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Corporate and Investor Communications Department
Hong Kong Exchanges and Clearing Limited
12/F One International Finance Centre
1 Harbour View Street
Central
Hong Kong

23 March 2018

Dear Sirs

Emerging and Innovative Companies CP

We write in response to the Consultation Paper on a Listing Regime for Companies from Emerging and Innovative Sectors (“Consultation Paper”). Unless the context otherwise requires, words and expressions used in this paper have the same meanings as those attributed to them in the Consultation Paper.

Please note that we would like this response to be anonymized upon disclosure. Please redact the name of this firm in the version put on public display.

Cornerstone investment in biotech listings

We welcome the proposal to allow existing shareholders of a Biotech Company (including those holding a 5% voting right or above before listing) to participate in the IPO as a cornerstone investor. We understand the Stock Exchange would require such shareholders to be subject to a six-month lock-up and that the shares subscribed for by such investors at the IPO will not be counted towards the public float for IPO purpose.

From the drafting of Rule 18A.06, we gather that other shares (apart from those subscribed in the cornerstone placing) acquired pre-IPO or post-IPO by such shareholders will be counted towards the public float. This is not spelt out in the Consultation Paper and the Stock Exchange may wish to clarify this to avoid confusion.

On this subject, we have conducted a study on 30 recent SEC-registered biotech IPOs listed in the U.S. between April 2017 and March 2018. We note that existing pre-IPO shareholders participated in 83% (25 out of 30) of the IPOs, on average covering 29% of the IPO base deal size. We believe this is a useful indication of international market trend for the Exchange’s reference. Please refer to the statistics in appendix 1 for details.

Existing shareholders’ / affiliates’ participate in follow-on offerings post-IPO

As a related point, the proposed Rule 18A.06 will to some extent relax the “double-dipping” restriction, by allowing shareholders and affiliates not meeting the conditions of GL85-16 to participate in the cornerstone placing. We support this initiative to give Biotech Companies more flexibility to raise additional funding from existing shareholders at IPO.

However, we believe that the same rationale should apply in subsequent follow-on offerings post-IPO. In practice, it is common for Biotech Companies to have frequent needs for cash injections, due to their long product development cycles and capital-intensive nature of their business, which often necessitate multiple rounds of equity financing before and post IPO. In this regard, shareholders’ support would be crucial both to meet such needs and as a sign of their ongoing commitment to the company. As opposed to this, it would be impractical if Biotech Companies have to identify new anchor investors in each additional round of financing. The problem would be even more acute where additional funds are required on an urgent basis, as new independent investors may require lengthy due diligence into the business before making an investment decision.

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We also take this opportunity to remind the Stock Exchange that for many Biotech Companies it will be very important to have access to additional funding by shareholders not just at the IPO stage but beyond. Please refer to the list in appendix 2 showing the participation of existing shareholders, directors and senior management and their affiliates in recent follow-on offerings in biotech companies in the U.S. Under the current Listing Rules (with connected persons disqualified from issues of securities out of general mandate unless in compliance with Chapter 14A), the Hong Kong regime remains relatively inflexible. To make our market genuinely competitive and attractive to Biotech Companies, we suggest a carve-out to be introduced – namely, that existing shareholders holding more than 10% but less than 30% of the total shares outstanding should be allowed to participate in post-IPO follow-on primary offerings pursuant to a general mandate without necessitating an extraordinary or special general meeting for a special mandate. This would allow financial investors to continue their much-needed support of a Biotech Company as it continues to develop, while preserving a requirement for controlling shareholders holding 30% or more to obtain shareholders’ approval in order to acquire additional shares.

Clinical trials for pharmaceutical products

In the Stock Exchange’s proposal, a pharmaceutical product that has completed Phase I clinical trials with no objection from the relevant authority against the commencement of Phase II will be considered as having developed beyond the concept stage.

As Hong Kong is opening up for the first time, we suggest that an applicant should instead demonstrate that it has completed Phase II clinical trials or otherwise completed “proof of concept” clinical trials which demonstrated the efficacy in humans of the Core Product. Typically Phase I clinical trials are designed to demonstrate the safety of a drug candidate at the potentially therapeutic dose. In many Phase I clinical trials there is no measurement of efficacy of the drug. In fact, Phase I clinical trials are often conducted on healthy humans, not in humans with the medical indication meant to be treated. Overall therefore, companies that have a Core Product which has only completed Phase I clinical trials may not have thereby demonstrated any efficacy of such Core Product in humans. According to FDA statistics, approximately 70% Phase I clinical trials are able to proceed to Phase II, of which approximately 33% move on to the next phase.

