market investigation indicates that some drugs for the prevention of SCD complications could potentially also be used for the treatment of SCD complications and vice versa. See para. 21(a) above. Similarly, in terms of the SCD subtype, the differences in efficacy profile of the drug according to SCD subtype are usually not clear until Phase III and some SCD drugs may be used for several SCD subtypes. See Form CO, para. 152.

57 Two clinical trials, one is indicated for the prevention of VOC, and the other of Acute VOC re-admission prevention.

58 Response to question 1.1 of questionnaire Q1 to competitors - SCD HS.

59 This information is based on the information provided on www.clinicaltrials.gov.

(33) *Third*, the Parties' SCD pipeline drugs are generally not seen by market participants as being particularly promising.[60] Whilst noting early stages of the clinical trials, competitors generally ranked a number of other drugs in development higher (on a scale 1 to 5, 1 as the lowest) in terms of how promising the potential treatment in development for SCD is expected to be.[61] According to the KOLs that responded, there are dozens of promising compounds in Phase I and Phase II clinical trials for the management of SCD/prevention of VOC, such as Mitapivat developed by Agios and Etavopivat which is being developed by Forma Pharmaceuticals and just entered Phase III.[62]

(34) *Finally*, no respondents to the market investigation expressed concerns about the impact of the Transaction on the market for SCD treatments in the EEA, and more specifically the potential discontinuation, re-orientation or delay of the Parties' pipeline drugs.[63]

*4.1.5. Conclusion*

(35) 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 treatment of SCD (and its plausible sub-segmentations).

## 4.2. Hidradenitis suppurativa ("HS")

*4.2.1. Introduction*

(36) Hidradenitis suppurativa ("HS"), also known as acne inversa, is a chronic disabling autoimmune inflammatory skin disease characterized by recurrent, painful nodules, boils, and abscesses. It is a long-term skin condition that causes painful bumps under the skin in the hair roots near some of the sweat glands. Complications of HS can include: secondary infection, psychological effects and negative impact on quality-of-life, pyogenic granuloma, lymphoedema (female genital), squamous cell carcinoma (male anogenital) and anemia of chronic disease.[64]

(37) The symptoms of HS range from mild to severe. Disease severity and extent is measured by clinical and ultrasound assessment. The most commonly used tool to characterize the severity of HS, and the universally recommended tool across guidelines, is the Hurley staging system. The Hurley system describes three clinical stages:[65]

- Stage I (mild): solitary or multiple isolated abscess formation without sinus tracts (draining tunnels) or scarring.

60 Response to question 12 of questionnaire Q1 to competitors - SCD HS.
61 Response to question 12 of questionnaire Q1 to competitors - SCD HS.
62 Non-confidential minutes of a call with a SCD KOL, dated 9 March 2022 (3:00PM CET), para. 10.
63 Response to question 17 of questionnaire Q1 to competitors - SCD HS and Responses to question 6 of e-mail questionnaire to KOLs – SCD.
64 Form CO, para. 191.
65 Form CO, para. 210.

- Stage II (moderate): recurrent abscesses, single or multiple spaced lesions, with sinus tract formation.

- Stage III (severe): diffuse involvement of an area with multiple interconnected sinus tracts and abscesses.

(38) The treatment algorithm for HS in the EEA can generally be summarized as follows: (i) first-line treatments include topical treatments such as topical clindamycin, (ii) second-line treatments include conventional systemic treatments with antibiotics (e.g. Rifampicin) and retinoids (e.g. Acitretin), and (iii) third-line treatments include systemic treatments with biologics (e.g. adalimumab and its biosimilar) and possibly in the future, novel agents currently in development.[66] The third-line treatments with biologics are especially relevant for moderate-to-severe HS patients as *"sooner or later antibiotics fail and patients with moderate-to-severe HS will start on biologicals".*[67]

(39) In the EEA, the only approved drug for the treatment of moderate-to-severe HS is an anti-TNF-alpha monoclonal antibody, adalimumab (Humira). There are also 8 Humira biosimilars marketed in the EEA.[68] Humira or its biosimilars are usually prescribed as a first-line biologic, before other biologics that are used off-label for HS (e.g. Infliximab) and potentially novel agents.[69] Market participants confirm that Humira and its biosimilars are, mainly for cost reasons, likely to continue being prescribed as first-line biologics before prescribing other biologics or the potential new drugs that are expected to reach the market.[70]

