Hong Kong Exchanges and Clearing Limited, The Stock Exchange of Hong Kong Limited (the “Stock Exchange”) and Hong Kong Securities Clearing Company Limited (“HKSCC”) take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.

This announcement is for information purposes only and does not constitute an invitation or offer by any person to acquire, purchase or subscribe for securities or any Shares under the Global Offering. This announcement is not a prospectus. Potential investors should read the prospectus dated 11 December 2018 (the “Prospectus”) issued by Shanghai Junshi Biosciences Co., Ltd.* (the “Company”, together with its subsidiaries, the “Group”) for detailed information about the Company and the Global Offering before deciding whether or not to invest in the Shares thereby offered. Any investment decision in relation to the Offer Shares should be taken solely in reliance on the information provided in the Prospectus.

Unless otherwise defined in this announcement, capitalized terms used herein shall have the same meanings as those defined in the Prospectus.

This announcement is not for release, publication, distribution, directly or indirectly, in or into the United States or any other jurisdiction where such distribution is prohibited by law. This announcement does not constitute or form a part of any offer to sell or solicitation of any offer to purchase or subscribe for securities in Hong Kong, the United States or elsewhere. The securities mentioned herein have not been, and will not be, registered under the United States Securities Act of 1933 (the “U.S. Securities Act”) or with any securities regulatory authority of any state or other jurisdiction of the United States. The securities may not be offered or sold in the United States except pursuant to an exemption from, or in a transaction not subject to the registration requirements of the U.S. Securities Act and in compliance with any applicable state securities laws. There will be no public offer of securities in the United States.

SHANGHAI JUNSHI BIOSCIENCES CO., LTD.*
(Stock code: 1877)

FURTHER UPDATE ON NDA PROGRESS FOR JS001 (TORIPALIMAB)

Reference is made to the announcement of the Company dated 18 December 2018, in which the board (the “Board”) of directors (the “Directors”) of the Company announces that the National Medical Products Administration of China (“NMPA”) conditionally granted approval for the new drug application (“NDA”) in respect of the Group’s drug candidate, JS001 or toripalimab (“JS001”).

The Board is pleased to announce that the Group has received the approval for drug registration (the “Approval”) and the new drug certificate (“Certificate”) for JS001 from the NMPA.

I. Summary of the Approval and the Certificate

Below is a summary of the Approval and the Certificate:

Drug name : Toripalimab Injection (特瑞普利单抗注射液) (generic name)
拓益 (Tuoyi*) (brand name)

Form of dosage and specification : Injection, 240 mg (6 ml) per bottle
Registration category : Therapeutic biologics category 1

Validity period of the Approval : Expiring on 16 December 2023

Holders of the new drugs certificate : The Company, Suzhou Junmeng Biosciences Co., Ltd.* (蘇州君盟生物醫藥科技有限公司) (a direct wholly-owned subsidiary of the Company) and Suzhou Union Biopharm Biosciences Co., Ltd.* (蘇州眾合生物醫藥科技有限公司) (“Suzhou Union Biopharm” a direct wholly-owned subsidiary of the Company)

Review conclusion : According to Drug Administration Law of the PRC and relevant regulations, upon reviewed, JS001 fulfils the relevant requirements of drug registration. Approval for registration is accordingly granted, and JS001 is conditionally approved for market launch for second line treatment of unresectable local progression or metastatic melanoma

Others : Application relates to registration of domestic drug. The acceptance number is CXSS1800006, and the approval number is 2018S00663. The Approval certificate number is S20180015 (國藥准字S20180015), and the Certificate number is S20180006 (國藥證字S20180006)

II. Further information of JS001

NDA filing for JS001 was accepted by the NMPA in March 2018. The Group also obtained from the FDA approval to conduct clinical trials in the United States for JS001 in January 2018 and the Group started Phase I clinical trial in the United States for JS001 in March 2018. JS001 is the first anti-PD-1 monoclonal antibody injection developed by a PRC company to have received approval for clinical trial from NMPA.

Currently, Opdivo, Keytruda and Libtayo are the only three marketed anti-PD-1 medications worldwide, which have been approved by FDA for multiple oncological indications that JS001 is also intended for. Opdivo and Keytruda have been approved for sales in the PRC in June and July 2018, respectively. Please also refer to the section headed “Industry Overview” in the Prospectus for further details of the competitive landscape.

Manufacturing of JS001 is also subject to the Group obtaining the GMP certification for the production of JS001.

Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Stock Exchange: We may not be able to ultimately develop and market JS001 (toripalimab) successfully. Accordingly, there is no assurance that all or any of the conditions to NDA approval will be satisfied. Investors are reminded to exercise caution. Investors are also reminded to review the Prospectus in detail in conjunction with the information contained in this announcement.
The Directors confirm that all material information relevant to the Global Offering and the Group has been disclosed in the Prospectus in accordance with the Companies (Winding Up and Miscellaneous Provisions) Ordinance, the Securities and Futures (Stock Market Listing) Rules and the Listing Rules. The Directors consider that the update outlined above does not constitute material information that would require issuance of a supplemental prospectus in accordance with the requirements of Rule 11.13 of the Listing Rules. Accordingly, the listing timetable shall remain the same with listing expected to take place on Monday, 24 December 2018.

By Order of the Board
Shanghai Junshi Biosciences Co., Ltd.
Mr. Xiong Jun
Chairman

Hong Kong, 19 December 2018

As at the date of this announcement, the board of directors of the Company comprises Mr. Xiong Jun, Dr. Li Ning, Dr. Feng Hui, Mr. Zhang Zhuobing, Dr. Wu Hai and Dr. Yao Sheng as executive Directors; Mr. Tang Yi, Mr. Li Cong, Mr. Yi Qingqing and Mr. Lin Lijun as non-executive Directors; and Dr. Chen Lieping, Dr. He Jia, Mr. Chen Xinjun, Mr. Qian Zhi and Dr. Roy Steven Herbst as independent non-executive Directors.

* For identification purpose only