Ascletis Pharma Inc.
歌禮製藥有限公司
(incorporated in the Cayman Islands with limited liability)
(Stock Code: 1672)

SUPPLEMENTAL ANNOUNCEMENT ON PROVISION FOR IMPAIRMENT OF ASSETS FOR 2022; BUSINESS UPDATES; AND CHANGE IN USE OF PROCEEDS

This announcement is made by Ascletis Pharma Inc. (the "**Company**", together with its subsidiaries, the "**Group**") pursuant to Rule 13.09 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "**Listing Rules**") and the Inside Information Provisions (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Cap.571 of the Laws of Hong Kong).

Reference is made to (i) the "Change in Use of Proceeds From the Global Offering" announcement of the Company dated November 18, 2020 (the "**Previous UoP Announcement**"); (ii) the 2022 annual results announcement published by the Company on March 20, 2023 (the "**2022 Annual Results Announcement**"); and (iii) the 2022 annual report published by the Company on April 25, 2023 (the "**2022 Annual Report**"). Unless the context requires otherwise, capitalized terms used herein shall bear the same meanings as defined in the Previous UoP Announcement, the 2022 Annual Results Announcement and the 2022 Annual Report.

DETAILS OF PROVISION FOR ASSETS IMPAIRMENTS

With reference to the 2022 Annual Results Announcement, the Company recorded provision for assets impairment of RMB103.3 million in 2022. The asset items for which impairment was provided by the Company included inventories and intangible assets relating to the HCV products of the Group.

In 2022, the Company made provision for inventories impairment of RMB48.6 million considering the following factors which affected the sales of relevant HCV products: (i) the changes of the competitive landscape of medical insurance on the HCV market, which resulted in relatively lower gross profit margin for HCV products; (ii) the impact of COVID-19 pandemic, which reduced the number of diagnosed HCV patients and further limited the sales of the Company's HCV products; and (iii) the publication of the "Guidelines for the Prevention and Treatment of Hepatitis C" (2022 Edition) (the "**HCV Guidelines**") in late 2022, the suggestions in which might limit the future clinical application of the Company's HCV products.

Since there was impairment indication identified related to intangible assets of Presidio, the Company performed an impairment test on the recoverable amount of Presidio. For the year ended December 31, 2022, the Company recognized an impairment of intangible assets of Presidio by approximately RMB54.7 million based on the result of impairment test with reference to valuation report prepared by an independent professional valuer.

The table below illustrates the breakdown of assets impairment provision made in 2022.

	For the year ended December 31, 2022
	(RMB'000)
Impairment on inventories	48,553
Impairment of intangible assets	54,748
	103,301

The Company's provisions for impairment of assets reflected its assets position and operating conditions for the year ended December 31, 2022 in an objective and fair manner, and the Board of Directors agreed the provisions for impairment of assets.

BUSINESS UPDATES

Adjustment of Marketing and Promotion Strategies for HCV Products

As disclosed in the 2022 Annual Report, the Company decided not to continue to proactively market and promote its HCV products due to a series of factors. The following sets forth the main factors attributed to such adjustments:

- Fierce pricing competition among the market participants (including the Company) as a result of negotiations for joining in the National Reimbursement Drug List;
- Suggestions in the latest HCV Guidelines, which are considered unfavorable to the future clinical application of the Company's HCV products; and
- Continuing impact from the COVID-19 pandemic, which resulted in significant decrease in the number of clinically diagnosed HCV cases and further decreased the number of HCV patients admitted to treatment.

Termination of Research and Development ("R&D") for ASC06

ASC06 is a drug candidate the Company used to develop to treat liver cancer. The Company aimed to develop ASC06 as the first systematically delivered therapeutic drug to treat liver cancer by using RNA interference ("**RNAi**") delivery technology back in 2018. However, the RNAi delivery technology of ASC06 was an early generation and had become outdated due to the recent significant advancements in RNAi delivery technologies developed by many companies in this field. As a result, ASC06 might not be able to demonstrate a competitive edge in the relevant market as the Company had planned before. The Company plans to develop a PD-L1 oral small molecule inhibitor (ASC61) to treat liver cancer, which might have greater market potential in replacement of ASC06, and decides to reallocate the resources original used in R&D of ASC06 to such drug candidate. As such, the Company decided not to continue with the R&D of ASC06 in 2020. As of the date of this announcement, ASC06 has completed Phase I clinical trial in the Unites States by its licensor, Alnylam Pharmaceuticals, Inc. but had not sought IND approval in China. Accordingly, no clinical data with respect to ASC06 has been generated in China.