(40) The KOLs and competitors confirmed that HS is a difficult disease to treat, and there is a high unmet need among HS patients.[71] This is notably explained by the fact that the development of the disease and the effective treatments vary significantly across patients, and therefore each patient often needs to try multiple different treatments before finding the one most effective for them. Moreover, patients often lose response to biologics that previously worked for them, further increasing the need for multiple alternative treatments.[72]

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66 See Responses to question 21 of questionnaire Q1 to competitors and Responses to question 2 of e-mail questionnaire to KOLs - HS. See also Non-confidential minutes of a call with HS KOL, dated 25.03.2021 (10:00 AM CET) and Non-confidential minutes of a call with HS KOL, dated 16. 03.2021 (10:00 AM CET).

67 Response to question 2 of e-mail questionnaire to KOLs – HS.

68 Form CO, para. 247. Biologics are medicines whose active substance is made by or derived from living organisms (e.g., immunological products and medicines derived from human blood and plasma). Biosimilars aim to mimic the original patented biopharmaceutical molecule with an identical therapeutic mechanism and clinical attributes and can be described as "generic" versions of originator biopharmaceuticals, but, unlike for small molecule generics, they are not exact copies of the originator drug.

69 See e.g. Non-confidential minutes of a call with HS KOL, dated 25.03.2022 (11:00 AM CET).

70 See responses to question 21.2 of questionnaire Q1 to competitors, and question 3 of email questionnaire to HS KOLs. See also Non-confidential minutes of a call with HS KOL, dated 25.03.2022 (11:00 AM CET).

71 See Non-confidential minutes of calls with HS KOL, dated 16 March 2022 (10:00 AM CET) and 14 March 2022 (12:30 PM CET), Non-confidential minutes of a call with HS competitor, dated 24 March 2022 (15:30 PM CET), and Responses to question 29 of questionnaire Q1 to competitors.

72 See e.g. Non-confidential minutes of a call with an HS KOL dated 16.03.2022 (10:00 AM CET).

*4.2.2. Market definition*

(A) Product market definition

(41) In the absence of Commission precedents for HS treatments, the Parties are of the view that a segmentation of the market for treatment of HS could be envisaged according to the Hurley stage of classification.[73] The Parties further argue that in any event, the exact scope of the product market can be left open because the Transaction will not raise competition concerns under any market segmentation.[74]

(42) Given that the starting point for all the developers of HS drugs is generally *either* moderate-to-severe HS *or* mild HS, with the Parties' drugs belonging to the former category, the starting point for defining the relevant product market is treatments for moderate-to-severe HS.

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

(a) *Segmentation based on the MoA:* moderate-to-severe HS 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.[75] That being said, at this stage, given the limited available data, the exact efficacy and safety profiles of various moderate-to-severe HS pipeline drugs remain highly speculative and it is thus difficult to predict which drugs are likely to compete with one another.[76] As a consequence, the feedback received from market participants regarding the relevance of a segmentation of the moderate-to-severe HS treatments by MoA was not conclusive.[77]

(b) *Segmentation based on the MoD:* The results of the market investigation were inconclusive on the question of whether the market for moderate-to-severe HS treatments should be further segmented based on MoD. On the one hand, all respondents recognised that efficacy and safety of the treatment (and not MoD) are the key parameters driving prescription decisions.[78] On the other hand, the majority of competitors and KOLs indicated that the MoD may play an important role in determining whether different types of moderate-to-severe HS treatment will compete more closely with each other,

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73 Form CO, para. 233.

74 Form CO, para. 233.

75 See e.g. Non-confidential minutes of a call with an HS competitor, dated 24.03.2022 (15:30 PM CET) and Non-confidential minutes of a call with a HS KOL, dated 25.03.2022 (11:00 AM CET).

76 See e.g. Non-confidential minutes of a call with a HS KOL, dated 25.03.2022 (11:00 AM CET).

77 Responses to question 22.1 of questionnaire Q1 to competitors and Responses to question 3 of email questionnaire to HS KOLs.

78 See Responses to question 22.2 of questionnaire Q1 to competitors and Responses to question 3 of email questionnaire to HS KOLs. For example, one KOL explained: *"Mode of delivery is secondary to efficacy, meaning if a drug is better than that is the reason it will be first- second or third-line rather than solely based on whether it has injection or oral delivery."*

as patients and physicians may often exhibit a preference for one MoD over another.[79] Market participants explain that in general in dermatology, oral treatments are used before subcutaneously or IV-administered treatments.

