EUROPEAN COMMISSION

DG Competition

Case M.9461 – ABBVIE/ALLERGAN

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Decision on the implementation of the commitments - Purchaser approval
Date:21.02.2020

EUROPEAN COMMISSION

Brussels, 21.2.2020
C(2020) 1161 final

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

To the notifying parties

Dear Sir/Madam,

Subject: Case M.9461 – ABBVIE / ALLERGAN
Approval of AstraZeneca plc as purchaser of Brazikumab Divestment Business following your letter of 31 January 2020 and the Trustee's opinion of 20 February 2020

1. FACTS AND PROCEDURE

(1) By decision of 10 January 2020 ("the Decision") based on Article 6(1)(b) in connection with Article 6(2) of Council Regulation No 139/2004,[1] the Commission declared the operation by which AbbVie Inc. ("AbbVie", United States) acquires, within the meaning of Article 3(1)(b) of the Merger Regulation, control of the whole of Allergan plc ("Allergan", Ireland) (the "Transaction") compatible with the internal market and the EEA Agreement. The Decision is subject to the conditions and obligations laid down in the commitments annexed to the Decision (the "Commitments"). AbbVie and Allergan are hereinafter collectively referred to as the "Parties".

(2) In particular, the Commitments consist of a full divestiture of the development, manufacturing and marketing rights related to Allergan's IL-23 inhibitor pipeline programme (brazikumab) at worldwide level (the "Brazikumab Divestment

1 OJ L 24, 29.1.2004, p. 1 (the "Merger Regulation")

Commission européenne, DG COMP MERGER REGISTRY, 1049 Bruxelles, BELGIQUE
Europese Commissie, DG COMP MERGER REGISTRY, 1049 Brussel, BELGIË

Tel: +32 229-91111. Fax: +32 229-64301. E-mail: COMP-MERGER-REGISTRY@ec.europa.eu.

Business") to a suitable purchaser. Brazikumab is currently being developed by Allergan for the treatment of ulcerative colitis ("UC") and Crohn's disease ("CD").

(3) By letter of 31 January 2020, the Parties proposed AstraZeneca plc ("AstraZeneca") for approval by the Commission as purchaser of the Brazikumab Divestment Business and submitted the License Termination Agreement (the "Proposed Agreement")[2] entered into between Allergan[3] and AstraZeneca[4] on 25 January 2020.[5]

(4) On 20 February 2020, Monitoring Trustee Partners (the "Trustee") submitted an assessment of AstraZeneca's suitability as a purchaser (the "Reasoned Opinion") and, in particular, indicated that AstraZeneca fulfils the criteria of the purchaser requirements in Section D of the Commitments attached to the Decision (the "Purchaser Criteria"). In this assessment, the Trustee also indicated that, on the basis of the Proposed Agreement, the Brazikumab Divestment Business would be sold in a manner consistent with the Commitments.

2. ASSESSMENT OF THE PROPOSAL

(5) As set out in Section D of the Commitments, in order to be approved by the Commission, the purchaser of the Brazikumab Divestment Business must fulfil the following criteria:

a. the purchaser shall be independent of and unconnected to the Parties and their affiliated undertakings (this being assessed having regard to the situation following the divestiture);

b. the purchaser shall have the financial resources, proven expertise and incentive to maintain and develop the Brazikumab Divestment Business as a viable and active competitive force in competition with the Parties and other competitors. The purchaser should in particular have the incentive to pursue the clinical trials for the EEA approval of brazikumab as they are designed as of the date of the Decision;

c. the acquisition of the Brazikumab Divestment Business by the purchaser must neither be likely to create, in light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed. In particular, the purchaser must reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Brazikumab Divestment Business;

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2 In 2012, AstraZeneca entered into a collaboration agreement with Amgen to jointly develop, manufacture and commercialise various products, including brazikumab. In April 2015, Amgen notified AstraZeneca of its decision to cease its participation in the brazikumab programme. In October 2016, AstraZeneca licensed the right to develop and commercialise brazikumab to Allergan (the "License Agreement"). The divestment has therefore been structured as the termination of that license […].

3 Through its subsidiaries […].

4 Through its subsidiary […].

5 […]

d. the purchaser shall have expertise and experience in the clinical development of medicinal products for EEA approval;

e. the purchaser shall have expertise and experience in having relevant interactions with relevant EEA-wide and national bodies that decide on approval of medicinal products in the EEA;

f. the purchaser shall have experience in the pricing and reimbursement, marketing, promotion, sales and distribution of medicinal products in the EEA, or the ability to develop such capabilities for the marketing of brazikumab.

2.1. Description of the purchaser

(6) AstraZeneca is a global pharmaceutical company headquartered in the United Kingdom. AstraZeneca is engaged in the development and commercialisation of medicines primarily in three therapeutic areas: (i) oncology, (ii) cardiovascular, renal and metabolism, and (iii) respiratory, inflammation and autoimmunity.