Termination of R&D for ASC09

ASC09 is a HIV protease inhibitor drug candidate the Company used to develop to treat HIV type-1 infections. However, alternative products to treat the same indication (i.e. HIV type-1 infections) such as HIV integrase inhibitor drugs have been launched and marketed in China, the major jurisdiction where the Company was licensed to commercialize ASC09, and are becoming the mainstream for treatment of HIV type-1 infections. Although ASC09 is the best-in-class HIV protease inhibitor, integrase inhibitor as a class have demonstrated better efficacy, safety and resistance profile than protease inhibitors as a class. As a result, ASC09 might not have competitive edges compared with such alternative products. The Company decided to terminate the R&D of ASC09 and is currently in the process of such termination. The licensor, Janssen Sciences Ireland UC (formerly Janssen R&D Ireland), had previously completed a Phase IIa trial in Europe with TMC310911 (ASC09) before the molecule was licensed to the Company. As of the date of this announcement, the Company has obtained an IND approval in China for ASC09F (fixed-dose combination of ASC09 and ritonavir) and completed the Phase I study of ASC09F in China.

LATEST MAJOR PRODUCTS PIPELINE AND R&D STATUS

Due to the fluctuant market dynamics and fierce competition faced by certain products as mentioned above, the Company plans to reallocate resources to the R&D of other pipeline products and new products to capture future market opportunities. Despite the above-mentioned termination of proactive promotion of its HCV products and the R&D for ASC06 and ASC09, the Company has been dedicated to researching and developing other pipeline products, especially in the anti-viral field, where the Company can best leverage its rich expertise and resource obtained during the proven track record. The following diagrams set forth the latest status of the Company's major pipeline products as of the date of this announcement:

Product (Modality)	Target	Indication	Commercial Rights	Pre-IND	IND	Phase I	Phase II	Phase III	NDA	Marketed
ASC22 (Subcutaneous mAb)	PD-L1	CHB functional cure	Global[1]							
ASC22 (Subcutaneous mAb)	PD-L1	HIV functional cure	Global[1]							
ASC22 (Subcutaneous mAb) +Chidamide	PD-L1	HIV functional cure	Global[1]							
ASC10 (Oral small molecule)	RdRp	COVID-19	Global							
ASC10 (Oral small molecule)	Viral polymerase	Monkeypox	Global							
ASC10 (Oral small molecule)	Viral polymerase	Respiratory syncytial virus	Global							
ASC11 (Oral small molecule)	3CLpro	COVID-19	Global							

Note:

1. ASC22 is licensed from Suzhou Alphamab Co., Ltd. for worldwide exclusive rights.

ASC22

ASC22 (Envafolimab) is the most advanced clinical-stage immunotherapy in the world for CHB functional cure, i.e. HBsAg loss, through blocking PD-1/PD-L1 pathway. A pre-Phase III clinical trial meeting between the Company and the Center for Drug Evaluation (CDE) of National Medical Products Administration (NMPA) has been conducted in June 2022, after which a pathway to the registration including patient population, dose, treatment duration, etc. of ASC22 for functional cure of CHB has been agreed. The dose of 1.0 mg/kg ASC22+NAs and the patient population with the baseline HBsAg≤100 IU/mL were agreed and the current Phase IIb study will be expanded to further confirm the rate of functional cure in such patient population and at such dose. Topline interim results from Phase IIb expansion cohort of subcutaneously administered PD-L1 antibody ASC22 (Envafolimab) for functional cure of CHB in patients with the baseline HBsAg≤100 IU/mL are expected to be available in the second half of 2023. Assuming the data from Phase IIb expansion cohort are positive, the Company may initiate a Phase III clinical trial and further kick off the commercialization of ASC22 in China within the next three years assuming the data from Phase III clinical trial are also positive.

ASC10

ASC10 is an oral double prodrug. NMPA has approved to conduct a Phase IIa clinical trial for ASC10 to treat respiratory syncytial virus (RSV) infection. The Company has obtained the approval to conduct Phase IIa clinical trial for ASC10 to treat RSV infection from FDA and NMPA in January 2023 and May 2023, respectively.

Assuming COVID-19 pandemic continues in China, a Phase III study of ASC10 for COVID-19 is expected to be initiated by the end of 2023 or early 2024. Assuming the data from Phase III study are positive and COVID-19 pandemic continues to impact China, the Company may kick off the commercialization of ASC10 for the treatment of COVID-19 within the next three years.

ASC11

ASC11 is an in-house discovered oral inhibitor drug candidate targeting 3-chymotrypsin like protease (3CLpro) for COVID-19 using various proprietary technologies including molecular docking. The Company has obtained IND approvals for COVID-19 from NMPA and FDA for ASC11. Phase I clinical trial in China has been completed in the first half of 2023.

Assuming COVID-19 pandemic continues in China, a Phase II/III study of ASC11 for COVID-19 is expected to be initiated by the end of 2023 or early 2024. If the data from the Phase III study of ASC11 are positive and COVID-19 pandemic continues to impact China, the Company may kick off the commercialization of ASC11 for the treatment of COVID-19 within the next three years.

CHANGE IN USE OF PROCEEDS

Following the adjustment of the Company's R&D focus and sales and marketing strategies, the Company has further revised the allocation and usage of the use of proceeds to better utilize its financial resources. As stated in the 2022 Annual Report, approximately HK$1,515.3 million of the net proceeds remain unutilized as of December 31, 2022 ("**Unutilized Net Proceeds**").