We believe a higher standard will help bring in better quality issuers with a higher chance of success in developing their products, and would ultimately be beneficial to Hong Kong in building its reputation as a biotech IPO market. In addition, given investors in the Hong Kong market (compared, for example, to the US market) have less experience in evaluating or investing in Biotech Companies, it would be helpful to introduce such companies in a more advanced development stage to start with.

Contact

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Yours faithfully

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Appendix 1 – Biotech Companies US IPO Precedents

Last 30 Greater Than \$50MM in Proceeds as at 9 March 2018 ⁽¹⁾

Pricing Date	Issuer	IPO ⁽²⁾⁽³⁾⁽⁴⁾			Therapeutic Category	Phase of Lead Asset ⁽⁵⁾
		Size (\$MM)	Insdr. Commit. on Cover (%)	Pre-Money (\$MM)		
3/8/18	BioXcel Therapeutics Inc	80	-	137	Infectious Disease / Anti-Virals	Phase II
1/25/18	resTORbio Inc	98	41	325	Infectious Disease / Anti-Virals	Phase II
1/25/18	ARMO BioSciences Inc	147	10	398	Oncology	Phase III
1/25/18	Solid Biosciences Inc	144	51	421	Orphan / Gene Therapy	Phase I/II
1/24/18	Menlo Therapeutics Inc	137	24	284	Dermatology	Phase II
12/7/17	Denali Therapeutics Inc	287	38	1,429	CNS / Psychiatric / Pain	Phase I
12/6/17	Odonate Therapeutics Inc	181	27	495	Oncology	Phase III Ready
11/10/17	Erytech Pharma SA (U.S. IPO)	125	-	283	Oncology / Orphan	Phase III Ready
11/8/17	Apellis Pharmaceuticals Inc	184	47	600	Autoimmune	Phase II
11/7/17	InfaRx NV	108	80	262	Autoimmune	Phase II
11/1/17	Spero Therapeutics Inc	84	39	130	Infectious Disease / Anti-Virals	Phase I
11/1/17	Allena Pharmaceuticals Inc	75	27	232	Orphan	Phase III Ready
10/24/17	Ablynx NV (U.S. IPO)	230	-	1,163	Other / Respiratory / Autoimmune	Phase III Complete
10/4/17	Rhythm Pharmaceuticals Inc	138	21	346	Orphan	Phase III
9/27/17	NuCana plc	114	14	428	Oncology	Phase III
9/27/17	Deciphera Pharmaceuticals Inc	139	20	471	Oncology	Phase II Ready
9/27/17	Nightstar Therapeutics Ltd	88	46	318	Ophthalmology / Gene Therapy	Phase III Ready
9/20/17	Zai Lab Ltd	172	12	847	Oncology / Other	Phase III Ready
8/8/17	Zealand Pharma A/S (U.S. IPO)	90	-	481	Endocrine / Metabolic	Marketed
8/1/17	Clementia Pharmaceuticals Inc	138	8	375	Orphan	Phase III Ready
7/28/17	Sienna Biopharmaceuticals Inc	75	32	242	Dermatology	Phase II
7/19/17	Kala Pharmaceuticals Inc	104	44	300	Ophthalmology	Phase III Complete
7/13/17	Akcea Therapeutics Inc	144	20 ⁽⁶⁾	335	Cardiology	Phase III
6/28/17	Aileron Therapeutics Inc	58	44	178	Oncology	Phase II
6/28/17	Dova Pharmaceuticals Inc	88	23	372	Orphan	Phase III Complete
6/27/17	Mersana Therapeutics Inc	78	37	305	Oncology	Phase I
6/13/17	Athenex Inc	78	83	598	Oncology	Phase III Complete
5/17/17	argenx (U.S. IPO)	115	-	451	Autoimmune	Phase II
5/16/17	G1 Therapeutics Inc	117	34	355	Oncology	Phase II
5/4/17	Ovid Therapeutics Inc	75	27	324	CNS / Psychiatric / Pain	Phase II
Mean		121	29	429		
Median		114	27	350		

