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CAPITAL GROUP℠

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March 20, 2018

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

Dear Sirs,

RE: Emerging and Innovative Companies CP

Reference is made to the Stock Exchange's consultation paper on the proposed new listing regime for emerging and innovative companies published on 23 Feb 2018 (the "Consultation Paper").

We, Capital Group as a significant institutional investor in the Hong Kong listed stocks, set out below our responses to the Consultation Paper especially on the draft rules for biotech companies listing in Hong Kong (the "Biotech Chapter"). In particular, we strongly suggest the Stock Exchange amending the Biotech Chapter to require FDA/CFDA/EMA Phase III (or later) clinical trial approval as a qualification requirement for listing in Hong Kong. We set out below our rationale, argument and supporting data.

Should you have any questions in relation to above, please do not hesitate to contact the following persons: Nick Chen, Partner, [redacted].

1. **Pipeline products which have completed Phase I clinical trials are subject to high development risk**

   According to the Tufts Center for the Study of Drug Development[1], therapeutic new molecular entities and new therapeutically significant biologic entities first tested in humans during 2000s- early 2010s had an overall clinical approval success rate of c.11.8%. Such clinical approval success rate decreased from c.23.0% in 1980s-early 1990s to the current level 11.8% which indicates an increasing new drug development risks markedly. The Reason for such failure rates is that Phase I clinical trials in most cases do not test the drug's efficacy in humans. For new molecular entities and biopharmaceuticals that had completed Phase I clinical trials during 2000s - early 2010s, they were still subject to c.80.1% probability of failure. By allowing companies with Phase II product candidates to list on the Main Board, it would expose investors to additional risks.

   From public investors' perspective, companies passing mere Phase 1 have significant unknown risks ahead. These risks may not be judged properly by most of the public investors in Hong Kong market. The only company materials that public investors have access to are prospectus and filings, which are not enough for them to fully identify these risks. Even sophisticated investors will need to do substantial due diligence and hire industry experts before investing in Phase 1 biotech companies, especially given that companies passing mere Phase 1 have 88.2% chance to fail and may go bankruptcy.

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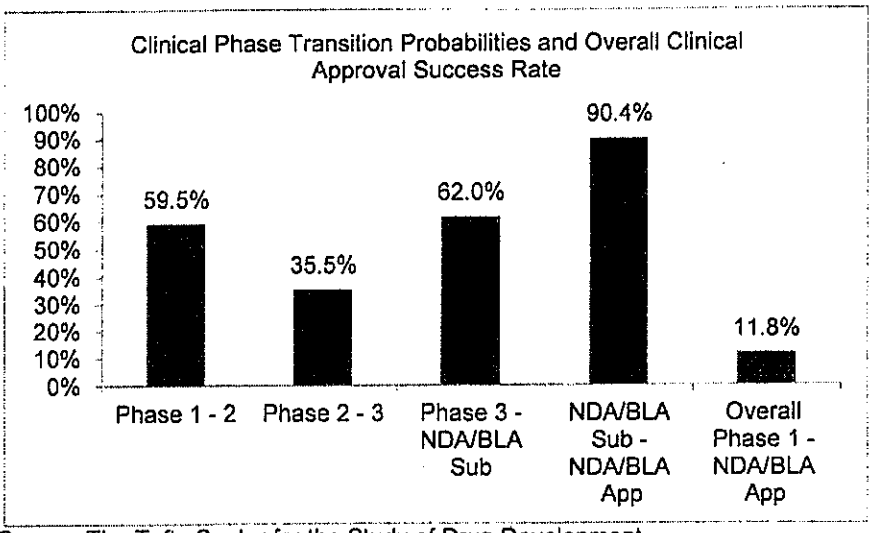
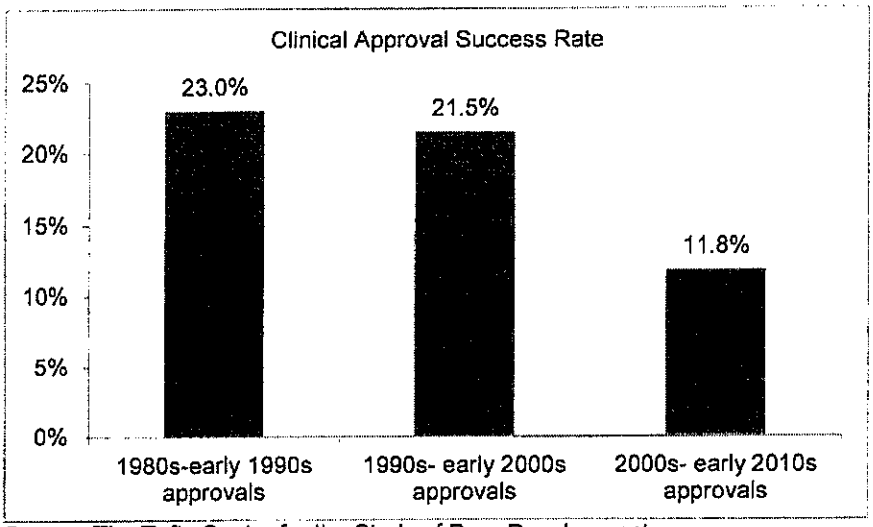


Source: The Tufts Center for the Study of Drug Development



Source: The Tufts Center for the Study of Drug Development

Drug Development' Note: The Tufts Center for the Study of Drug Development is an independent, academic, non-profit research group at Tufts University in Boston, Massachusetts, USA. The organization focuses on the development of strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical and biopharmaceutical development, review, and utilization.