(44) In any event, for the purposes of this decision, the Commission concludes that the exact scope of the market for treatments of moderate-to-sever HS 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 definition (i.e. segmentations by MoA and by MoD).

(B) Geographic Market

(45) As regards the geographic market definition, the Commission has consistently considered the markets for pipeline drugs to be at least EEA-wide in scope.[80] The Notifying Party does not contest the above.[81] Nothing in the market investigation suggests that the Commission should depart from its previous practice in the present decision with respect to HS.

*4.2.3. The Parties' products*

(46) The Parties' pipeline drugs for the treatment of SCD are detailed in Table 3 below. The Parties have no marketed treatments for HS in the EEA.

**Table 3 – Parties' pipeline products for HS**

| Party | Product | Pipeline | MoA | MoD | (expected) EEA launch |
|---|---|---|---|---|---|
| CSL | CSL324 | Phase I | Granulocyte colony-stimulating factor receptor antagonist | IV | […] |
| CCXI/Vifor Pharma | avacopan | Phase II | Complement C5a receptor antagonist | Oral | […] |

*Source: Form CO, Table 9*

(47) Vifor Pharma has, under a collaboration agreement with ChemoCentryx, Inc. ("CCXI"), exclusive rights to the commercialisation of **avacopan (Tavneos)** in Europe (for all current and future indications).[82] Avacopan is a small-molecule drug, a complement 5a receptor (C5aR) antagonist that is notably being developed by CCXI for the treatment of patients with Hurley stage 3 severe HS. Avacopan is currently in Phase II clinical trials and, if successful, its launch in the EEA is expected in […]. Avacopan is administered orally.

(48) CSL is currently developing **CSL324**, a monoclonal antibody against GCSF (granulocyte colony-stimulating factor). CSL324 is in a Phase Ib clinical trial for the treatment of patients with moderate-to-severe HS and, even if successful, its launch

79 Responses to question 22.2 of questionnaire Q1 to competitors and Responses to question 3 of email questionnaire to HS KOLs.

80 See Section 3.2. above.

81 Form CO, para. 216.

82 Avacopan is currently being developed by CCXI for the treatment of orphan and rare renal diseases. The most advanced orphan and rare disease clinical program is in patients with anti-neutrophil cytoplasmic anti-antibody ("ANCA")-associated vasculitis ("AAV"). Under a collaboration agreement with Vifor Pharma, CCXI retains commercialization rights for avacopan in the US, while Vifor Pharma retains commercialization rights in the rest of the world. See Form CO, para. 70.

in the EEA is not expected before year […]. CSL324 is administered by way of subcutaneous injection.

(49) Therefore, in the market for treatments for moderate-to-severe HS, the Transaction gives rise to pipeline-to-pipeline overlaps between Vifor Pharma's avacopan and CSL's CSL324. No overlap arises if the market is segmented based on MoAs or on MoDs.

*4.2.4. Competitive Assessment*

(50) The Notifying Party argues that there is no risk of significant loss of innovation competition resulting from this pipeline-to-pipeline overlap, for the following reasons: (i) the Parties' pipeline products are not close alternatives, as they have distinct MoAs and MoDs, and have different target populations, (ii) the Parties face multiple competitor products at various stages of development, (iii) avacopan is under development by CCXI […],[83] and (iv) the Parties' products have different time to market.[84]

(51) 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 moderate-to-severe HS treatments.

(52) *First*, the Parties' HS pipeline drugs are not seen by market participants as particularly promising. On a scale from 1 (not promising: potentially poor efficacy/safety profile) to 5 (very promising: potentially very good efficacy/safety profile) market participants generally give the Parties' HS pipeline drugs a rating of 3.[85] Respondents also stressed that the Parties' products are early stage pipeline drugs, with highly uncertain prospects.[86]

(53) Moreover, all competitors expect promising late-stage pipeline drugs for HS to be launched in the EEA within the next 3 years.[87] One competitor for example states that *"There are various promising late-stage pipeline assets with promise, including anti-IL17s such as Novartis Cosentyx (secukinumab) and UCB's Bimzelx (bimekizumab)."*[88] KOLs share the view that late-stage pipeline drugs for HS are expected to be launched in the short/medium term, stating for example: *"Probably IL17A and IL17A/F antibodies will be quickly launched in Europe followed by IL36*

83 […]. See Form CO, para. 251.