Notes

1. SEC-registered biotech offerings greater than \$50MM (post-shoe)
2. Full deal size
3. Cover commitment represents indications from insiders as well as external strategic, institutional, or other parties who are existing shareholders pre-IPO
4. Pre-Money valuation based on treasury stock method diluted share count
5. Phase of lead asset at pricing
6. Novartis participated in a \$50MM private placement concurrent with the IPO

Appendix 2 - Biotech Companies US Follow-on Offering Precedents

Recent US Biotech FO Insider Participation Precedents

Pricing Date	Company	Offer Size		Insider Commitment		Disclosure
		(US\$MM)	% TSO	# Shares	% of Deal Size	
21-Mar-18	DBV Technologies SA	150	12.50	1,728,597	49.0%	Certain of our existing shareholders, including Pierre-Henri Benhamou, our chief executive officer, have agreed to purchase an aggregate of 1,728,597 ordinary shares in this offering at the public offering price.
21-Feb-18	Aimmune Therapeutics Inc	202	11.02	937,500	17.0%	Nestlé Health Science US Holdings, Inc., one of our existing holders of greater than 5% of our common stock and an affiliate of one of our directors, has agreed to purchase 937,500 shares of the common stock offered hereby at the price offered to the public.
17-Jan-18	Beigene Ltd	800	14.86	3,555,075	47.9%	Two of our existing affiliates, including investors affiliated with Baker Bros. Advisors and Hillhouse Capital Management, Ltd., have agreed to purchase an aggregate of 3,555,075 ADSs in this offering on the same terms as other investors.
10-Aug-17	Beigene Ltd	201	6.63	352,112	14.3%	Two of our existing affiliates, including investors affiliated with Baker Bros. Advisors and Hillhouse Capital Management, Ltd., have agreed to purchase 352,112 ADSs in the aggregate in this offering on the same terms as other investors.
24-Jul-17	Sarepta Therapeutics Inc	374	13.80	47,069	0.6%	Douglas S. Ingram, our President and Chief Executive Officer, has indicated an interest in purchasing up to \$2,000,000 of shares of our common stock in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, less or no shares to Mr. Ingram, and Mr. Ingram could determine to purchase more, less or no shares in this offering.
18-Jan-17	Heron Therapeutics Inc	173	26.53	2,459,016	20.0%	In addition, Tang Capital Partners, LP, an affiliate of Kevin Tang, the Chairman of our Board of Directors, has agreed to purchase 2,459,016 shares of our common stock in this offering at the public offering price. The underwriters will not receive any underwriting discounts or commissions with respect to this sale.
17-Nov-16	Beigene Ltd	227	17.93	2,425,000	38.8%	Two of our existing affiliates, including investors affiliated with Baker Bros. Advisors and Hillhouse Capital Management, Ltd., have agreed to purchase an aggregate of approximately \$77.6 million of our ADSs in this offering on the same terms as other investors.
06-Oct-16	Idera Pharmaceuticals Inc	52	17.65	5,125,000	20.5%	Entities affiliated with two of our directors, Julian C. Baker and Dr. Kelvin M. Neu, and entities affiliated with one of our directors, Youssef El Zein, have agreed to purchase an aggregate of 5,125,000 shares of the common stock offered in this offering at the price offered to the public. We have two significant securityholders. If these securityholders choose to act together, they could exert substantial influence over our business. In addition, in connection with any merger, consolidation or sale of all or substantially all of our assets, they would be entitled to receive consideration in excess of their reported beneficial ownership of our common stock.
09-Aug-16	Acadia Pharmaceuticals Inc	230	5.78	1,303,030	21.5%	Entities affiliated with Baker Bros. Advisors LP and two of our directors, Julian C. Baker and Dr. Stephen R. Biggar, have agreed to purchase an aggregate of approximately \$43.0 million of the shares of common stock offered in this offering at the public offering price.
05-Jan-16	Acceleron Pharma Inc	150	10.15	800,000	21.3%	Our collaboration partner and one of our principal stockholders, Celgene, has agreed to purchase 800,000 shares of our common stock in this offering at the public offering price, as described under "Underwriting" beginning on page S-43 of this prospectus supplement. The underwriters will receive the same underwriting discount on any shares purchased by Celgene as they will on any other shares sold to the public in this offering.
05-Mar-15	Intra-Cellular Therapies Inc	130	15.50	875,000	18.4%	Certain of our principal stockholders have agreed to purchase 875,000 shares of our common stock in this offering at the public offering price.