(Ref No.: RFI/2020/BMT/GMP001)

Hong Kong Science and Technology Parks Corporation ("HKSTP")
Request for Information
To Utilize Process Development and GMP Manufacturing Capacity for Advanced Therapy Products

Advanced therapy products ("**ATPs**") comprise of gene therapy, somatic cell therapy products and tissue engineered products that can potentially deliver highly innovative and life-saving treatments for diseases with limited or no treatment options, such as cancers, cardiovascular diseases and Parkinson's disease.

To facilitate the development of ATPs whilst simultaneously safeguarding public health, the Government of the Hong Kong Special Administrative Region of the People's Republic of China passed the Pharmacy and Poisons (Amendment) 2020 Ordinance (CAP. 138), which, in effect, provides that the requirements for pharmaceutical products under this ordinance together with those under other relevant ordinances shall also apply to ATPs. Furthermore, as the Pharmacy and Poisons Board of Hong Kong (the "**PPBHK**") is also a participating authority of the Pharmaceutical Inspection Co-operation Scheme ("**PIC/S**"), manufacturers of ATPs will need to obtain a licence from the PPBHK and to fully comply with the PIC/S GMP standards when producing ATPs for both clinical trial and the commercial market. The introduction of these measures is a clear testament towards medicines produced in Hong Kong being on par with international standards.

Currently, as there are no manufacturing facilities in Hong Kong which comply with PIC/S GMP standards for ATPs, HKSTP has entered into strategic collaborations with university partners in Hong Kong with the primary objective of establishing such facilities. To enable and enhance the development and clinical translation of ATPs, HKSTP will, on a fee-charging basis, provide such GMP capacity to suitable entities to conduct process development and GMP manufacturing.

HKSTP now wishes to invite entities in the biomedical technology industry who have an interest in utilizing process development and GMP manufacturing facilities for ATPs to engage in preliminary but substantive dialogue with HKSTP, on a strictly confidential basis, to gauge and better understand the demands and

needs in these areas. Entities who are interested in conducting such dialogue must, however, first complete and submit the pre-requisite information listed in the table below to assist HKSTP in determining the process in which such dialogue, if any, is to be conducted. Interested entities are reminded that, other than maintaining confidentiality of the identity of all interested entities and the content of their respective dialogue with HKSTP, such submission of pre-requisite information and dialogue will not amount to or in itself constitute any legally-binding commitment on the part of HKSTP to any interested entities. All interested entities are further reminded that it shall be solely responsible for all costs (if any) associated with or arising out of any dialogue that it conducts with HKSTP in this regard.

Pre-requisite Information

Name and address of entity	
Name of contact person Email Telephone number	
Name of product	
Qualitative & quantitative composition	
Pharmaceutical form	
Therapeutic indication	
Route of Administration	☐ Intravenous ☐ Intradermal ☐ Subcutaneous ☐ Others _____

Type of ATP product	☐ Cell therapy product ☐ Gene therapy product ▪ ☐ non-viral vector ▪ ☐ viral vector ☐ Tissue engineered product
Intended use	☐ First-in-human Phase I trial ☐ Phase II trial ☐ Phase III trial ☐ As HK Department of Health Registered Pharmaceutical Product ☐ Others _____
Starting and raw materials	☐ Cord blood ☐ Peripheral blood ☐ Bone marrow ☐ Cord tissue ☐ Adipose tissue ☐ Others _____
Type of process	☐ Open manual ☐ Closed system
Has the process development of the product been completed?	☐ Yes ☐ No If No, how much further process development would be required? _____ _____

Has product been previously manufactured according to GMP?	☐ Yes ☐ No
Does your company have an Authorized Person to perform the batch release of this product?	☐ Yes ☐ No
Would your company require GMP training for key personnel such as Authorized Person, Head of Production and/or Head of Quality Control?	☐ Yes If Yes, please state which training required _____ ☐ No
Expected date of commencement of project	

Based on the evaluation of the pre-requisite information, HKSTP **may** proceed with issuing an invitation to the interested entity to engage in discussions with HKSTP and its university partners in the utilization of the process development and GMP manufacturing capacity for ATPs.

Evaluation by HKSTP of any expression of interest will take into consideration the following aspects of each interested entity:

1) Readiness of product for clinical translation;
2) Technical capacity and competence;
3) Professional credibility and track record;
4) Pipeline sustainability from the company;
5) Investment from the company;
6) Job creation and training; and
7) Any other intangibles that the company can bring to benefit Hong Kong.

For enquiries, please contact Dr Rose Qin at (+852) 2629 6979 or via email at rose.qin@hkstp.org. You should not contact any other HKSTP personnel unless directed to do so by a HKSTP representative. HKSTP reserves the right to reject any

proposals that do not follow the above guidelines.

Submission of pre-requisite information

If your company is interested in conducting preliminary discussions with HKSTP on this matter, please submit the pre-requisite information via email at gmp.atp@hkstp.org .