2.7 Major pharma companies starting outsourcing preclinical and toxicology research in China

As more and more preclinical and clinical studies are being conducted in China, China has become a favored destination for outsourcing of both drug discovery and development. The significant cost reduction, abundant choice of qualified CROs and the possibility of simultaneous approval of new drugs in multiple markets are the major attractions to many drug companies around the world.

2.7.1 Motivations of major pharma companies outsourcing preclinical and toxicology research to China

Before local Chinese CROs strengthened their service in preclinical and toxicology research, most major pharma companies sought preclinical outsourcing service from the China divisions of those Western CROs (such as those discussed above). However, the majority of these outsourcing projects then were small in size. For example, in terms of the dollar value, most preclinical and toxicology research projects were valued at less than half a million dollar each. It was partly because the China R&D facilities of these major pharma companies then had not reached the designed full scale yet (most of these China R&D centers were built at around 2005/2006; some were even much later such as the China R&D center of Sanofi-Aventis which was just opened recently). On the other hand, the China service facilities of these multinational CROs were also still small and less capable as they were just opened for not a long time (so that their service capability was not as sophisticated as what these major pharma companies had desired.)

For example, since Roche first established its first Asia R&D center in Shanghai in 2004, almost all other major pharma companies followed that trend and now all have their R&D centers in China (mostly in Shanghai or Beijing). Initially, almost all of them focused on discovery research (also partly serving as the chemistry center for their global R&D research). After constant expansions for several years, these centers now have reached decent sizes (such as having 200 to 300 scientists) and research capability. The key measure of the success of their R&D progress in China is the discovery of a bunch of lead compounds of each company during these years. These lead compounds are now ready to move to the next stage, i.e. early preclinical development. Some of them have actually reached this stage already. For example, GSK's Shanghai center has already started phase I clinical trial for its first drug candidate discovered by the Shanghai center itself.

Situation is very similar in most other major pharma companies that have R&D center in China. After practicing for several years, the China R&D centers of these major pharma companies have all generated fruitful results. Most of these centers now have a number of lead compounds in their pipelines. To move these compounds to the next

stage, these companies are now going to seek outsourcing service in preclinical research. Moreover, the size of these outsourcing projects is expected to be significantly large as they now need a full scope of studies. The outsourcing deal of *in vitro* ADME/Tox study forged between WuXi AppTec and Pfizer is a good example (see Case Study 18 on page 72). The latest development has also triggered those multinational CROs to significantly expand their China service facility. The recent broken deal between Charles River and WuXi AppTec was just an attempt.

Figure 7 summarized the key motivations of major pharma companies outsourcing preclinical and toxicology research to China.

Figure 7
Motivations of major pharma companies outsourcing preclinical and toxicology research to China

Motivations of major pharma companies outsourcing to China

- China has demonstrated the commitment to improve IP protection environment. In the past, most major pharma companies only outsourced custom synthesis (mostly pharma intermediates, building blocks and compound libraries) to Chinese CROs (or CMOs). Nowadays, full scale drug discovery outsourcing including structure-activity-relationship (SAR) study that involves highly sensitive IP information has become norm in the Chinese CRO industry. Major pharma companies are now no longer concerned about the IP protection environment when considering outsourcing to China.

- Most major pharma companies have been conducting drug discovery research in China either in house or using local Chinese CROs (or research institutes) with whom they generally have large projects [such as employing several hundred FTEs (mostly chemists)]. They have been doing this for couple of years and the results are generally satisfactory to them (in some case even exceeding their expectation especially in terms of the cost and quality). For example, Astra-Zeneca has had such large drug discovery projects with WuXi AppTec for several years already. Pfizer, Merck and Eli Lilly, etc. all have been doing similarly in China.

- Chinese companies have demonstrated honest collaboration with their customers. This is evidenced by the high level close collaboration in drug discovery research between a number of major pharma companies and local Chinese CROs. It is apparent that the major pharma companies have changed their attitude about the Chinese outsourcing industry and trust the Chinese CROs.

- Full scale small molecule drug discovery outsourcing has been practiced in China by these major pharma companies for a number of years and the time is mature for them to move to the next stage.