84 Form CO, paras. 235-260.

85 See Responses to question 25 of questionnaire Q1 to competitors.

86 See e.g. Non-confidential minutes of a call with a HS KOL, dated 25 March 2022 (11:00 AM CET), and Responses to question 25 of questionnaire Q1 to competitors. A competitor for example states: *"Since most competitive drugs are still in clinical development, it is difficult to know how competitive the HS pipeline is and how promising pipeline drugs would be for the treatment of HS."*

87 Responses to question 24 of questionnaire Q1 to competitors.

88 Response to question 24 of questionnaire Q1 to competitors.

*antibodies and JAK inhibitors at a later time point."*[89] This is also confirmed in the Parties' internal documents.[90]

(54) <u>*Second,*</u> as illustrated in Table 4 below, the Parties more generally face a large number of alternative pipeline drugs for moderate-to-severe HS (at least 12 in total), many of which are further along the stages of development than the Parties' pipeline drugs (including 3 pipeline drugs in Phase III clinical trial).

(55) In this respect, market participants generally consider that the HS pipeline is competitive, including drugs that are more advanced (and more promising) than those of the Parties.[91] Competitors for instance state the following: *"*[m]*ore than 15 molecules including different modes of action are currently under development,", "Competitive pipeline with 2-3 in Phase 3, over 15 in Phase 2 and several in Phase 1. All kinds of different MoAs."* and *"*[m]*ultiple new assets are coming to market during a similar timeframe and for similar patient populations".*[92] The KOLs views also support the views that there are treatments in the pipeline, some of which are promising.[93] A KOL for example explained: *"there are dozens of other drugs in the pipeline, including pipeline drugs which could compete very closely with CSL324 and Avacopan (more closely than they would with each other)."*[94] In addition, there is one marketed biological drug available, for which several biosimilars exist, and other biological drugs that are used off-label for HS (e.g. Infliximab).[95]

**Table 4 – Main competitors in HS[96]**

| Party | Product | Marketed / pipelines | MoA | MoD | (expected) EEA launch |
|---|---|---|---|---|---|
| AbbVie | Humira (adalimumab) | Marketed | Anti-TNF | Sub-cutaneous (SC) | Marketed |
| Novartis | Cosentyx (secukinumab) | Phase III | Human monoclonal immunoglobulin G1 kappa antibody that selectively binds to IL-17A | SC fixed-dose injections | 2023 |
| UCB SA | Bimzelx (bimekizumab) | Phase III | humanized anti-IL17A, anti-IL-17F, and anti-IL17AF monoclonal antibody | SC fixed-dose injections | 2023 |
| InflaRx N.V. | Vilobelimab (IFX-1) | Phase III | Complement C5a | IV biologic | 2026 |

89 Responses to question 4 of email questionnaire to KOLs – HS.

90 See e.g. Vifor Pharma's internal document named *[...]* (Section 5 of the Form CO).

91 See Responses to question 23 of questionnaire Q1 to competitors. On a scale from 1 (not competitive: very few pipeline drugs with likely poor efficacy/safety profiles) to 5 (very competitive: many pipeline drugs with promising efficacy/safety profiles) the competitors' on average estimate the competitiveness of the HS pipeline as 4.

92 Responses to question 23.1 of questionnaire Q1 to competitors.

93 Responses to question 4 of email questionnaire to KOLs – HS.

94 Non-confidential minutes of a call with an HS KOL, dated 16 March 2022 (10:00 AM CET).

95 See Non-confidential minutes of a call with a KOL dated 16 March 2022 (10:00 AM CET).

96 In addition to Table 4, which is based on the Form CO, the market investigation identified an additional pipeline drugs for HS; that is Lutikizumab (ABT-981), an IL-36 inhibitor, developed by AbbVie and currently in Phase II clinical stage. See Response to question 28 of questionnaire Q1 to competitors.