Change in Use of Unutilized Net Proceeds

On June 14, 2023, the Board resolved to change the use of the Unutilized Net Proceeds (the "**New Allocation**"). Set out below is a summary of the planned usage as disclosed in the Previous UoP Announcement and the proposed changes in the use of the Unutilized Net Proceeds.

Planned usage as disclosed in the Previous UoP Announcement	The unutilized amount as at December 31, 2022	Percentage of Net Proceeds as disclosed in the Previous UoP Announcement	Proposed new usage of the Unutilized Net Proceeds	The unutilized amount after the New Allocation	Percentage of Unutilized Net Proceeds after the New Allocation	Expected timeframe for use of proceeds after the New Allocation
	(HK$ million)	*(%)*		*(HK$ million)*	*(%)*	
For continued research and development of ~~the Core Product pipeline in viral hepatitis, non-alcoholic steatohepatitis (NASH)/(PBC), HIV/AIDS~~	924.4	50.4	For continued research and development of **ASC22, ASC11 and ASC10, and other pipeline products in viral hepatitis, HIV/AIDS and other viruses**	681.9	45.0	The remaining amount is expected to be utilized in around five years from December 31, 2022
~~For continued enhancement of current commercialization capability of marketed core products and future products~~	153.1	18.0	For continued research and development of **pipeline products in oncology**	227.3	15.0	The amount is expected to be utilized in around four years from December 31, 2022
			For continued research and development of **pipeline products in NASH/PBC**	227.3	15.0	The amount is expected to be utilized in around five years from December 31, 2022
For upfront and milestone payments of in-licensing new drug candidates	395.3	15.0	For upfront and milestone payments of in-licensing new drug candidates	151.5	10.0	The remaining amount is expected to be utilized in around five years from December 31, 2022
For supporting the research and development of new pipeline drug candidates	2.9	9.6	For supporting the research and development of new pipeline drug candidates	151.5	10.0	The remaining amount is expected to be utilized in around four years from December 31, 2022
For the working capital and other general corporate purposes	39.6	7.0	For the working capital and other general corporate purposes	75.8	5.0	The remaining amount is expected to be utilized in around four years from December 31, 2022
Total	**1,515.3**	**100.0**		**1,515.3**	**100.0**	

Reasons for Change in Use of the Unutilized Net Proceeds

The main reasons for the above changes in the proposed applications in the Previous UoP Announcement and change of the Unutilized Net Proceeds are as follows:

(a) As disclosed in the Previous UoP Announcement, approximately 55.7% of the Net Proceeds is originally used for continued R&D of the Core Product pipeline in viral hepatitis, NASH/PBC, HIV/AIDS. As the the Company has decided to terminate the R&D of ASC09 and ASC06, the Company intends to reallocate 45.0% of the remaining Unutilized Net Proceeds as of December 31, 2022 for continued R&D of the major pipeline products, namely ASC22, ASC11 and ASC10, as well as other pipeline products in viral hepatitis, HIV/AIDS and other viruses. Such changes in the use of Unutilized Net Proceeds is made in response to the fluctuant market competitions and to reallocate fund and resources to the Company's core R&D area, particularly viral hepatitis, HIV/AIDS and other viruses; and

(b) As disclosed in the Previous UoP Announcement, approximately 18.0% of the Net Proceeds were originally used for enhancement of current commercialization capability of marketed core products and future products, which primarily include the commercialization of HCV products (i.e. GANOVO® (danoprevir) and ASCLEVIR® (ravidasvir)). As the Company has decided not to proactively promote GANOVO® and ASCLEVIR®, the relevant Unutilized Net Proceeds are expected to be used in R&D of drug candidates in oncology. The Company currently possesses seven drug candidates in oncology pipeline, among which, ASC40 is the most advanced drug candidates. The first patient was dosed in the Phase III clinical trial of ASC40 combined with bevacizumab for treatment of rGBM in 2022.

The Board confirms that there is no material change in the business nature of the Group as set out in the Prospectus, and considers that the above changes in the use of the Unutilized Net Proceeds will not have any material adverse impact on the operations of the Group and is in the best interests of the Company and its shareholders as a whole.

Cautionary Statement required by Rule 18A.05 of the Listing Rules: We cannot guarantee that we will be able to ultimately commercialize ASC22, ASC40, ASC10 and ASC11 successfully.

Shareholders and potential investors of the Company are advised to exercise caution when dealing in the securities of the Company.

By order of the Board
Ascletis Pharma Inc.
歌禮製藥有限公司
Jinzi Jason WU
Chairman

Hangzhou, the People's Republic of China
June 14, 2023

As at the date of this announcement, the Board comprises Dr. Jinzi Jason WU and Mrs. Judy Hejingdao WU, as executive Directors; and Dr. Yizhen WEI, Mr. Jiong GU and Ms. Lin HUA, as independent non-executive Directors.