CAMARGO'S KEN PHELPS IN KOREAN PRESS

Ken Phelps, CEO of Camargo Pharmaceutical Services, has been traveling and giving seminars on 505(b)(2) Opportunities in Asia, including a seminar in Seoul, South Korea. Based on interviews given while in Seoul, in conjunction with CMG Pharmaceutical, journalists wrote the following three articles. The links provided contain the original Korean text, and the content below contains the English translations.

PHARMNEWS

http://www.pharmnews.co.kr/1news_view.asp?sno=89926&ng=&part=&page=1

Amongst the Korean pharmaceutical entities, it is common that their aim is on the development of new global drugs, but so far still find themselves lacking capital and capability. As 'Incrementally Modified Drug (IMD)" is more competitive than "Generic drug" and pharmaceutical companies can reduce the astronomical budget and the duration of development of new drug, Korean pharmaceutical entities continuing the development of IMD. Numerous "IMD" have been gradually succeeding in global market, such as Hanmi Pharmaceutical's 'Amozatan', United Pharmaceutical's 'Silosutan CR', LG Chem's 'Jemimet' and Boryeong Pharmarcy's 'Canav'. Even though, Korean 'IMD' have reached comparable levels to global markets, they are still experiencing difficulties in entering the global markets, especially in the more developed countries.

So we have asked Ken Phelps, who is the Chief Executive Officer of Camargo Pharmaceutical Services. Camargo Pharma is the world's leading strategic consultancy specializing in helping clients seek U.S market access.

Ken Phelps traveled to Seoul and held seminars on 505(b)(2) drug development. The 505(b)(2) new drug application (NDA) applies for:

- Drugs that is efficacious
- Drugs with changes in dosage form, strength, formulation, dosing regimen or route of administration.
- New combination products

- Prodrugs of an existing,
- Drugs with new active ingredients, meaning IMD.

In US, if products approved under the 505(b)(2), you can gain 3,5 or 7 years of exclusive rights in the market.

He said, “Camargo have FDA-provided proven process of showing whether it is practicable drug or not with 505(b)(2).”

According to the report, more than 200 candidates from the FDA ‘s NDA and ANDA have been approved in more than 25 countries worldwide. In particular, Ravicti, a treatment for urinary tract disorders (UCD), was one of the most successful cases of Camargo’s.

Ravicti, which is classified as an Orphan drug, was developed by US biotechnology company, Hyperion Therapeutics. The company was acquired by “Horizon Pharma”, Irish pharmaceutical company in a deal valued at $1.1 billion in 2015. In the US, the price of “Ravicti” was about $ 780,000 annually (about 860 million won), and sales increases by 73.5% after Horizon acquired Hyperion.

Ken Phelps said, “Unfortunately, Korea is not well aware of 505 (b) (2),” and also, “I have held a seminar of 505 (b) (2) pathway every year in many countries which hosted one hundred or more companies in average, but in Korea, there were only about 30 companies.”

Currently there are only 3 companies in Korea, including CMG that cooperate with Camargo. He stated, “Because 505(b)(2) can gain higher selling price than Generic Drugs, it will be fantastic opportunity for entities to achieve increased profit. He also emphasized, “In Camargo, we have all the specialists in clinical study, toxicity, chemical and more. Also we have strong relationship with FDA managers, which will help significantly on patents to commercializing drugs at rational price and as quickly as possible.”

NEWSMP

http://www.newsmp.com/news/articleView.html?idxno=178672

One of the key issues in Korean pharmaceutical industry is entering into “Global Market”, especially into US Market, as it is the biggest market, even though it is difficult to access at first. So far, Korea pharmaceutical companies are developing new drugs or biosimilar to access the U.S market. On the other hand, they were approached the market with generic products.
Ken Phelps, Camargo Pharmaceutical Services’ Chief Executive Officer, suggests the possibility of access though Incrementally Modified Drug.

WORLD’S ONLY 505 (B) (2) CONSULTANCY

Camargo is the world’s leading strategic consultancy specializing in helping clients navigate the 505(b)(2)FDA approval pathway. From the feasibility testing to FDA submission, Camargo executes complete development plan that align with strategies and that ensure FDA approval. Camargo is the only one company in the world which is specialized for the 505(b)(2).
In addition, after FDA approval, Camargo also provides the services which introduce the partner to clients who want to sell the products in the U.S. Camargo is the only company in the world which supports for the 505(b)(2) approval.

Currently, there are three Korean pharmaceutical companies that have collaborated with Camargo. Two companies are conducting pre-meeting (Pre IND meeting) with the FDA for clinical trials, and the other one completed the NDA meeting. Camargo is mainly focused on 505(b)(2) as market is growing fast in the U.S. According to JP Morgan, around 10 companies developed the products under 505(b)(2) in the last 5 years. but it increased to more than 120 companies . Last year, around 50 products are approved by FDE through the 505(b)(2).
Ken Phelps, CEO said that 505(b)(2) takes into account the cost of conducting clinical studies and the time saved by not conducting. Also, it could be an opportunity to access to the U.S market quickly.

NEED PRESCRIPTION PATTERN-BASED STRATEGY

Ken Phelps said that when Korea pharmaceutical companies want to enter the U.S. market, it is important to look at the current status and pattern of a physician's prescribing. Therefore, it is important to get large amount of prescription by telling the advantage over the original drug. In particular, Camargo stated that since doctors give prescription depending on the indication of medicine, they are consulting on how to approach the indication.

Camargo has been concentrating on FDA approval, but they will expand their business area which is introducing partners for sales. Ken Phelps said "We have concentrating on the 505(b)(2) so far, but we also want to help find partners who needed it commercially. Also, I don't know where it will be, but I am thinking about setting up a branch in Asia in the near future."

DIGITALTIMES

http://www.dt.co.kr/contents.html?article_no=2017121202101176029 00

Camargo Pharmaceutical Services is a company that assists other pharmaceutical companies enter “Incrementally Modified Drug” market in the U.S. Currently Camargo is actively cooperating with numerous Korean pharmaceutical companies. Ken Phelps who met at a dining hall in Pankyo told that Camargo will be a good partner from clinical study to FDA approval for Korean pharmaceutical company.

Camargo is providing comprehensive drug development services specialized for the 505(b)(2) approval pathway in U.S. which is applied to Koreans’ Incrementally Modified Drugs. It is not a new drug, but it refer to medicine that have changed the properties and types of the latter to produce the effectiveness

Amosartan is the first Korea’s Incrementally Modified Drug and it tops Hanmi’s sales list according to UBIST with the annual turnover of 67 billion won. Other companies such as CMG Pharm and Korea United pharm are also actively developing the incrementally modified drug.

Last year, around 50 products are approved by FDA through the 505(b)(2) pathway and about 120 companies are developing the products which could be approved by 505(b)(2) pathway. Approximately 20% of the approval process was supported by Camargo and their company size was about 4 times larger than 4 years ago.

Ken Phelps, CEO said that 505(b)(2) takes into account the cost of conducting clinical studies and the time saved by not conducting. Currently there are only 3 companies in Korea, including CMG that cooperate with Camargo.