(7) AstraZeneca employs more than 60 000 employees globally and markets medicines in more than 100 countries. In 2018, it achieved more than 20% of its turnover (equivalent to USD 4.5 billion) in Europe.

(8) AstraZeneca is a publicly traded company. The principal exchanges in which it is listed are the London Stock Exchange, the Nasdaq Stockholm and the New York Stock Exchange.

2.2. Independence from the Parties

(9) No shareholder holds more than 10% in AstraZeneca’s stock, on the one hand, and either AbbVie’s stock or Allergan’s stock, on the other hand.

(10) Furthermore, there are no links between the members of the AbbVie or Allergan board of directors, on the one hand, and AstraZeneca, on the other hand.

(11) Finally, the existing commercial relationships between AstraZeneca and the Parties are standard collaboration agreements that are common practice in the pharmaceutical industry. These agreements are not material (i.e. limited in financial scope and/or in terms of remaining duration of the contracts) and have been concluded at arm's length.

(12) In light of the above, the Commission considers that AstraZeneca is independent of and unconnected to the Parties.

2.3. Financial resources, proven expertise and incentive to maintain and develop the Brazikumab Divestment Business as a viable and active competitor

(13) Firstly, as regards AstraZeneca's financial resources, the Commission notes that AstraZeneca is a global pharmaceutical company which generated total revenues of USD 22.1 billion in 2018. The company is expected to generate an EBITDA of over USD 6.6 billion in 2019, performance which the company expects to further increase in the next couple of years. Furthermore, AstraZeneca’s long term debt is rated as

investment grade.[6] In its Reasoned Opinion, the Trustee concludes that AstraZeneca has multiple significant sources to fund the acquisition and subsequent development of the Brazikumab Divestment Business.

(14) Allergan will fund the development costs of brazikumab, contingent on AstraZeneca certifying that it continues developing brazikumab for the treatment of UC and CD […]. The funding contributed by Allergan will increase AstraZeneca's resources to develop brazikumab, therefore financially de-risking the development of the programme at the heart of the Brazikumab Divestment Business.

(15) Secondly, as regards AstraZeneca's proven expertise, the company is active in more than 100 countries worldwide. It has an established commercialisation infrastructure in Europe and distributes its medicines (directly or indirectly) in virtually all EEA countries. AstraZeneca also has a vast experience in the development of medicines, including biological medicinal products, as evidenced by its large portfolio of pipeline drugs.

(16) Thirdly, as regards the incentive to develop brazikumab, the Trustee noted in its Reasoned Opinion that AstraZeneca's integration plans, which are based on reasonable projections and quite conservative assumptions, show a solid net present value and internal rate of return of the Brazikumab Divestment Business.

(17) The Commission also notes that under the terms of the License Agreement,[7] AstraZeneca was entitled to […]. By terminating the License Agreement, AstraZeneca will […], demonstrating its seriousness about developing brazikumab itself.[8]

(18) Furthermore, the acquisition of the Brazikumab Divestment Business is in line with AstraZeneca's business strategy[9] […].

(19) In light of the above, the Commission considers that AstraZeneca has the financial resources, proven expertise and incentive to maintain and develop the Brazikumab Divestment Business as a viable and active competitive force in competition with the Parties and their competitors on the market.

2.4. Absence of prima facie competition concerns and implementation risks

(20) AstraZeneca does not have any products (marketed or in the pipeline) for the treatment of UC or CD (and, in particular, no IL-23 inhibitors).

(21) In addition, the acquisition of the Brazikumab Divestment Business by AstraZeneca will not trigger merger control filings in the EEA or in other jurisdictions.

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6 Long term credit rating BBB+ by Standard and Poor's and A3 by Moody's.

7 As explained in footnote 2 above, in October 2016, AstraZeneca licensed the right to develop and commercialise brazikumab to Allergan.

8 In addition to […].

9 […]

(22) In light of the above, the Commission considers that AstraZeneca is neither likely to create *prima facie* competition concerns, nor to give rise to a risk that the implementation of the Commitments will be delayed.

2.5. Expertise and experience in the clinical development of medicinal products for EEA approval

(23) AstraZeneca has three main R&D sites, two of which are located in Europe. The company has more than 8 900 employees in R&D and has made significant annual investments in recent years.

(24) AstraZeneca is currently developing several medicinal products, including programs in phase III clinical trials or registration preparation. In particular, AstraZeneca currently has ongoing clinical trials for several biological medicinal products covering various indications. […].

(25) Furthermore, AstraZeneca has relevant expertise in the development of brazikumab, having originally licensed the rights to develop brazikumab to Allergan in 2016. […].

(26) In light of the above, the Commission concludes that AstraZeneca has established capabilities in the clinical development of medicinal products for EEA approval.

