HKEX LISTING DECISION

HKEx-LD135-2022 (May 2022)

[Streamlined and incorporated into the Guide for New Listing Applicants in January 2024]

Summary	
Party	Company A – a biotech Main Board listing applicant
Issue	Whether Product X (being one of Company A's Core Products) which completed the Phase 1 clinical trials under the Therapeutic Goods Administration ("**TGA**") in Australia and subsequently obtained approval from both the European Medicines Agency ("**EMA**") and the National Medical Products Administration ("**NMPA**") to commence the global pivotal Phase 2/3 clinical trial satisfies the relevant core product eligibility requirements under GL92-18 and Chapter 18A of the Main Board Rules
Listing Rules	Main Board Rule 18A.01
Related Publications	Guidance Letter HKEX-GL92-18 ("**GL92-18**") FAQ No. 036-2018 of FAQs-Main Board Listing Rules-Chapter 18A
Decision	The Exchange determined that Product X meets the eligibility requirements of Core Product under paragraph 3.3(b)(i) of GL92-18

FACTS

1. Company A is a biotech listing applicant under Chapter 18A of the Main Board Rules (the "**Proposed Listing**"). It has identified Product X (a biologic product) as one of its Core Products for the purpose of the Proposed Listing.

2. Company A conducted the Phase 1 clinical trials on Product X in Australia ("**Australian Trial**"). Subsequently, Company A decided to conduct the global pivotal Phase 2/3 clinical trials on Product X in multi-centers, including the EU and China markets. Prior to the completion of the Australian Trial, Company A requested a rapid scientific advice ("**RSA**") from the EMA and initiated the investigational new drug ("**IND**") application with the NMPA.

3. Company A submitted the clinical trial designs for the Australian Trial and the global pivotal Phase 2/3 clinical trials on Product X and presented the clinical data from the Australian Trial to both the EMA and the NMPA. After reviewing the materials on the clinical data of the Australian Trial and protocol of the global pivotal Phase 2/3 clinical trials, both the EMA and the NMPA confirmed their acknowledgement and acceptance of the results of the Australian Trial and that they had no objection for Company A to progress to the pivotal global Phase 2/3 clinical trials on Product X.

4. Subsequently, Company A had obtained approval from both the EMA and the NMPA to commence the global pivotal Phase 2/3 clinical trials on Product X.

ISSUE RAISED FOR CONSIDERATION

5. Whether Product X, which completed the Australian Trial and subsequently obtained approval from both the EMA and the NMPA to commence the global pivotal Phase 2/3 clinical trials, satisfies the relevant Core Product eligibility requirements under GL92-18 and Chapter 18A of the Main Board Rules?

APPLICABLE RULES AND GUIDANCE

6. Under Main Board Rule 18A.01, each of the US Food and Drug Administration ("**FDA**"), the NMPA and the EMA are recognized as a **Competent Authority**. It further provides that the Exchange may, at its discretion, recognize another national or supranational authority as a Competent Authority in individual cases.

7. Paragraph 3.3(b)(i) of GL92-18 states that in the case of a Core Product that is a biologic product, the applicant must demonstrate that it has completed Phase I clinical trials (being clinical trials on human subjects categorized as Phase I clinical trials by the FDA) and the relevant Competent Authority has no objection for it to commence Phase II (or later) clinical trials.

8. FAQ No. 036-2018 further states that the Exchange may accept clinical trials of a Biotech Product that are conducted by authorities other than the Competent Authorities under Chapter 18A of the Main Board Rules. The assessment will be conducted on a case by case basis with reference to:

   (i) whether such authority can be regarded or authorized as a comparable authority as to the Competent Authorities;

   (ii) whether the approval process of that authority in relation to the Biotech Product in question is comparable to the process and expertise of a Competent Authority in terms of assessing the robustness of a Biotech Product; and

(iii) whether there are precedent cases and the basis of other Biotech Products seeking such comparable authority for guidance or reference.

ANALYSIS

9. The Exchange took into account all relevant facts and circumstances when assessing whether or not the Australian Trial (which is not a clinical trial regulated by a Competent Authority recognized under Chapter 18A of the Main Board Rules) satisfies the relevant Core Product eligibility requirements under GL92-18 and Chapter 18A of the Main Board Rules.

10. In this case, given both the EMA and the NMPA (both being Competent Authorities under Chapter 18A of the Main Board Rules) have (i) reviewed and taken into account the clinical trial design and data of the Australian Trial in granting their approval for Company A to commence the global pivotal Phase 2/3 clinical trials on Product X and (ii) confirmed their acknowledgement and acceptance of the results of the Australian Trial and that they had no objection for Company A to progress to the pivotal global Phase 2/3 clinical trials on Product X based on the clinical results of the Australian Trial, the Exchange considered that the Australian Trial meets the requirement under paragraph 3.3(b)(i) of GL92-18.

DECISION

11. Based on the specific facts and circumstances, the Exchange accepted that Product X meets the eligibility requirements of a Core Product under paragraph 3.3(b)(i) of GL92-18.

12. Such conclusion is specifically related to Product X and should not be construed as (i) a clinical trial conducted in Australia being generally accepted as a trial regulated by a Competent Authority; and/or (ii) the TGA being generally accepted as a Competent Authority under Chapter 18A of the Main Board Rules.