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2. **There is a large number of companies that have commenced Phase II clinical trials, potentially bringing an influx of poor quality companies to HKEx**

   Before the Stock Exchange releases the new chapter in the Listing Rules for biotech, many Chinese biotech companies choose to list in U.S. But now, many of these biotech companies are likely to choose Hong Kong as the listing venue.

   In 2017, China announced several initiatives to reform its regulation of drugs review and approval process. In general, the initiatives focus on (1) reforming clinical trial management, (2) accelerating drug review and approval process, (3) balancing the development of innovative drugs and generic drugs, and (4) enhancing drug review and enforcement force. As a result of these efforts, it is expected that more product candidates will be approved to commence Phase II clinical trials in China, which will result in more qualified listing candidates. According to the data from Center for Drug Evaluation CFDA, the number of public disclosed clinical trials registered in mainland China is 1,258 in 2017, growing by 62.66% compared with 2016. Within these clinical trials, 335 of them are in Phase 1, 111 are in Phase 2 and 212 are in Phase 3. Phase 2 and Phase 3 trials take up 50% of phase 1, phase 2 and phase 3 clinical trials in total, which may indicate that there is no huge difficulty to pass Phase 1 and many companies will satisfy the requirement.

   As explained in rationale #1, since a number of companies that have passed Phase 1 could face product development failure in the future, we suggest the Stock Exchange raising the bar to only allow high quality candidates to apply for listing.

3. **It is important to maintain the listing qualifications of the Biotech Chapter in order to attract more issuers to come to Hong Kong**

   From 2015 to 2017, U.S. biopharma IPO volume remains stable. Biopharma IPO companies include pre-Phase 1, Phase 1 or 2 and Phase 3 or approved companies. For companies listed in 2015, Phase 1 or 2 companies' stock price has decreased 34.8% until now, while Phase 3 or approved companies' stock price has increased 42.0%. Phase 3 or approved companies has a much better investment return compared with early stage companies and it encouraged more Phase 3 or approved biopharma companies to IPO. From 2015 to 2017, Phase 3 or approved biopharma IPO companies as a percentage of total biopharma IPO companies increased from 33% to 46%.

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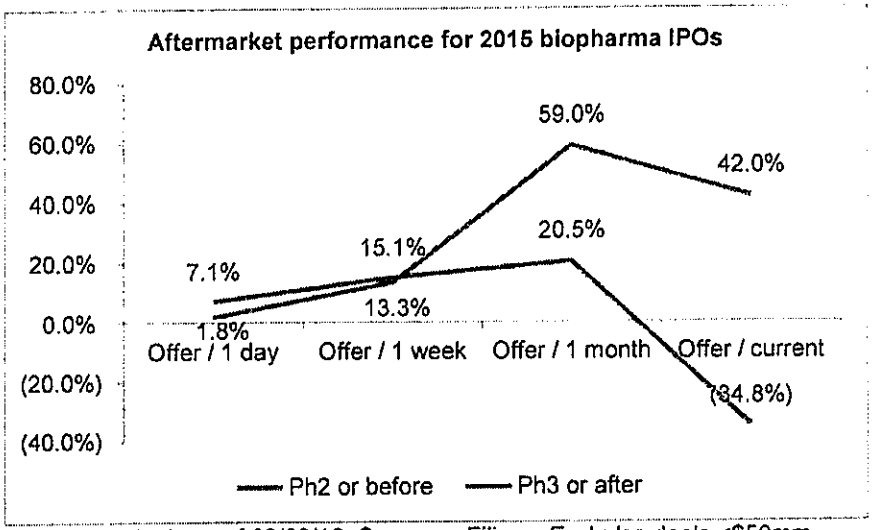
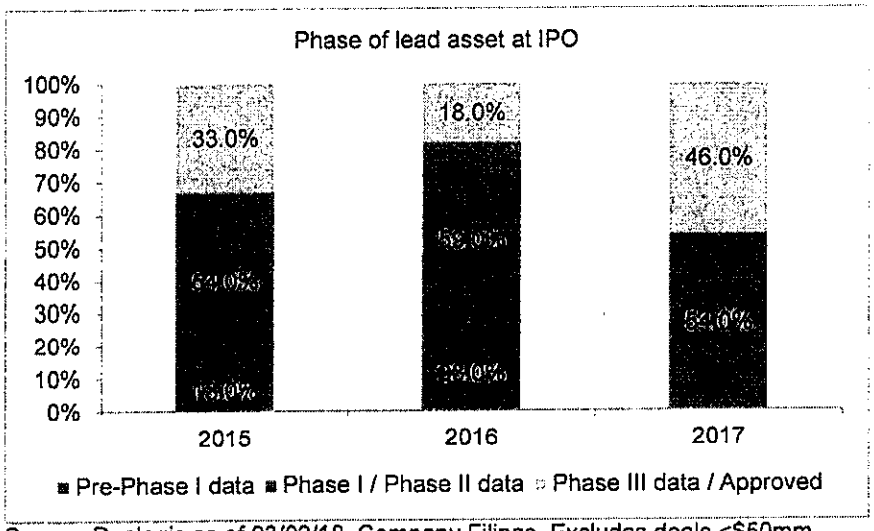


Source: Dealogic as of 03/02/18, Company Filings, Excludes deals <$50mm



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4. Conclusion

We hold the view that it is critical to ensure quality of the first batch of issuers as they will likely act as core comparables to any forthcoming listing candidates. We believe a successful track record of quality listing under the Biotech Chapter will help attract more issuers to come to Hong Kong.

Sincerely,

Nick CHEN
Partner
Capital Group Private Markets