2.6. Expertise and experience in having relevant interactions with relevant EEA-wide and national bodies that decide on approval of medicinal products in the EEA

(27) AstraZeneca has global specialist regulatory teams for each of its main therapy areas. The regulatory team for its […] business unit (of which brazikumab will be part) comprises over […] employees; […] of these being based in the EEA. […].

(28) […].

(29) In 2019, AstraZeneca's regulatory team secured a total of six major regulatory approvals across its oncology and biopharmaceuticals portfolio in the EEA and eight regulatory approvals in 2018. Examples of regulatory approvals for new molecular entities secured by AstraZeneca over the last five years include Lokelma, approved for hyperkalaemia in March 2018, Fasenra (biological medicinal product), approved for severe asthma in January 2018, or Bevespi Aerosphere, approved for chronic obstructive pulmonary disease in December 2018.

(30) In light of the above, the Commission concludes that AstraZeneca has established capabilities in having interactions with relevant EEA-wide and national bodies that decide on approval of medicinal products in the EEA.

2.7. Experience in the pricing and reimbursement, marketing, promotion, sales and distribution of medicinal products in the EEA, or the ability to develop such capabilities for the marketing of brazikumab

(31) AstraZeneca has an established commercialisation infrastructure in Europe, which accounts for more than 20% of its global sales.

(32) AstraZeneca has a significant presence in all major EEA markets, with more than […] field-based employees located across the EEA. AstraZeneca has been

successfully commercializing an extensive portfolio of pharmaceuticals, including biological medicinal products, across the EEA.

(33) Between January 2018 and November 2019, AstraZeneca successfully launched 14 medicines across multiple therapeutic areas in the EEA. It also obtained positive recent reimbursement decisions in many EEA territories for a large number of products.

(34) In light of the above, the Commission concludes that AstraZeneca has established capabilities concerning the pricing and reimbursement, marketing, promotion, sales and distribution of medicinal products in the EEA.

2.8. Conclusion

(35) In view of the above, the Commission considers that AstraZeneca meets the Purchaser Criteria.

3. ASSESSMENT OF THE PROPOSED AGREEMENT

(36) The Proposed Agreement was signed on 25 January 2020 between Allergan and AstraZeneca.

(37) The Trustee provided an assessment of the Proposed Agreement, and confirmed that it fulfils the condition of the Commitments to transfer the Brazikumab Divestment Business to a suitable purchaser in a manner consistent with the Commitments. However, the Reasoned Opinion highlighted in particular the following main variations compared to the Commitments:

a. *Personnel*. AstraZeneca […].

b. *Extension of the transitional period*. The Parties have agreed […].

(38) The Commission considers that these variations are not liable to impact the viability and competitiveness of the Brazikumab Divestment Business for the following reasons:

a. *Personnel*. AstraZeneca has indicated to the Trustee that […].

b. *Extension of the transitional period*. The Trustee notes that […]. The Trustee therefore concludes that this deviation impacts neither AstraZeneca's incentives not its independence.

(39) Based on the above, the Commission considers that AstraZeneca has the necessary workforce to ensure the development of brazikumab and concludes that the […][10] […][11] will not be detrimental to the viability and competitiveness of the Brazikumab

10 Pursuant to Clause 6 of the Commitments, the transfer of the Key Personnel to Allergan is subject to their consent.

11 Pursuant to Clause 6 of the Commitments, AstraZeneca will have the opportunity to interview the Personnel and to offer an employment contract to any Personnel over a period of […] after the transfer of the legal title to the Brazikumab Divestment Business to AstraZeneca.

Divestment Business.[12] This is particularly the case as (i) the Key Personnel and Personnel should remain with Allergan during the transitional period, and (ii) AstraZeneca retains the right to offer employment contracts to any of the Key Personnel and Personnel until […]. Moreover, the Commission concludes that […] work to the benefit of AstraZeneca and does not affect the viability and competitiveness of the Brazikumab Divestment Business.

(40) The Commission concludes that the Brazikumab Divestment Business is being sold in a manner consistent with the Commitments.

4. CONCLUSION

(41) On the basis of the above assessment, the Commission approves AstraZeneca as a suitable purchaser.

(42) On the basis of the Proposed Agreement, the Commission further concludes that the Brazikumab Divestment Business is being sold in a manner consistent with the Commitments.

(43) This decision only constitutes approval of the proposed purchaser identified herein and of the Proposed Agreement. This decision does not constitute a confirmation that the Parties have complied with the Commitments.

(44) This decision is based on Section D of the Commitments attached to the Commission Decision of 10 January 2020.

For the Commission

(Signed)
Olivier GUERSENT
Director-General

12 Pursuant to Clause 20 of the Commitments: "*The Commission may approve the sale of the Divestment Business without one or more Assets, or parts of the Key Personnel, or by substituting one or more Assets or parts of the Key Personnel with one or more different assets or different personnel, if this does not affect the viability and competitiveness of the Divestment Business after the sale, taking account of the proposed purchaser*."