| Table 4 – Main competitors in HS[96] | | | | | |
|---|---|---|---|---|---|
| **Party** | **Product** | **Marketed / pipelines** | **MoA** | **MoD** | **(expected) EEA launch** |
| | | | inhibitors | | |
| Boehringer Ingelheim | Spesolimab | Phase II | IL-36R inhibitor | SC | 2026 |
| AbbVie | Risankizumab (Skyrizi®)[97] | Phase II | IL-23 antagonist | SC prefiled syringe | 2026 |
| Eli Lylli | LY-3041658 | Phase II | CXCR1/2 Inhibitor | i.v. | 2026 |
| Incyte | INCB-054707 | Phase II | JAK1 Inhibitor | oral | 2026 |
| AbbVie | Upadacitinib | Phase II | JAK1 Inhibitor | oral | 2026 |
| Pfizer | PF-06650833 PF-06826647 Brepocitinib | Phase II | Kinase Inhibitors (JAK, TYK, IRAK) | oral | >2026 |
| Novartis | Iscalimab LYS006 MAS825 | Phase II | Multiple MoA | SC | >2026 |
| Janssen | Bermekimab | Phase II | IL-1 inhibitor | SC | 2027 |
| AnaptysBio | Imsidolimab | Phase II | IL-36R inhibitor | i.v. | 2027 |
| Azora Therapeutics | AT-193 | Phase I | Aryl hydrocarbon hydroxylase inhibitors; Aryl hydrocarbon receptor agonists | Topical | >2028 |

*Source: Form CO, Table 9*

(56) *Third,* the feedback received by the Commission about the differentiation between the Parties' pipeline drugs was inconclusive. Indeed, while respondents agree that different MoAs translate into different efficacy and safety profiles, they generally emphasize the fact that, given the early stage of development of the Parties' pipeline drugs and the limited available data, it is too early to assess the closeness of competition between these pipeline drugs.[98]

(57) However, KOLs and competitors were able to identify other pipeline drugs that are likely to compete more closely with each of the Parties' drugs than they do with each other.[99] One KOL for example explains:[100] *"*[t]*he group of pipeline drugs with the MoA most similar to CSL324 are antibodies that inhibit the function of the interleukin-36-receptor (IL-36R), which currently include Imsidolimab and Spesolimab. On the other hand, the closest competitor to Avacopan is the monoclonal antibody Vilobelimab with a MoA almost identical to that of Avacopan targeting C5a receptors."* The fact that avacopan and CSL324 are unlikely to compete closely is also reflected in the Parties' internal documents.[101]

(58) *Fourth,* market participants consider that, given the complexity of treatment of the HS and the need for patients to try several treatments, the combined entity would have an incentive – as other pharmaceutical companies do – to pursue in parallel the

97 The market investigation responses indicate that Risankizumab is, contrary to the Form CO, not being developed for HS. See Responses to question 28 of questionnaire Q1 to competitors.

98 Responses to questions 26 and 27 of questionnaire Q1 to competitors.

99 Responses to question 28 of questionnaire Q1 to competitors, Responses to question 5 of email questionnaire to KOLs – HS, Non-confidential minutes of a call with an HS KOL, dated 16 March 2022 (10:00 AM CET).

100 Non-confidential minutes of a call with an HS KOL, dated 16 March 2022 (10:00 AM CET).

101 See e.g. Vifor Pharma's internal document named *[...]*.

development of two drugs for the treatment of HS.[102] One market participant for instance states: *"pharmaceutical companies are likely to have an incentive to develop more than one drug for HS."*[103] and a KOL: *"*[p]*ost-Transaction the new entity would therefore highly likely retain the incentive to continue developing both CSL324 and Avacopan for HS."*[104]

(59) *Finally*, no market participants expressed concerns about the impact of the Transaction on the market for (moderate-to-severe) HS in the EEA and the potential discontinuation, re-orientation and delay of the Parties' pipeline drugs.[105]

*4.2.5. Conclusion*

(60) 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 treatments of moderate-to-severe HS (and its plausible segmentations).

## 5. CONCLUSION

(61) For the above reasons, the European 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*

[102] See Responses to question 31 of questionnaire Q1 to competitors, Responses to question 6 of email questionnaire to KOLs – HS, and Non-confidential minutes of a call with HS KOLs, dated 16 March 2022 (10:00 AM CET) and 25 March 2022 (11:00 AM CET).

[103] Non-confidential minutes of a call with an HS market participant, dated 24 March 2022 (15:30 PM CET).

[104] Non-confidential minutes of a call with HS KOLs, dated 16 March 2022 (10:00 AM CET).

[105] See Responses to question 32 of Q1 questionnaire to competitors and Responses to question 6 of email questionnaire to HS KOLs.